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THE STATE OF SOUTH CAROLINA
In the Court of Appeals

APPEAL FROM THE ADMINISTRATIVE LAW COURT

Ralph King Anderson, III, Administrative Law Judge

Case No 2007-ALJ-07-0389-CC

MRI at Belfair, LLC,

Appellant,

v

South Carolina Department of Health and Environmental Control
and Coastal Carolina Medical Center,

Respondents

RECORD ON APPEAL

VOLUME I

John F Beach
John J Pringle, Jr
Ellis Lawhorne & Sims P A
1501 Main Street, 5th Floor (29201)
Post Office Box 2285
Columbia, SC 29202
(803) 343-1269
Attorneys for Appellant
MRI at Belfair, LLC

Travis Dayhuff
Holly G Gillespie
Nelson Mullins Riley & Scarborough LLP
1320 Main Street, 17th Floor
Post Office Box 11070 (29211-1070)
Columbia, SC 29201
(803) 799-2000
Attorneys for Respondent
Coastal Carolina Medical Center

Ashley C Biggers
South Carolina Department of Health and
Environmental Control
2600 Bull Street, 3rd Floor
Columbia, SC 29201
(803) 898-3350
Attorneys for Respondent
South Carolina Department of Health and
Environmental Control

July 22, 2010

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**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

MRI at Belfair, LLC,	)	Docket No 04-ALJ-07-0399-CC
	)	
Petitioner,	)	
	)	
vs	)	FINAL ORDER AND DECISION
	)	
South Carolina Department of Health and	)	
Environmental Control and,	)	
Coastal Carolina Medical Center,	)	
	)	
Respondents	)	
	)	

APPEARANCES M. Elizabeth Crum, Esquire, and A. Victor Rawl, Jr, Esquire, for
Petitioner MRI at Belfair, LLC

Nancy S Layman, Esquire, and Ashley C Biggers, Esquire, for
Respondent SC DHEC

David B Summer, Jr, Esquire, and Susan B Lipscomb, Esquire,
for Respondent Coastal Carolina Medical Center

STATEMENT OF THE CASE

This matter arises from a Request for a Contested Case Hearing by Petitioner MRI at Belfair, LLC (Belfair), in which it contests a decision by Respondent South Carolina Department of Health and Environmental Control (DHEC or Department) to approve the Certificate of Need (CON) application of Respondent Coastal Carolina Medical Center (CCMC) for the addition of a 1.5 T Magnetic Resonance Imaging (MRI) unit at its Jasper County, South Carolina hospital facility. A hearing in this matter was held at the offices of the Court in Columbia, South Carolina on August 23, 2005 through August 25, 2005.

DISCUSSION

The ultimate issue in this case is whether to grant a CON to CCMC for one fixed MRI. A CON must be obtained from the Department before a new health service may be added by a health services provider. The State Certification of Health and Health Facility Licensure Act (Act) creates a CON program that, among other things, requires health

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SC ADMIN LAW COURT

care facilities to apply for and receive, a CON before undertaking certain projects. See S C Code Ann. §§ 44-7-110 to 44-7-240 (2002) The purpose of the Act, as set forth in Section 44-7-120, is

[T]o promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State.

(Emphasis added) To achieve these ends, the Department is required to prepare a State Health Plan for use in the administration of the CON program. The Act requires that the CON must comply with the South Carolina State Health Plan S C Code Ann. § 44-7-210(C) (2002) The 2003 State Health Plan (2003 Plan) is the applicable State Health Plan for consideration and evaluation of the CON in this case

SUMMARY JUDGMENT

Prior to the hearing in this case, both Respondent CCMC and Petitioner Belfair filed Motions for Summary Judgment. CCMC filed its Motion for Summary Judgment on the grounds that the 2003 Plan dictates that, as a hospital, CCMC should have at least one MRI unit available for the diagnosis of emergency patients, inpatients and outpatients Accordingly, CCMC argues that since it does not have a MRI unit it is unconditionally authorized to receive a MRI unit and, therefore, there is no genuine issue of material fact to consider in this case. Respondent DHEC joined in Respondent CCMC's Motion for Summary Judgment. Subsequently, Petitioner filed its own Motion for Summary Judgment on the grounds that the 2003 Plan's provisions for MRI services violate the authorizing statute.

Rule 68 of the Rules of Procedure for the Administrative Law Court provides that "[t]he South Carolina Rules of Civil Procedure may, where practicable, be applied in proceedings before the Court to resolve questions not addressed by these rules." Rule 56(c), SCRCP, and the accompanying case law set forth that a party may bring a motion for summary judgment.

Petitioner's Motion for Summary Judgment

Petitioner contends that the MRI Standards of the 2003 Plan do not comply with the requirements set forth in S C Code Ann. § 44-7-180 (2002) and 24A S C Code Ann

Regs. 61-15 (Supp 2004) ¹ Section 44-7-180(B) provides, in part.

The plan at a minimum must include

* * *

(2) projections of need for additional health care facilities, beds, health services, and equipment;

* * *

(4) a general statement as to the project review criteria considered most important in evaluating certificate of need applications for each type of facility, services, and equipment, including a finding as to whether the benefits of improved accessibility to each such type of facility, service, and equipment may outweigh the adverse affects caused by the duplication of any existing facility, service or equipment.

The State Health Plan must address and include projections and standards for specified health services and equipment which have a potential to substantially impact health care costs and accessibility

(Emphasis added) As set forth above, at the time the application in the present case was filed, the 2003 Plan was in effect That 2003 Plan provides two specific standards for MRIs as follows

- (1) Each hospital should have at least one MRI unit available for diagnosis of emergency patients, inpatients and outpatients
- (2) In order to promote cost-effectiveness, the use of shared mobile MRI units should be considered.

Petitioner argues that the 2003 Plan fails to set forth any projection of need and standards for MRI services and equipment as required by the CON Act, and, therefore, by relying on the 2003 Plan in granting the CON to CCMC, the Department exceeded its statutory authority

Summary Judgment is appropriate when it is clear there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law Rule 56, SCRPC, Vermeer Carolina's, Inc v Wood/Chuck Chipper Corp., 336 S C 53, 518 S E.2d 301 (Ct. App 1999) In determining whether any triable issue of fact exists such as to preclude summary judgment, the evidence and all inferences reasonably drawn therefrom must be viewed in the light most favorable to the non-moving party Strother

¹ Two sections of this regulation were amended effective June 27, 2003 However, those amendments are not at issue in this matter

v Lexington County Recreation Comm'n, 332 S.C. 54, 504 S.E.2d 117 (1998) Moreover, "[s]ummary judgment is not appropriate where further inquiry into the facts of the case is desirable to clarify the application of the law" Middleborough Horizontal Property Regime Council of Co-Owners v Montedison S.p.A., 320 S.C. 470, 479, 465 S.E.2d 765 771 (Ct. App. 1995)

Here, the 2003 Plan sets forth that each hospital should have an MRI unit available for emergency patients, inpatients and outpatients. Whether that projection is sufficient and whether the ALC can question the efficacy of the 2003 Plan are questions that warrant inquiry into the facts of the case to clarify the application of the law. Accordingly, Petitioner's Motion for Summary Judgment is denied.

Respondent CCMC's Motion for Summary Judgment

The basis for Respondent CCMC's Motion for Summary Judgment is that CCMC is a hospital, and, therefore, pursuant to the 2003 Plan, its application for a CON for an MRI should be granted. Therefore, Respondent CCMC submits that under the 2003 Plan there is no need to demonstrate (a) Community Need Documentation, (b) Distribution (Accessibility), (c) Acceptability; and (d) Cost Containment.

Here, the very language of the 2003 Plan reflects that each hospital have at least one MRI unit "available for diagnosis of emergency patients, inpatients and outpatients"² Furthermore, the undisputed evidence established that in the 2003 Plan the DHEC Board, in keeping with the State Health Planning Committee, made a public policy decision that each hospital, if it could afford it, should have an MRI. In other words, each hospital needs an MRI. Moreover, the Board eliminated the requirement in the 2003 Plan that a hospital applying for a MRI must address the utilization of existing resources in order to be approved for its first MRI.

Summary judgment is appropriate where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a

² As when seeking to determine the meaning of statutes, the rules of statutory construction apply to the interpretation of the meaning of regulations. See Converse Power Corp. v. South Carolina Dept. of Health and Environment Control, 350 S.C. 39, 564 S.E.2d 341 (Ct. App. 2002). Accordingly, the legislative intent of a regulation's meaning must "prevail if it can be reasonably discovered in the language used, and that language must be construed in light of the intended purpose of the [regulation]" McClanahan v. Richland County Council, 350 S.C. 433 438, 567 S.E.2d 240, 242 (2002).

judgment as a matter of law " Rule 56(c), SCRPC, see also Tupper v. Dorchester County, 326 S C 318, 487 S.E.2d 187 (1997) Furthermore, where "plain, palpable and indisputable facts exist on which reasonable minds cannot differ," summary judgment in favor of the moving party is proper Williams v. Chesterfield Lumber Co., 267 S C 607, 610, 230 S.E.2d 447, 448 (1976)

I find that the MRI standards under the 2003 Plan do not require CCMC to establish. (a) Community Need Documentation, (b) Distribution (Accessibility), (c) Acceptability; and (d) Cost Containment. Accordingly, since there is no genuine issue of material fact regarding those criteria, I find that Respondent CCMC's Motion for Summary Judgment should be granted, in part. Nevertheless, there is a question of material fact as to whether CCMC needs an MRI "available for diagnosis of emergency patients, inpatients and outpatients," and whether "the use of shared mobile MRI units should be considered" in determining availability Since these issues warrant further inquiry, I find that summary judgment is not justified regarding those specific issues

FINDINGS OF FACT

Having observed the witnesses and exhibits presented at the hearing and closely passed upon their credibility, taking into consideration the burden of persuasion of the Petitioner and the Respondents, I make the following findings of fact by a preponderance of evidence

1 Notice of the date, time, place and subject matter of the hearing was properly given to all the parties

2 CCMC is a forty-one (41) bed hospital located in Jasper County, South Carolina, which opened to the public in November 2004 The hospital is open twenty-four hours a day, seven days a week. It has an emergency room which is also open twenty-four hours a day, seven days a week. The facility is located near Interstate 95 (I-95) and its primary service area is Jasper and Beaufort Counties The area serves a full-time population as well as a large vacation population Moreover, it is anticipated that by 2006 over 48,000 people will reside full-time in this service area. Additionally, due to its proximity to I-95, CCMC frequently receives patients injured in traffic accidents as well as those in need of treatment for other reasons As a result, its emergency room is often busy

After it began its initial operation, CCMC determined that it needed an MRI scanner. The use of MRI scans is ever increasing in South Carolina. The scans have become a commonplace diagnostic modality and are being used by physicians with greater frequency as a diagnostic tool to analyze conditions of the spine, brain, abdomen and other parts of the body. The use of an MRI can eliminate the need for other more invasive tests, in addition to reducing risk and discomfort to the patient. New uses for MRIs are also continually being discovered. At present, no MRI services are available in Jasper County.

In assessing its needs for an MRI unit, CCMC considered the use of a shared mobile MRI unit. CCMC determined, however, that a shared unit would not meet the needs of its patients. Rather, CCMC concluded that a fixed base MRI would best meet the needs of its patients and physicians who utilize the hospital. In making its decision, CCMC considered immediate accessibility for patients and physicians and convenience for the inpatients and outpatients. It also considered the number of patients that would be seen in CCMC's emergency room, that it was located in a growing community, and the accessibility of the hospital from I-95, Jasper County, and southern Beaufort County, among other things.

Therefore, on May 7, 2004, CCMC submitted to the Department an application for a CON to purchase a GE Signa LX 1.5 Tesla MRI to be located in its existing facility. The total project cost is \$3.2 million dollars. The application for the CON was submitted pursuant to the 2003 State Health Plan. The Department determined that the CCMC CON application was consistent with the applicable standards in the 2003 Plan and approved the issuance of the CON by letter dated November 22, 2004.³ After the Department issued its decision, Petitioner requested a contested case hearing by letter dated November 24, 2004.

3 Petitioner Belfair is a free-standing imaging facility providing MRI services in Bluffton, South Carolina. It is located approximately 13.8 miles from CCMC in Beaufort County. Belfair is a limited liability corporation owned by Albert J. Borelli,

³ Prior to approving this MRI project, the Department required assurances that the project was financially feasible. Wayne Gower of Province Healthcare Company stated in a letter to the Department that Province Healthcare Company, owner of CCMC, had "an adequate cash balance on hand and available for funding the proposed MRI project."

Jr., M.D. Dr. Borelli is the sole practitioner. He personally reads the MRI scans at Belfair and is only open for business from 7:00 a.m. to 6:00 p.m., Monday through Friday. Belfair, however, currently has no on-call responsibilities with any health care facilities.

4 Petitioner Belfair contends that the existing MRI facilities provide sufficient capacity for diagnosis of emergency patients, inpatients, and outpatients without CCMC having a fixed, in-house MRI unit on-site. Dr. Borelli argues that the hospital would not have "an overwhelming number of scans" and could, therefore, contract with providers of mobile MRI services or use existing MRI centers for outpatients. Inpatients and emergency patients could be accommodated by an on-site mobile unit, or, if the mobile unit was not there when it was needed, CCMC could have a transfer agreement with another facility.

However, Dr. Dean Vincent Moesch, a radiologist with Chatham Radiologists which currently provides most of the radiology services to CCMC, testified that the MRI needs to be available 24/7 at CCMC for emergency trauma patients from traffic accidents alone. Furthermore, the image quality from a mobile unit is generally not as good as a fixed site scanner. Most of the existing mobile MRI units are older, lower-cost equipment with smaller magnets. Thus, the mobile and "free-standing" fixed MRI units are usually less effective diagnostic tools.⁴

Additionally, although ten (10) MRI units exist in Beaufort County, including both mobile and fixed MRI units, numerous problems result from a hospital depending on a mobile unit or having to transfer a patient. CCMC is open twenty-four hours a day, seven days a week. To the contrary, a mobile unit is usually present only three days a week and a patient must wait for the unit to return to the hospital.⁵ Furthermore, the free-standing MRI providers, such as Belfair, are not open twenty-four hours a day, seven days a week. Other MRI units are in physician offices and limited to use for patients of those particular practices. Accordingly, use of such facilities could unreasonably delay

⁴ Belfair, nevertheless, is an exception to that general inadequacy. It operates a 1.5 Tesla General Electric (GE) fixed MRI and is one of several GE MRI national show sites in the United States. Additionally, Belfair serves as a clinical evaluation site for GE's newly developed MRI products, giving it and the community it serves advanced access technology.

⁵ It is cost prohibitive to have a mobile MRI unit on site twenty-four hours a day, seven days a week.

the diagnosis by the physician, which can alter the type of treatment the physician orders in the interim. The patient's length of hospital stay may also be extended, resulting in an increased cost to the patient and his insurer.

Furthermore, even if another MRI unit is open, transporting a patient has its own risks. Without an on-site MRI unit, if a CCMC physician determines that an inpatient should have an MRI scan, the hospital must locate a provider that has the availability to administer the MRI, determine if the patient is stable enough to be transported, determine if the patient needs a nurse or other caregiver to accompany the patient, locate appropriate transportation (either ambulance or van), load the patient, and then transport the patient. A transferred inpatient must leave the safety net of services and providers who are on site in the hospital, which can produce additional stress and harm to the patient. There may also be an interruption in the patient receiving necessary medications. In addition, there is always the possibility an ambulance could be involved in an accident while transporting the patient. Moreover, both CCMC and Belfair are located near Hilton Head, South Carolina. The area has a substantial increase in tourist population at different times of the year. The traffic and the travel time between CCMC and any of the other providers of MRI services depends on a number of factors, including the time of year, the time of day, traffic congestion, and highway construction and maintenance. Therefore, transferring patients interrupts the continuity of care of the patient, delays the patient receiving services at the hospital, and is inconvenient to the patient and the family. The process can potentially jeopardize patient care.

Currently, if a patient presents to the CCMC emergency room and the physician determines an MRI is necessary, the patient generally will be transferred to hospitals located in Savannah, Georgia, which is about forty (40) to forty-five (45) minutes from CCMC. The result is that a Jasper County resident has to leave his home and family to go out of state to receive medical care. In addition, the patient will generally be admitted for the rest of the patient's care at the receiving facility rather than be transported back to CCMC. Accordingly, only small, rural hospitals in South Carolina "that absolutely do not have the funding" are using mobile MRI units.

5 Therefore, though the current need for urgent MRI scans at CCMC may be limited, I find that upon considering the impact to CCMC's emergency patients and

inpatients, the existing MRI facilities in the area do not sufficiently meet the hospital's needs of "availability" to warrant disapproving CCMC's fixed, in-house MRI

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact, I conclude the following as a matter of law

1 The Administrative Law Court has jurisdiction over CON contested case proceedings and consequently over this matter pursuant to S C Code Ann. § 44-7-210 (2002) and § 1-23-600(B) (Supp 2002) An Administrative Law Judge's review of an administrative decision of the Department to grant a CON request is governed by S C Code Ann. § 44-7-210(E) (2002), which provides

The department's proposed decision is not final until the completion of reconsideration or contested case proceedings The burden of proof in a reconsideration or contested case hearing must be upon the moving party The contested case hearing before the board or its designee is conducted as a contested case under the Administrative Procedures Act. The issues considered at the contested case hearing are limited to those presented or considered during the staff review and decision process

In contested case hearings, the Administrative Law Judge is the fact finder Brown v S C Department of Health and Environmental Control, 348 S C 507, 560 S.E.2d 410 (2002) Furthermore, Petitioner bears the burden of proving its case by a preponderance of the evidence S C Code Ann. § 44-7-210(E) (2002), see also Nat'l Health Corp v SCDHEC, 298 S C 373, 380 S.E.2d 841 (Ct. App 1989) In the present case Petitioner has the burden of proving by a preponderance of the evidence that the Department's recommendation to approve CCMC's CON application was in error Id.

2 As trier of fact, the Administrative Law Judge (ALJ) is not compelled to accept an expert's testimony, but may give it the weight and credibility the ALJ determines it deserves Florence County Dep't. of Social Serv v Ward, 310 S C 69, 425 S.E.2d 61 (Ct. App 1992) Nevertheless, it is appropriate to give due consideration to the CON staff's utilization of its specialized knowledge and expertise in the application of the CON Act and CON regulations See S C Code Ann. § 1-23-330(4) (Supp 2002)

3 The Department administers the CON program for South Carolina pursuant to the State Certification of Need and Health Facility Licensure Act, S C Code Ann. §§ 44-7-110, et seq (2002) Under the Act, before an entity can operate certain

health care facilities and services in South Carolina, the Department must issue a Certificate of Need to that entity, subject to certain statutory exemptions See S C Code Ann. §§ 44-7-160 & 44-7-180 (2002) The CON program is also administered under the guidelines of 24A S C Code Ann. Regs. 61-15 (Supp. 2003) Additionally, Section 44-7-210(C) provides that, "[t]he Department may not issue a Certificate of Need unless an application complies with the State Health Plan, Project Review Criteria, and other regulations" In considering the State Health Plan, the Department's decision must be based on the currently approved State Health Plan in effect at the time such application is accepted See Regulation 61-15 § 504

The Act was enacted to "promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities" in South Carolina. S C Code Ann. § 44-7-120 (2002) Here, CCMC is a health care facility as defined by the CON Act. S C Code Ann. § 44-7-130(10) (2002) Furthermore, Belfair is an affected party as defined in the CON Act. See S C Code Ann. § 44-7-130(1) (2002)

4 The CON Act and regulations require that CCMC obtain a CON prior to undertaking "the acquisition of medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of that prescribed by regulation" S C Code Ann. § 44-7-160(6) (2002) A health care facility is required to obtain a CON before acquiring "medical equipment which is to be used for diagnosis or treatment if the total project cost is in excess of \$600,000" or spending in excess of \$2,000,000 on behalf of a health care facility S C Code Ann. Reg. 61-15 § 102 1(c) and (f)(2002) At the time the Application in the present case was filed, the 2003 Plan was in effect. The 2003 Plan provides, in relevant part, as follows

- (1) Each hospital should have at least one MRI unit available for diagnosis of emergency patients, inpatients and outpatients
- (2) In order to promote cost-effectiveness, the use of shared mobile MRI units should be considered

The Plan does not define "available" for purposes of determining whether a CON application for a MRI unit should be granted. The Department and CCMC interpret the word "available" in standard 1" of the 2003 Plan as meaning immediate access twenty-

four hours, seven days a week. Thus, every hospital should be granted a CON for at least one fixed MRI unit (either within its four walls or in a permanent facility adjacent to the hospital on its grounds) if the hospital can afford a unit. In other words, in instances in which a hospital seeks a MRI unit, the use of shared mobile MRI units is not a consideration.

As when seeking to determine the meaning of statutes, the rules of statutory construction apply to the interpretation of the meaning of regulations. See Converse Power Corp v South Carolina Dept. of Health and Environment Control, 350 S C 39, 564 S.E.2d 341 (Ct. App 2002) "Statutes dealing with the same subject matter must be reconciled, if possible, so as to render both operative" Hodges v Rainey, 341 S C 79, 88, 533 S.E.2d 578, 583 (2000) See also Statutes and Statutory Construction, § 46 05, at 154 (6th ed. 2000) (A statute is passed as a whole and not in parts or sections and is animated by one general purpose and intent. Consequently, each part or section should be construed in connection with every other part or section so as to produce a harmonious whole.)⁶ The 2003 State Health Plan clearly sets forth the determination that hospitals need at least one MRI unit available. However, the 2003 Plan does not set forth that only fixed, in-house units meet the requisite availability. In other words, the 2003 Plan simply does not set forth a mandatory requirement that "at least one" MRI must be available to all hospitals without considering shared units.

Furthermore, there are certainly plausible instances in which both standards would be applicable to an MRI application by a hospital. Not all hospitals are necessarily open twenty-four hours, seven days a week or even treat individuals who would need an

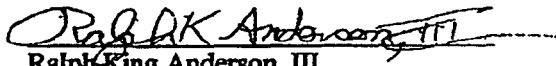
⁶ CCMC argues that the Department's staff's interpretation of the meaning of The State Health Plan should be accorded deference. The law is well established that construction of a statute by the agency charged with its administration will be accorded the most respectful consideration and will not be overruled absent compelling reasons. Dorman v Dep't of Health and Envtl. Control, 350 S C 159, 565 S.E.2d 119 (Ct. App 2002) (quoting, in part, Brown v S.C. Dep't of Health & Envtl. Control, 348 S C 507 560 S.E.2d 410 (2002)). Here, however, the Department's Board and not the Department's staff, is the policymaker for the Department and thus possesses the authority to establish its interpretation of its regulatory and statutory provisions. Therefore, the Department's Board's interpretation of its regulations and statutes, not its staff, are to be accorded deference. S.C. Coastal Conservation League v. South Carolina Dept. of Health and Environmental Control, 363 S C 67, 610 S.E.2d 482 (2005). Consequently, though it is appropriate to give due consideration to the Department's staff's factual utilization of its specialized knowledge and expertise, I find that construction of the meaning of The State Health Plan by the Department's staff is not entitled to "most" respectful consideration. See S C Code Ann. § 1-23-330(4) (Supp 2002) (The agency's experience, technical competence and specialized knowledge may be utilized in the evaluation of the evidence.)

MRI Therefore, "available" as used in the 2003 Plan does not mean that any hospital is entitled to at least one onsite MRI unit as long as it can afford the unit. Rather, the application of the above two standards must be made based upon the facts of the case in light of the MRI needs of the hospital. Construing "standard 1" as mandatory, without specific language requiring that reading would render "standard 2" meaningless in all hospital applications, no matter what the circumstances

Nevertheless, CCMC is open twenty-four hours a day, seven days a week. Moreover, CCMC not only treats individuals who would need MRI scans, but treats individuals who urgently need MRI scans. There are times when patients are too unstable to be transported off site. Therefore, though "standard 2" may be a consideration, the facts of this case clearly establish that to be sufficiently "available" to CCMC, it needs a fixed, in-house MRI unit.

ORDER

Based upon the above Findings of Fact and Conclusions of Law, it is hereby
ORDERED that the application of CCMC for its Certificate of Need is granted.
AND IT IS SO ORDERED


Ralph King Anderson, III
Administrative Law Judge

November 10, 2005
Columbia, South Carolina

DEPARTMENT OF SERVICE
This is to certify that the data
served upon the person upon all
parties to the order is a copy hereof,
in the United States or in the Interagency
Mail Service sent to the party(ies) or their attorney(s)

This 10th day of November, 2005
By Elizabeth L. Berger

**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

MRI at Belfair LLC

Petitioner

vs

South Carolina Department of Health
and Environmental Control and Coastal
Carolina Medical Center,

Respondents

Docket No 07-ALJ-07-0389-CC

FINAL ORDER AND DECISION

APPEARANCES John J Pringle Jr Esquire and John F Beach Esquire for MRI at Belfair, LLC,
Travis Dayhuff Esquire and Holly G Gillespie, Esquire for Coastal Carolina Medical Center
Ashley C Biggers Esquire, for South Carolina Department of Health and Environmental Control

STATEMENT OF THE CASE

This matter comes before the Administrative Law Court (ALC or Court) pursuant to a request for a contested case hearing under the Administrative Procedures Act filed by MRI at Belfair, LLC (Belfair). Belfair claims that the Certificate of Need (CON) Coastal Carolina Medical Center (Coastal) obtained for a magnetic resonance imaging (MRI) unit on its hospital campus should be voided because Coastal substantially changed its MRI project.¹ Respondents assert that the amendments to the MRI project are not substantial because they did not change the project's compliance with the relevant project review criteria. A hearing was held before me on August 4, 2009 at the offices of the ALC. For the reasons set forth below, the Court holds that the amendments to the MRI project are not substantial under Regulation 61-15 section 605, and, therefore, Coastal's MRI CON is not void.

¹ Belfair also claims that if the changes are found by the Court to be substantial, the 2007 sale of the hospital would also void the MRI CON.

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BACKGROUND

Belfair previously challenged the decision of the South Carolina Department of Health and Environmental Control (Department) to issue a CON to Coastal for the acquisition of a 1.5 tesla MRI and construction of an addition to its hospital. On November 10, 2005, the Administrative Law Court (ALC) granted partial summary judgment for Coastal and the Department and determined, after an evidentiary hearing, that a CON for Coastal was appropriate because an on-site MRI was necessary to make MRI services "available" to Coastal's inpatients and emergency patients under the applicable State Health Plan standard. MRI at Belfair, LLC v. S.C. Dept. of Health & Environmental Control and Coastal Carolina Medical Center, 04-ALJ-07-0399-CC (November 10, 2005).

After the Department's Board affirmed the ALC's order issuing the CON to Coastal, Belfair appealed the Board's decision to the Court of Appeals. However, Belfair did not move the ALC or Court of Appeals to stay the decision to grant the CON to Coastal. Accordingly, the Department issued the CON for the on-site MRI to Coastal on August 3, 2006.

On June 12, 2007, Coastal requested a determination from the Department that converting the mobile MRI Coastal was temporarily operating, pursuant to its approval, into a fixed unit was an acceptable implementation of Coastal's CON. More particularly, Coastal sought a determination that this proposal would not constitute a substantial amendment to the originally approved project. 24A S.C. Code Ann. Regs. 61-15 § 605. In support of this request, Coastal submitted information regarding the MRI unit, the location the MRI would occupy on the hospital campus, and the revised cost of the project.

The Department determined that Coastal's plan to convert its mobile MRI to a fixed MRI was not a substantial change to its CON project. It made this determination because the location of the MRI project did not change, the cost of the project decreased, and the 1.5 tesla mobile MRI is substantially the same as the 1.5 tesla MRI proposed in the CON application. After receiving that determination, Coastal purchased the 1999 refurbished 1.5 tesla General Electric MRI housed in a trailer and affixed it to a concrete pad adjacent to the hospital. Coastal thereafter submitted a final completion report to the Department for the project, and the Department closed its file on the CON on June 27, 2007.

Belfair subsequently requested the DHEC Board to review its staff's decision that the amendments to the MRI project were not substantial. After the Board declined to conduct a final review, Belfair filed for contested case review of this final agency decision.

On July 14, 2008, the Supreme Court remanded the original case, Docket No. 04-ALJ-07-0399-CC, to the ALC to permit Belfair the opportunity to put up its evidence that the MRI project did not satisfy the project review criteria set forth in the State Health Plan. MRI at Belfair, LLC v. S.C. Dept. of Health & Environmental Control, 379 S.C. 1, 664 S.E.2d 471 (2008). After the remand, the ALC consolidated contested cases 04-ALC-07-0399-CC and 07-ALJ-07-0389-CC. On July 9, 2009, upon the motion of Belfair and with the consent of Coastal and DHEC, the ALC dismissed contested case 04-ALC-07-0399. With this motion, Belfair conceded its claim that the MRI project set forth in the CON application did not satisfy the relevant project review criteria. Therefore, the issue remaining for determination is whether the amendments to the MRI project are substantial.

FINDINGS OF FACT

Having observed the witnesses and exhibits presented at the hearing and taking into consideration the burden of persuasion and the credibility of the witnesses, I make the following findings of fact by a preponderance of evidence:

Coastal is a forty-one (41) bed hospital located in Jasper County, South Carolina, which opened to the public in November 2004. Belfair is a free-standing imaging facility, located in Beaufort County, South Carolina, providing MRI services for Beaufort and Jasper Counties. Albert J. Borelli, Jr., M.D., a radiologist, is the owner of Belfair, which competes with Coastal for MRI services.

The Original Project versus the Implemented Project

The original CON approved new construction at the hospital to house the fixed MRI unit. The MRI unit and associated equipment were to be located inside the hospital, adjacent to the emergency room, in an MRI suite (comprised of an MRI Room, MRI Control Room, and MRI Equipment Room). The MRI suite as implemented is not located within the hospital and adjacent to the emergency room, but rather in a location just outside the hospital. The MRI unit is in a trailer that has been skirted and connected via a non-enclosed walkway. The MRI Suite has an external lift that raises patients up when necessary so that they can be wheeled into the

MRI unit. Though it requires a several minute walk from the emergency room, it is nevertheless built to be an integral part of the hospital.

Clinical and Operational Issues

Basically, the operational functions of Coastal's MRI and the proposed MRI are quite similar. Coastal's MRI and the proposed MRI both

- Have 1.5 tesla² magnets
- Were manufactured by GE and are similar models
- Are short bore³ systems
- Have patient tubes that are the same diameter
- Are four channel⁴ systems
- Run similar software
- Have the same coils⁵

Dr. Borelli nevertheless contends that the implemented project is substantially different from the original.⁶ He points out that the MRI unit to be incorporated into the Original Project offered a maximum gradient amplitude of 33 millitesla per meter squared, whereas the MRI unit for the Implemented Project has a maximum gradient amplitude of 23 millitesla per meter squared. The lower gradient strength is noteworthy because the higher the gradient strength, the faster the MRI completes a scan. Nevertheless, in terms of the actual operation of the units, the gradient strength in this case is not a significant difference. For example, given the ten (10) millitesla per meter difference in gradient strength, an MRI of a knee would take approximately sixty seconds longer on Coastal's MRI than the proposed MRI. This certainly would not increase the wait time for patients since Coastal's volume is approximately four scans per day. Moreover, despite its lower gradient strength, there was no evidence that the proposed MRI would produce substantially better images than Coastal's current MRI.

² Tesla is the measure of the magnetic field strength generated by the MRI's main magnet.

³ The bore describes the length of the tube where the patient lies to be scanned.

⁴ The number of channels affects the speed of the scan.

⁵ A coil is essentially a radio frequency antenna placed on or around the body part to be scanned. In this instance, Coastal's MRI in fact has additional coils making it superior to the proposed unit.

⁶ In addition to the arguments below, Dr. Borelli testified that the proposed MRI has an MRI-safe wheelchair, MRI safe IV stand, and a 3-D workstation, and suggested that these items may not be present with Coastal's MRI. However, Coastal's MRI has an MRI safe wheelchair, an MRI safe IV track. Moreover, no evidence was offered as to whether Coastal's MRI has a 3-D workstation. Dr. Borelli also testified that it is more difficult to access the back of the magnet on Coastal's MRI while the Original Project did not present that concern. There was no persuasive evidence offered that the access to the magnet would result in substantial clinical or operational differences between these MRI units. Therefore, these contentions will not be addressed further.

Dr Borelli also testified that Coastal does not have MRI-safe monitoring equipment and thus cannot scan patients who require constant monitoring.⁷ Indeed Coastal does not have MRI-safe monitoring equipment and thus Coastal does not scan patients too unstable to be removed from monitoring equipment. However the lack of this equipment is not a substantial change because MRI-safe monitoring equipment was not present in the Original Project application nor did that application state that patients on constant monitoring will be scanned. Moreover the lack of that equipment does not preclude Coastal from scanning unstable patients.⁸ Coastal does provide MRI scans to unstable patients if the radiologist and the patient's physician determine that the patient can be safely removed from monitoring during the MRI scan.

Dr Borelli further objected that because the Implemented Project is located outside of the hospital building, it requires a separate, MRI-specific Code Blue procedure that would not exist had the Original Project described in CCMC's Application been implemented. When a code blue is called at a hospital, a code blue team normally consisting of an Emergency Room physician and certain staff rush to the patient who is in distress. The Original MRI would have utilized a phone connected to the hospital intercom to call a code blue, while Coastal's MRI requires an MRI technician to press a code blue button and then the hospital operator announces the code blue over the hospital intercom. This difference however did not make Coastal's MRI less safe than the proposed MRI.

Dr Borelli also noted other differences between the projects that he believed raised safety concerns. For instance, 1) the Implemented Project requires the use of a lift to access and leave the unit which is more limited in space than the Original Project and 2) the Implemented Project is not adjacent to the emergency room as was the Original Project. Dr Borelli believes the limited space on the lift will make it more difficult to remove patients from the Implemented Project. MRIs with lift openings similar in size to Coastal's have been approved by the Department to operate all over South Carolina and meet the recognized quality of care and safety standards. Moreover the evidence did not establish that the size of the lift opening of Coastal's MRI has caused any actual incidents or problems with the removal of patients. Additionally, the change in the proximity to the emergency room also does not raise safety

⁷ Monitoring equipment is used to monitor a variety of vital signs and other aspects of a patient's condition. MRI safe monitoring equipment is non-ferrous and it does not produce radio frequency interference that harms image quality.

⁸ These patients may also be referred to as acutely ill patients or critically ill patients.

issues. In fact, the evidence did not reflect that distance between the emergency room and the Coastal's MRI unit would reduce the standard of care of emergency room patients at this hospital or is even distinct from the distances of other approved hospitals.

Project Review Criteria

The amendments to the MRI project did not substantially change the project's compliance with the following project review criteria: (1) need, (2) accessibility/distribution, (3) cost containment, (4) acceptability, (5) financial feasibility, and (6) adverse impact. 24A S.C. Code Ann. Regs. 61-15 § 802. More specifically, the need for the project did not change because the CON application projected that the proposed MRI would be utilized by inpatients, outpatients, and emergency patients from certain Jasper and Beaufort county zip codes. Furthermore, the actual utilization of Coastal's MRI is substantially the same as the projection. Likewise, compliance with the geographic accessibility/distribution criterion did not change because the Original Project was, and Coastal's MRI is located on the hospital campus. Compliance with financial accessibility also did not change because Coastal's MRI serves the same variety of payors that the proposed MRI was projected to serve.

The proposed MRI also established the acceptability criterion through letters of support from physicians, patients, and others in the service area. Recent interviews with physicians of varying specialties as well as the actual utilization data establish that Coastal's MRI is supported by the physicians and patients in the service area.

The MRI project as amended meets the cost containment criterion significantly better than the more costly original MRI project. The original CON approved new construction at the hospital to house the fixed MRI unit. The total project cost for the Original Project was \$3.2 million, with equipment costs of \$1.8 million. The total project cost for the Implemented Project was \$836,822, approximately \$2.3 million less than the Original MRI Project that DHEC had approved. Moreover, the estimated cost for the MRI equipment itself changed from \$1.8 million to approximately \$535,000. The changes to the project thus resulted in significant savings of health care dollars. Obviously, compliance with the financial feasibility criterion did not change because the proposed MRI was projected to be financially feasible, and analysis of the contribution margin of Coastal's MRI reveals that it is even more financially feasible.

Finally, the MRI project would not adversely impact MRI providers in the area, and the project as implemented is not causing adverse impact. For example, despite Coastal beginning

operation in 2006, Belfair's MRI scan volume has continued to grow. In 2007 Belfair's MRI performed 6713 scans as compared to 993 scans for Coastal. In 2008 Belfair's MRI performed 7019 scans, as compared to 845 scans for Coastal. Belfair has thus not suffered adverse impact from the operation of the MRI project.

Conclusion

There are not substantial clinical or operational differences between Coastal's MRI and the Original Project. In other words, the MRI will operate in substantially the same manner, provide substantially the same services, and serve substantially the same patients. I therefore find that Coastal's MRI and the Original Project are substantially the same from a clinical and operational perspective.

Additionally, the amendments to the MRI project do not substantially change the project's compliance with need, accessibility/distribution, acceptability, cost containment, financial feasibility, and adverse impact. I therefore find that the changes to the MRI project do not alter its compliance with those project review criteria.

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact, I conclude the following as a matter of law:

General Conclusions

The Administrative Law Court has jurisdiction over this contested case proceeding pursuant to S.C. Code Ann. § 44-1-60(F) (Supp. 2008) and § 1-23-600(A) (2005). In contested case hearings, the Administrative Law Judge is the fact finder. Brown v. S.C. Dept. of Health & Env'tl Control, 348 S.C. 507, 560 S.E.2d 410 (2002). The ALC review of matters it heard from the Department is de novo. Marlboro Park Hosp. v. S.C. Dept. of Health & Env'tl Control, 358 S.C. 573, 595 S.E.2d 851 (Ct. App. 2004). Furthermore, Petitioner bears the burden of proving its case by a preponderance of the evidence. Leventis v. S.C. Dept. of Health & Env'tl Control, 340 S.C. 118, 132-33, 530 S.E.2d 643, 651 (Ct. App. 2000). Anonymous v. State Bd. Of Med. Exam'rs, 329 S.C. 371, 375, 496 S.E.2d 17, 19 (1998). Thus, Belfair must prove by a preponderance of the evidence that the changes to CCMC's MRI project are substantial enough to warrant voiding the CON.

Change to the Original Project

2. In this case, Coastal requested the Department to determine that proposed amendments to the MRI project are not substantial ones that would void Coastal's MRI CON.

pursuant to 24A S C Code Ann Regs 61-15 § 605 DHEC issued a determination that the proposed amendments are not substantial Belfair challenges that determination

The Department administers the CON program for South Carolina pursuant to the State Certification of Need and Health Facility Licensure Act, S C Code Ann §§ 44-7-110 et seq (2002) Under the Act before an entity can operate certain health care facilities and services in South Carolina, the Department must issue a Certificate of Need to that entity subject to certain statutory exemptions See S C Code Ann §§ 44-7-160 & 44-7-180 (2002) The CON program is also administered under the guidelines of 24A S C Code Ann Regs 61-15 (Supp 2003) Additionally, Section 44-7-210(C) provides that, “[t]he Department may not issue a Certificate of Need unless an application complies with the State Health Plan Project Review Criteria, and other regulations See also, MRI at Belfair, LLC v S C Dept of Health & Envtl Control, 379 S C 1, 664 S E 2d 471 (2008) In considering the State Health Plan the Department’s decision must be based on the currently approved State Health Plan in effect at the time such application is accepted See Regulation 61-15 § 504

The Act was enacted to “promote cost containment, prevent unnecessary duplication of health care facilities and services guide the establishment of health facilities and services which will best serve public needs and ensure that high quality services are provided in health facilities’ in South Carolina S C Code Ann § 44-7-120 (2002) Here, Coastal is a health care facility as defined by the CON Act S C Code Ann § 44-7-130(10) (2002) Furthermore Belfair is an affected party as defined in the CON Act See S C Code Ann § 44-7-130(1) (2002)

A CON is “valid only for the project described in the application except as may be modified in accordance with regulations” S C Code Ann § 44-7-230(A) (2002) Once a CON is issued an applicant may not substantially amend or alter the project 24A S C Code Ann Regs 61-15 § 605 If the project is substantially amended or altered it constitutes a new project Id Review of this issue requires a comparison of the amended project to the original project proposed in the CON application to determine whether the amendment is substantial Because the project review criteria are applied and analyzed when the Department initially grants a CON, presumably these same criteria must be re-examined to determine whether a project has substantially changed under Section 605 If the amendments to the project do not substantially

change the project's compliance with the relevant project review criteria then the amendment is not substantial under Section 605

The evidence established that there are not substantial clinical or operational differences between Coastal's MRI and the Original Project. In other words, the MRI will operate in substantially the same manner, provide substantially the same services, and serve substantially the same patients. Furthermore, the amendments to the original MRI project did not substantially change the project's compliance with the project review criteria. The amended MRI project satisfies need, accessibility/distribution, acceptability, cost containment, financial feasibility, and adverse impact in substantially the same way that the original project satisfied these criteria. Coastal's amended MRI project also retained the character and essential services upon which the original CON was based. Therefore, the amendments to Coastal's MRI project do not constitute substantial amendments to a CON project under section 605, and, thus, Coastal's MRI CON is not void.

Sale of Hospital

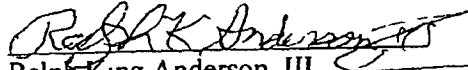
On July 1, 2007, the hospital was purchased by Tenet HealthSystem Medical Inc. Belfair contends that the sale of CCMC voided the CON for the Project. S.C. Code Ann. § 44-7-230(E) provides that "[a] Certificate of Need or rights thereunder may not be sold, assigned, leased, transferred, mortgaged, pledged or hypothecated, and any actual transfer or attempt to make a transfer of this sort results in an immediate voidance of the Certificate of Need." Belfair nevertheless recognized that this claim is dependent upon a determination that Coastal's amendments to its MRI project were substantial under Regulation 61-15 § 605. In other words, on June 26, 2007, Coastal completed its MRI project and submitted a final completion report to DHEC. DHEC determined the project was complete and closed its file on Coastal's MRI project the following day. If the changes to the Original Project were not substantial, then the project was completed before the date of sale. However, if the changes to the Original Project were substantial, then the project was not completed before the date of sale, and the CON is thus voided as a result of that sale. This Court's decision that the changes to the project were not substantial therefore renders this contention moot.

ORDER

Based upon the above Findings of Fact and Conclusions of Law

IT IS HEREBY ORDERED that the changes to CCMC s MRI project are not substantial and do not warrant voidance of the CON

AND IT IS SO ORDERED


Ralph King Anderson, III
Chief Administrative Law Judge

October 23, 2009
Columbia, South Carolina

CERTIFICATE OF SERVICE

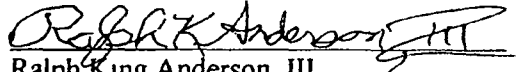
This is to certify that the undersigned has this date served this order in the above entitled action upon all parties to this cause by depositing a copy hereof in the United States mail postage paid or in the Interagency Mail Service addressed to the party(ies) or their attorney(s)

This 23rd day of October, 2009
By Frank M. Scott
Judicial Law Clerk

Under Section 605 evidence of how the original project proposed in the CON application complied with the criteria is probative as to whether the amendments to the project will substantially change how the project will comply with the criteria. Following that reasoning this Court consideration included an analysis of whether the amended project meets those same project review criteria it originally met **in substantially the same way**.¹ Nevertheless, the Final Order and Decision has been amended to dispel any misapprehension concerning the analysis of this evidence.

IT IS HEREBY ORDERED that the Petitioners' Motion for Reconsideration is **DENIED**.

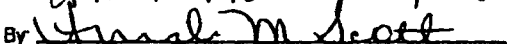
AND IT IS SO ORDERED


Ralph King Anderson, III
Chief Administrative Law Judge

November 24, 2009
Columbia, South Carolina

CERTIFICATE OF SERVICE

This is to certify that the undersigned has this date served this order in the above entitled action upon all parties to this cause by depositing a copy hereof in the United States mail postage paid or in the Interagency Mail Service addressed to the party(ies) or their attorney(s).

This 24th day of November, 2009
By 
Judicial Law Clerk

¹ I appreciate the in depth analysis proposed by the parties regarding this issue but choose to dispose of the issue more succinctly.

RECEIVED

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

NOV 25 2009

Ellis, Laworne
& Sims, PA

MRI at Belfair LLC)
)
Petitioner)
)
vs)
)
South Carolina Department of Health)
and Environmental Control and Coastal)
Carolina Medical Center,)
)
Respondents)
)

Docket No 07-ALJ-07-0389-CC

AMENDED FINAL ORDER
AND DECISION

APPEARANCES John J Pringle, Jr , Esquire and John F Beach, Esquire, for MRI at
Belfair LLC,
Travis Dayhuff, Esquire and Holly G Gillespie Esquire for Coastal
Carolina Medical Center
Ashley C Biggers, Esquire, for South Carolina Department of
Health and Environmental Control

STATEMENT OF THE CASE

This matter comes before the Administrative Law Court (ALC or Court) pursuant to a request for a contested case hearing under the Administrative Procedures Act filed by MRI at Belfair LLC (Belfair) Belfair claims that the Certificate of Need (CON) Coastal Carolina Medical Center (Coastal) obtained for a magnetic resonance imaging (MRI) unit on its hospital campus should be voided because Coastal substantially changed its MRI project¹ Respondents assert that the amendments to the MRI project are not substantial because they did not change the project's compliance with the relevant project review criteria. A hearing was held before me on August 4 2009 at the offices of the ALC and a Final Order and Decision was issued on October 23 2009 Following that decision, Petitioner timely filed a Motion for Reconsideration on November 5, 2009 In response to the issues raised in that Motion, I am issuing this Amended Final Decision and Order

¹ Belfair also claims that if the changes are found by the Court to be substantial the 2007 sale of the hospital would also void the MRI CON

FILED

NOV 24 2009

SC ADMIN LAW COURT

BACKGROUND

Belfair previously challenged the decision of the South Carolina Department of Health and Environmental Control (Department) to issue a CON to Coastal for the acquisition of a 1.5 tesla MRI and construction of an addition to its hospital. On November 10, 2005, the Administrative Law Court (ALC) granted partial summary judgment for Coastal and the Department and determined after an evidentiary hearing, that a CON for Coastal was appropriate because an on-site MRI was necessary to make MRI services 'available to Coastal's inpatients and emergency patients under the applicable State Health Plan standard. MRI at Belfair, LLC v. S.C. Dept. of Health & Envtl. Control and Coastal Carolina Med. Ctr., 04-ALJ-07-0399-CC (November 10, 2005).

After the Department's Board affirmed the ALC's order issuing the CON to Coastal, Belfair appealed the Board's decision to the Court of Appeals. However, Belfair did not move the ALC or Court of Appeals to stay the decision to grant the CON to Coastal. Accordingly, the Department issued the CON for the on-site MRI to Coastal on August 3, 2006.

On June 12, 2007, Coastal requested a determination from the Department that converting the mobile MRI Coastal was temporarily operating, pursuant to its approval, into a fixed unit was an acceptable implementation of Coastal's CON. More particularly, Coastal sought a determination that this proposal would not constitute a substantial amendment to the originally approved project. 24A S.C. Code Ann. Regs. 61-15 § 605. In support of this request, Coastal submitted information regarding the MRI unit, the location the MRI would occupy on the hospital campus, and the revised cost of the project.

The Department determined that Coastal's plan to convert its mobile MRI to a fixed MRI was not a substantial change to its CON project. It made this determination because the location of the MRI project did not change, the cost of the project decreased, and the 1.5 tesla mobile MRI is substantially the same as the 1.5 tesla MRI proposed in the CON application. After receiving that determination, Coastal purchased the 1999 refurbished 1.5 tesla General Electric MRI housed in a trailer and affixed it to a concrete pad adjacent to the hospital. Coastal thereafter submitted a final completion report to the Department for the project and the Department closed its file on the CON on June 27, 2007.

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⁶ In addition to the arguments below, Dr. Borelli testified that the proposed MRI has an MRI-safe wheelchair, MRI-safe IV stand, and a 3-D workstation, and suggested that these items may not be present with Coastal's MRI. However, Coastal's MRI has an MRI-safe wheelchair, an MRI-safe IV track. Moreover, no evidence was offered as to whether Coastal's MRI has a 3-D workstation. Dr. Borelli also testified that it is more difficult to access the back of the magnet on Coastal's MRI while the Original Project did not present that concern. There was no persuasive evidence offered that the access to the magnet would result in substantial clinical or operational differences between these MRI units. Therefore, these contentions will not be addressed further.

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Dr. Borelli further objected that because the Implemented Project is located outside of the hospital building, it requires a separate, MRI-specific "Code Blue" procedure that would not exist had the Original Project described in CCMC's Application been implemented. When a code blue is called at a hospital, a code blue team, normally consisting of an Emergency Room physician and certain staff, rush to the patient who is in distress. The Original MRI would have utilized a phone connected to the hospital intercom to call a code blue, while Coastal's MRI requires an MRI technician to press a code blue button, and then the hospital operator announces the code blue over the hospital intercom. This difference, however, did not make Coastal's MRI less safe than the proposed MRI.

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Project Review Criteria

The amendments to the MRI project did not substantially change the project's compliance with the following project review criteria: (1) need, (2) accessibility/distribution, (3) cost containment, (4) acceptability, (5) financial feasibility, and (6) adverse impact. 24A S.C. Code Ann. Regs. 61-15 § 802. More specifically, the need for the project did not change because the CON application projected that the proposed MRI would be utilized by inpatients, outpatients, and emergency patients from certain Jasper and Beaufort county zip codes. Furthermore, the actual utilization of Coastal's MRI is substantially the same as the projection. Likewise, compliance with the geographic accessibility/distribution criterion did not change because the Original Project was, and Coastal's MRI is located on the hospital campus. Compliance with financial accessibility also did not change because Coastal's MRI serves the same variety of payors that the proposed MRI was projected to serve.

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The MRI project as amended meets the cost containment criterion significantly better than the more costly original MRI project. The original CON approved new construction at the hospital to house the fixed MRI unit. The total project cost for the Original Project was \$3.2 million, with equipment costs of \$1.8 million. The total project cost for the Implemented Project was \$836,822, approximately \$2.3 million less than the

Original MRI Project that DHEC had approved. Moreover, the estimated cost for the MRI equipment itself changed from \$1.8 million to approximately \$535,000. The changes to the project thus resulted in significant savings of health care dollars. Obviously, compliance with the financial feasibility criterion did not change because the proposed MRI was projected to be financially feasible, and analysis of the contribution margin of Coastal's MRI reveals that it is even more financially feasible.

Finally, the MRI project would not adversely impact MRI providers in the area, and the project as implemented is not causing adverse impact. For example, despite Coastal beginning operation in 2006, Belfair's MRI scan volume has continued to grow. In 2007, Belfair's MRI performed 6,713 scans, as compared to 993 scans for Coastal. In 2008, Belfair's MRI performed 7,019 scans, as compared to 845 scans for Coastal. Belfair has thus not suffered adverse impact from the operation of the MRI project.

Conclusion

There are not substantial clinical or operational differences between Coastal's MRI and the Original Project. In other words, the MRI will operate in substantially the same manner, provide substantially the same services, and serve substantially the same patients. I therefore find that Coastal's MRI and the Original Project are substantially the same from a clinical and operational perspective.

Additionally, the amendments to the MRI project do not substantially change the project's compliance with need, accessibility/distribution, acceptability, cost containment, financial feasibility, and adverse impact. I therefore find that the changes to the MRI project do not alter its compliance with those project review criteria.

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact, I conclude the following as a matter of law:

General Conclusions

The Administrative Law Court has jurisdiction over this contested case proceeding pursuant to S.C. Code Ann. § 44-1-60(F) (Supp. 2008) and § 1-23-600(A) (2005). In contested case hearings, the Administrative Law Judge is the fact finder. Brown v. S.C. Dept. of Health & Env't'l Control, 348 S.C. 507, 560 S.E.2d 410 (2002). The ALC review of matters it heard from the Department is de novo. Marlboro Park Hosp. v. S.C. Dept. of

Health & Env'tl Control 358 S C 573 595 S E 2d 851 (Ct App 2004) Furthermore, Petitioner bears the burden of proving its case by a preponderance of the evidence Leventis v S C Dept of Health & Env'tl Control 340 S C 118 132-33 530 S E 2d 643 651 (Ct App 2000), Anonymous v State Bd Of Med Exam'rs, 329 S C 371 375, 496 S E 2d 17, 19 (1998) Thus Belfair must prove by a preponderance of the evidence that the changes to CCMC s MRI project are substantial enough to warrant voiding the CON

Change to the Original Project

2 In this case Coastal requested the Department to determination that proposed amendments to the MRI project are not substantial ones that would void Coastal's MRI CON, pursuant to 24A S C Code Ann Regs 61-15 § 605 DHEC issued a determination that the proposed amendments are not substantial Belfair challenges that determination

The Department administers the CON program for South Carolina pursuant to the State Certification of Need and Health Facility Licensure Act, S C Code Ann §§ 44-7-110 et seq (2002) Under the Act, before an entity can operate certain health care facilities and services in South Carolina, the Department must issue a Certificate of Need to that entity subject to certain statutory exemptions See S C Code Ann §§ 44-7-160 & 44-7-180 (2002) The CON program is also administered under the guidelines of 24A S C Code Ann Regs 61-15 (Supp 2003) Additionally, Section 44-7-210(C) provides that, "[t]he Department may not issue a Certificate of Need unless an application complies with the State Health Plan, Project Review Criteria, and other regulations See also, MRI at Belfair, LLC v S C Dept of Health & Env'tl Control, 379 S C 1, 664 S E 2d 471 (2008) In considering the State Health Plan the Department s decision must be based on the currently approved State Health Plan in effect at the time such application is accepted See Regulation 61-15 § 504

The Act was enacted to 'promote cost containment, prevent unnecessary duplication of health care facilities and services guide the establishment of health facilities and services which will best serve public needs and ensure that high quality services are provided in health facilities" in South Carolina S C Code Ann § 44-7-120 (2002) Here, Coastal is a health care facility as defined by the CON Act S C Code Ann § 44-7-

130(10) (2002) Furthermore Belfair is an affected party as defined in the CON Act See S C Code Ann § 44-7-130(1) (2002)

A CON is 'valid only for the project described in the application except as may be modified in accordance with regulations ' S C Code Ann § 44-7-230(A) (2002) Once a CON is issued an applicant may not substantially amend or alter the project 24A S C Code Ann Regs 61-15 § 605 If the project is substantially amended or altered it constitutes a new project Id Review of this issue requires a comparison of the amended project to the original project proposed in the CON application to determine whether the amendment is substantial A CON is "valid only for the project described in the application except as may be modified in accordance with regulations S C Code Ann § 44-7-230(A) (2002) Once a CON is issued an applicant may not substantially amend or alter the project 24A S C Code Ann Regs 61-15 § 605 If the project is substantially amended or altered, it constitutes a new project Id Review of this issue requires a comparison of the amended project to the original project proposed in the CON application to determine whether the amendment is substantial In making that determination, I find that consideration of the project review criteria is relevant In other words whether the amendments to the project substantially change the project's compliance with the relevant project review criteria is pertinent in determining whether amendments to this permit were substantial under Section 605

The evidence established that there are not substantial clinical or operational differences between Coastal's MRI and the Original Project In other words the MRI will operate in substantially the same manner, provide substantially the same services and serve substantially the same patients Furthermore the amendments to the original MRI project did not substantially change the project's compliance with the project review criteria The amended MRI project satisfies need accessibility/distribution acceptability cost containment, financial feasibility and adverse impact in substantially the same way that the original project satisfied these criteria Coastal's amended MRI project also retained the character and essential services upon which the original CON was based Therefore, the amendments to Coastal's MRI project do not constitute substantial amendments to a CON project under section 605 and thus Coastal's MRI CON is not void

Sale of Hospital

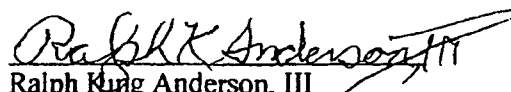
On July 1, 2007 the hospital was purchased by Tenet HealthSystem Medical, Inc. Belfair contends that the sale of CCMC voided the CON for the Project. S.C. Code Ann. § 44-7-230(E) provides that "[a] Certificate of Need or rights thereunder may not be sold, assigned, leased, transferred, mortgaged, pledged or hypothecated and any actual transfer or attempt to make a transfer of this sort results in an immediate voidance of the Certificate of Need." Belfair nevertheless recognized that this claim is dependent upon a determination that Coastal's amendments to its MRI project were substantial under Regulation 61-15 § 605. In other words, on June 26, 2007 Coastal completed its MRI project and submitted a final completion report to DHEC. DHEC determined the project was complete and closed its file on Coastal's MRI project the following day. If the changes to the Original Project were not substantial then the project was completed before the date of sale. However, if the changes to the Original Project were substantial then the project was not completed before the date of sale and the CON is thus voided as a result of that sale. This Court's decision that the changes to the project were not substantial therefore renders this contention moot.

ORDER

Based upon the above Findings of Fact and Conclusions of Law

IT IS HEREBY ORDERED that the changes to CCMC's MRI project are not substantial and do not warrant voidance of the CON.

AND IT IS SO ORDERED


Ralph King Anderson, III
Chief Administrative Law Judge

November 24, 2009
Columbia, South Carolina

CERTIFICATE OF SERVICE

This is to certify that the undersigned has this date served this order in the above entitled action upon all parties to this cause by depositing a copy hereof in the United States mail, postage paid, or in the Interagency Mail Service addressed to the party(ies) or their attorney(s).

This 24th day of November, 2009
By Shirley M. Scott
Judicial Law Clerk

McNAIR LAW FIRM, P.A.
ATTORNEYS AND COUNSELORS AT LAW

ADAM B. KIRK
akirk@mcnair.net

WWW.MCNAIR.FIRM

THE TOWER AT 1301 GERVAIS
1301 GERVAIS STREET 11TH FLOOR
COLUMBIA, SOUTH CAROLINA 29201

POST OFFICE BOX 11390
COLUMBIA, SOUTH CAROLINA 29211
TELEPHONE (803) 799-9800
FACSIMILE (803) 753-3219

January 9, 2007

HAND DELIVERED

The Honorable Jana Shealy
Clerk
Administrative Law Court
1205 Pendleton Street
Edgar Brown Building
Columbia, SC 29211

Re Request by MRI at Belfair, LLC for Contested Case Review of the December 14, 2006 decision of the Department of Health and Environmental Control to permit Coastal Carolina Medical Center to use a mobile MRI 24/7 during pendency of appeal before the S.C. Court of Appeals (MRI At Belfair, LLC, vs. South Carolina Department of Health and Environmental Control and Coastal Carolina Medical Center—Docket No 04-ALC-07-0399-CC) and during the implementation of the CON issued to Coastal Carolina Medical Center on August 3, 2006 and the construction of building to house the fixed MRI—(MRI at Belfair, LLC v Department of Health and Environmental Control and Coastal Carolina Medical Center)

Dear Ms Shealy

On behalf of our client, MRI at Belfair, LLC ("Belfair"), we request a contested case hearing on the above referenced Department of Health and Environmental Control ("DHEC" or "Department") final Board decision ("Final Agency Decision") pursuant to the S. C. Administrative Procedures Act as amended by Act 387 (effective July 1, 2006) and Rule 11, RPALC

On July 3, 2006, Belfair appealed the decision of the Board of Health and Environmental Control ("Board") to affirm the Administrative Law Court ("ALC") Order and Decision. That appeal is pending before the South Carolina Court of Appeals. Belfair did not seek a stay of the Board's Order. On July 20, 2006 pursuant to § 4 of Act 387, Coastal Carolina Medical Center ("CCMC") requested that DHEC issue the CON to construct an addition to CCMC to house a fixed 1.5 Tesla MRI unit and to purchase the unit for a total project cost in excess of \$3,201,000 ("Fixed MRI CON"). On August 3, 2006 DHEC issued the Fixed MRI CON.

ANDERSON CHARLESTON CHARLOTTE COLUMBIA GEORGETOWN GREENVILLE HILTON HEAD ISLAND MYRTLE BEACH RALPH

COLUMBIA 877283v1

On August 9, 2006 a news article in the *Island Packet* announced that CCMC would begin providing mobile MRI services at CCMC. Upon his return from testifying out of state as an expert witness, Dr. Borelli, CEO and President of Belfair saw the newspaper article. On August 22, Belfair's counsel e-mailed¹ DHEC CON staff to determine what, if any, regulatory approval DHEC has issued to CCMC for the institution of mobile MRI services. Approval of a mobile MRI was not covered by the Fixed MRI CON issued on August 3, 2006 and was expressly rejected as an alternative in CCMC's CON application for the Fixed MRI. A copy of CCMC's CON Application rejection is attached as Exhibit 2.

After a follow-up call to the DHEC CON staff on August 24, 2006, on August 24, 2006 DHEC sent a facsimile copy of the August 4, 2006 request from CCMC, with attached mobile MRI lease agreement, to DHEC for permission to install and utilize a mobile MRI unit twenty-four hours a day seven days a week, during the implementation and construction of the Fixed MRI CON. See Exhibit 3, Letter dated August 4, 2006 with attachments from David B. Summer, Jr., Esquire to Victoria R. Tibshirany. On that same day, without notice to Belfair (despite the pending appeal and Belfair's status as an affected person in that appeal), DHEC issued its letter which approved CCMC for the "temporary full-time use of a mobile MRI unit during the interim period of the Fixed MRI construction and installation as outlined in [Mr. Summer's] August 4, 2006 letter." See Exhibit 4, Letter dated August 4, 2006 from Victoria R. Tibshirany to David B. Summer, Jr., Esquire ("Final Agency Decision"). There is neither statutory nor regulatory authority for DHEC to issue such approval.

On September 8, 2006, Belfair timely filed its initial request for a contested case hearing on the August 8, 2006 DHEC CON staff decision. On September 15, 2006, Belfair had a letter hand-delivered to the Court pointing out that § 1-23-600(G)(2) provided for an automatic stay of a final agency determination upon the filing of a contested case. The Court declined to enforce the statutory automatic stay and, following a hearing, issued an Order of Remand to the DHEC Board on October 18, 2006. Belfair filed a motion for reconsideration of the Order of Remand on October 26, 2006. After a hearing on the Motion on November 17, 2006, Judge Anderson's order denying Belfair's motion for reconsideration was filed on November 30, 2006.

As stated in the Order of Remand, Judge Anderson remanded the contested case to the DHEC Board "for its consideration of Belfair's request in accordance with Section 44-1-60." Nonetheless, the DHEC Board determined on December 14, 2006 – without any notice to Belfair – not to hear Belfair's request. No written or oral notice was given to Belfair that the DHEC Board would be considering whether to hear its request on December 14, 2006. Upon DHEC's issuance of the January 11, 2006 DHEC Board Meeting Agenda on December 29, 2006, counsel for Belfair e-mailed DHEC to ask whether Belfair's request for final agency review would be heard on that date.

¹ A copy of this e-mail is attached as Exhibit 1.

However, due to DHEC Board's Clerk's vacation schedule, Belfair's counsel received no response. On January 2, 2007, through discussion with counsel for DHEC, Belfair's counsel learned that the DHEC Board had already decided not to hear Belfair's request on December 14, 2006. On January 8, 2007, Belfair's attorneys received the Board's decision not to hear the request for final agency conference, Belfair herewith files its request for a contested case. A copy of the Board's decision is attached as Exhibit 5.

CCMC can only acquire and utilize MRI equipment in accordance with the provisions of the State Certificate of Need and Health Facility Licensure Act, S.C. Code Ann. § 44-7-110, et seq. (Rev. 2002) ("CON Act"). Certainly, CCMC can go forward at its own risk² with the project as approved in the August CON. However, the Fixed MRI CON does not authorize CCMC to acquire and operate a MRI unit not subject to the CON. The language of the CON Act is plain and unambiguous. Section 44-7-230(A) provides:

The Certificate of Need, if issued, is valid only for the project described in the application including location, beds and services to be offered, physical plant, capital or operating costs, or other factors as set forth in the application, except as may be modified in accordance with regulations. The department shall require periodic reports and make inspections to determine compliance with the Certificate of Need. Implementation of the project or operation of the facility or medical equipment that is not in accordance with the Certificate of Need application or conditions subsequently agreed to by the applicant and the department may be considered a violation of this article.

(Emphasis added) As this Court has noted previously, "[w]hether the provision of mobile MRI services by CCMC is subsumed in the hospital's CON for the fixed MRI unit is questionable." Order denying motion for reconsideration dated November 30, 2006, p. 2. In fact, the mobile project proposed by CCMC is NOT the same project described in the application resulting in the August CON. In its CON application, CCMC expressly rejected the use of a mobile MRI as an alternative.

The effect of DHEC's Final Agency Decision in this case is to grant a non-applicability determination or to take "other action" which may give rise to a contested case in order to approve CCMC's use of the mobile MRI. See § 48(A), Act 387, effective July 1, 2006. The Final Agency Decision is a final agency determination pursuant to § 48(E), Act 387 and is subject to contested case review pursuant to § 4(B), Act 387 (§ 1-23-600(B)). Certainly, by approving CCMC's request to institute a different MRI service

² Mr. Tom Berry, DHEC spokesman, was quoted in the *Island Packet* as follows: "We have told Coastal Carolina that our interpretation of the law is that they may go ahead and proceed with the project, but do so with the full knowledge that at any time the state Court of Appeals may issue a stop-work order," Berry said. "If they proceed, they are doing so at their own risk." The "project" is the Fixed MRI CON and nothing else.

McNAIR LAW FIRM, P.A.
ATTORNEYS AND COUNSELORS AT LAW

than that approved in the Fixed MRI Application without notice to an admittedly affected person, DHEC's staff acted in violation of the CON Act and due process

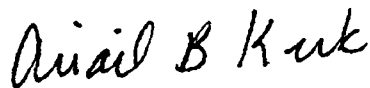
We point out that pursuant to § 4(G)(2) of Act 387 (§1-23-600(G)(2)), this request for contest case review stays all actions for which the approval is a prerequisite (including the operation of the MRI). Visual observation shows that there is an MRI truck parked on site at CCMC. On information and belief, CCMC has been using the mobile MRI to diagnose patients since Monday, September 11, 2006.

We request that the Court reverse the Department's Final Agency Decision and require that CCMC cease and desist providing MRI services with the mobile MRI unit until such time as it has either a valid NAD or CON to acquire and operate the same and that the mobile unit be removed from the CCMC campus. While we believe that our initial filing fee prior to remand is sufficient, in an abundance of caution I have enclosed our check in the sum of \$250 for the filing fee for the Court. I would appreciate your clocking in a copy of this letter and returning it to our courier. Thank you for your attention to this matter.

Should you have any questions with respect to these filings, please do not hesitate to contact me at my direct line number 753-3298.

Thank you for your time and attention to this matter. If you have any questions, please do not hesitate to contact me.

Sincerely,



Anail B. Kirk

Enclosures

cc A Joseph Borelli, Jr, M D
 Kelly M Jolley, Esquire
 Ashley C. Biggers, Esquire
 Nancy S Layman, Esquire
 David B Summer, Esquire
 Susan B Lipscomb, Esquire
 (all VIA HAND DELIVERY and e-mail)

Crum, Liz

From: Crum, Liz
Sent: Tuesday, August 22 2006 3:55 PM
To: Nancy S Layman Esquire (laymanns@dhec.sc.gov); Ashley C Biggers (biggerac@dhec.sc.gov), Joel C Grice (gricejc@dhec.sc.gov); Victoria (Tori) Reich Tibshirany (tibshrvt@dhec.sc.gov), jborell@mriatbelfair.net
Cc: Kirk, Ariall, Rawl, Vic; Jolley Kelly
Subject: FW: Islandpacket.com | Hospital gets green light for MRIs

Tracking	Recipient	Read
	Nancy S. Layman Esquire (laymanns@dhec.sc.gov)	
	Ashley C. Biggers (biggerac@dhec.sc.gov)	
	Joel C. Grice (gricejc@dhec.sc.gov)	
	Victoria (Tori) Reich Tibshirany (tibshrvt@dhec.sc.gov)	
	jborell@mriatbelfair.net	
	Kirk, Ariall	Read: 8/22/2006 4:43 PM
	Rawl, Vic	
	Jolley, Kelly	Read: 8/22/2006 4:09 PM
	A. Joseph Borell, Jr., M.D.	

Subject: islandpacket.com | Hospital gets green light for MRIs

Nancy Ashley Joel and Tori Please review article below I saw where the CON was issued to CCMC for the CON MRI project under appeal to the Court of Appeals. Obviously if CCMC wants to go forward with the Project as approved we have not sought a stay. However to our knowledge CCMC has not obtained either a CON nor a NAD to put mobile MRI services in place. Clearly Sec. 44-7-230(A) authorized CCMC only to go forward with the project as approved ("The Certificate of Need, if issued, is valid only for the project described in the application.") The article states that the mobile services are to be initiated Sept. 1 2006. If a NAD has been issued for this project we expressly request pursuant to FOIA that we be provided a copy of the same. If one has not, please ask CCMC to cease and desist until it has regulatory approval to undertake mobile MRI services. Thank you for your prompt attention to this matter. Liz Crum

M Elizabeth (Liz) Crum
 McNair Law Firm, P.A.
 1301 Gervais Street
 P O Box 11390 (29211)
 Columbia, South Carolina 29201
 (803) 799-9800
 (803) 753-3219 (fax)
 lcrum@mcnair.net
<http://www.mcnair.net>

Hospital gets green light for MRIs

Court appeal could affect construction

BY PETER FROST *The Island Packet*

8/29/2006



Published Wednesday August 9 2006

[Comments \(0\)](#) → [Add Comment](#)

The Coastal Carolina Medical Center is going forward with plans to install an MRI machine, but the hospital's two-year legal battle with a provider may not be over.

After receiving approval from the state Department of Health and Environmental Control late last week to begin installing the equipment, hospital will begin offering mobile magnetic resonance imaging services Sept. 1, said CEO Eric Deaton.

An estimated \$3 million construction project to install a permanent MRI unit is expected to begin shortly thereafter and be completed with that project would mean a separate room would be built to house the MRI unit.

However, should the hospital begin construction, it could be halted at any point pending an appeal to the state Court of Appeals by MRI at Bluffton opposing the project, said Thom Berry, a DHEC spokesman.

"We have told Coastal Carolina that our interpretation of the law is that they may go ahead and proceed with the project, but do so with the understanding the state Court of Appeals may issue a stop-work order," Berry said. "If they proceed, they are doing so at their own risk."

MRI at Belfair in July notified DHEC of its plans to appeal the state-issued permit for a fourth time. The company could petition the state the project pending a hearing on the case.

It's unclear, however, if the court would issue a stop-order, or if MRI at Belfair will ask it to. Dr. Joe Borelli, the company's president and for comment.

Since Coastal Carolina opened in November 2004, its efforts to add the imaging equipment have been blocked by a series of appeals by MRI. It continued to appeal the permits on claims that the area doesn't need another MRI provider and the hospital doesn't see enough patients to

But after MRI at Belfair lost each of the three appeal decisions — two by DHEC and another by the state Administrative Law Court — DHEC the go-ahead to install its long-awaited MRI unit.

"It's been a long process, but we're very pleased to have it in place soon," Deaton said. "To refuse the hospital the ability to provide this type of service is unthinkable."

For its first 20 months of operation, the hospital has been forced to take patients in need of MRI scans by ambulance to other hospitals or to other states. The process costs upward of \$400 per trip and wastes valuable time in patient diagnosis and treatment, Deaton said.

In many after-hours emergency cases, patients have been taken across the state line into Georgia for imaging.

"Obviously, this has been reviewed three times now and the State Health Plan says every hospital should have immediate access to MRI," said. "It's an extremely important piece of diagnostic equipment that's essential to providing high-quality care to our patients."

Contact Peter Frost at 706-8169 or pfrost@islandpacket.com. To comment on this story, please go to islandpacket.com.

8/29/2006

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

ALTERNATIVE NO. 1 *Do not construct an addition for a fixed in-house MRI and utilize mobile services*

DISPOSITION NO. 1 *REJECT Without an in-house MRI, Coastal Carolina's acutely ill and emergent patients would need to be transported to an outside MRI provider which is costly, risky, and stressful. All patients would incur delays in diagnosis and treatment as well.*

ALTERNATIVE NO. 2 *Construct an addition to the facility to house one fixed MRI.*

~~**DISPOSITION NO. 2** *ACCEPT This is the most cost-efficient, convenient, and safest option for the patients of Coastal Carolina. Not having to transport the acutely ill and emergent patients of Coastal Carolina to an off-site MRI scanner will provide these patients with the highest standard of care, in the most safe and cost-effective manner. In-house MRI services at Coastal Carolina will avoid the inconvenience of traveling to an outside provider, and avoid delays in diagnosis, decision-making, and treatment.*~~

000058



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

As previously discussed, an in-house fixed MRI is the most cost-effective and safest manner to meet the need for MRI services at Coastal Carolina.

•Absent of an onsite MRI at Coastal Carolina's will require its acutely ill and emergent patients to be transported by ambulance to outside providers for their MRI scans, which will result in additional expenses for these patients as well as third party providers.

•Absent of an onsite MRI at Coastal Carolina can result in situations whereby more invasive diagnostic tests may be performed to achieve a diagnosis in a more timely fashion than would be more appropriately obtained by an MRI scan in a non-invasive manner

~~Patient privacy is also an issue as mobile MRI units do not offer dressing rooms for patients, making it necessary for those patients to change in another location, then be transported to the MRI unit, or transported to the MRI unit in hospital clothing~~

Have the availability of an in-house MRI will afford all patients at Coastal Carolina with the convenience of having their scans done at one location, thereby reducing any delay in diagnosis, decision making, and treatment in the safest, most cost-effective manner.

000059

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

Because Jasper County and the community of Ridgeland operated an acute care hospital for many years, Coastal Carolina will draw first on any local personnel who are qualified as hospital employees who may want to work for the new facility. Labor resources in or near Jasper County will always receive priority. Efforts to fill staff positions will be launched in nearby areas through active and early recruitment/advertising programs. Province Healthcare is completely geared up to recruit healthcare professionals and all needed support staff. A management team will be selected and onsite several months prior to the completion of the hospital and MOB. All Province Healthcare hospitals have salary/wage scales that are regionally competitive.

000070



February 6, 2004

Mr Eric Deaton, CEO
Coastal Carolina Medical Center
108 Traders Cross, Suite 100
Bluffton, SC 29910

Re MRI Addition
Coastal Carolina Medical Center
Hardeeville, South Carolina
GTG Project No. 22066 6

Dear Eric:

The square footages for the individual rooms, which comprise the MRI addition, are as follows:

MRI Room	440 s.f
Control Room	130 s.f
Equipment Room	213 s.f
Circulation/Exterior Walls	687 s.f.
TOTAL	1,470 square feet

Should you have any questions, please call me

Sincerely,

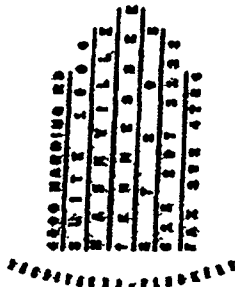
GOULD TURNER GROUP, INC


Michael A. Jones, AIA
Principal

jcn

xc: File 22066.6/Owner

000088



Hardeeville, SC
MRI Projection

	Forecasted 1st 12 months	Forecasted 2nd 12 months	Forecasted 3rd 12 months
Procedures			
Inpatient	276	303	333
Outpatient	825	908	908
Total	1 100	1 210	1 331
Average Charge per Proc	\$2,200	\$2,310	\$2,426
Revenues:			
Inpatient	\$605,000	\$698,775	\$807,085
Outpatient	\$1,815,000	\$2,096,325	\$2,421,255
Total Gross Revenue	\$2,420,000	\$2,795,100	\$3,228,341
Revenue Deductions			
Charity Care	\$1,080,000	\$1,257,795	\$1,452,753
	\$24,200	\$27,951	\$32,283
Total Rev Deducts	\$1,080,000	\$1,257,795	\$1,452,753
Net Patient Revenue	\$1,331,998	\$1,637,305	\$1,775,587
Salaries & wages	\$141,856	\$146,112	\$150,485
Benefits	\$27,882	\$28,492	\$29,347
Contract Labor	\$0	\$0	\$0
Professional Fees	\$0	\$1	\$2
Supplies	\$166,375	\$182,163	\$221,948
Purchased Svc's	\$0	\$0	\$0
Utilities	\$8,643	\$9,075	\$9,529
Insurance	\$626	\$657	\$690
Rent / Lease	\$0	\$0	\$0
Repairs & Maint	\$0	\$120,400	\$120,400
Property Taxes	\$73,689	\$73,689	\$73,689
Bad Debt	\$121,000	\$138,755	\$161,417
Total Oper Exp's	\$539,856	\$719,344	\$767,517
EBITDA	\$791,156	\$928,041	\$1,008,071
Depreciation	\$136,333	\$276,687	\$276,687
Pre Tax Income	\$652,817	\$651,294	\$731,404
Income Taxes	\$291,127	\$226,116	\$282,551
Net Income	\$391,690	\$435,177	\$448,852

Assumptions:

Salaries - 3.1 FTEs @ \$22.00 per hour (3% increase per year)
Benefits - 19.5% of Salaries - Prior Yr @ 6/30/03 is 19.5%
Contract Labor - none
Physician Fees - none
Supplies - 12.5% of net revenue
Purchased Svcs - none
Utilities - \$5.88 per square foot @ 1,470 square feet with 5% increase
Insurance - \$2.35 per square foot @ 1,470 square feet with 5% increase
Rent / Lease - none
Repairs & Maint - under contract year 1 / cost years 2 and 3
Property Tax - 1st yr based on Tax Dept. estimates
Bad Debts - 5% of gross revenue
Depreciation - 1,800,000 / 7.5 = 240,000 + 1,100,000 / 30 = 36,666 Total: \$276,667 per year (half year in 1st year)
Interest - none
Income Taxes - 40%

000117

- More costly than fixed-site arrangement
- Compromises patient privacy as mobile units do not have private dressing rooms for patients
- Based upon projected utilization, use of a mobile unit would be impractical

Use of Mobile Unit

Area physicians and community leaders lend their support citing the following

- MRI unit is a standard of care for the only hospital within the primary service area supporting both a growing and aging population.
- MRI unit is needed for the evaluation of patients with strokes, spinal abscesses, spinal cord injuries, and herniated disks.
- MRI unit serves acutely ill patients more efficiently and effectively
- MRI unit onsite reduces the inconveniences surrounding transportation issues facing local patient populations

Acceptability

000249

Certificate of Need Summary Sheet

I. Project Description

Facility Name: Coastal Carolina Medical Center

Location of Facility: Hardeeville, South Carolina

Project Description: Coastal Carolina Medical Center proposes to provide on-site MRI services by construction of an addition to the hospital to house one (1) fixed MRI system, a 1.5T, GE Signa. PHC-Jasper, Inc., d/b/a Coastal Carolina Medical Center, is a new inpatient bed hospital currently under construction, located in Jasper County, South Carolina, along the extension of Highway 278 (CON No SC-02-29), in the vicinity of the intersection of Highway 278 extension and I-95. The project will be developed under the "Certificate of Need Standards for Magnetic Resonance Imaging (MRI)" in the 2003 South Carolina Health Plan.

Ownership: The proposed project will be owned by PHC-Jasper, Inc., d/b/a Coastal Carolina Medical Center

Profit or Non-profit status: The facility is for-profit.

II. Staff findings

A. The estimated total project cost is \$3,201,000 and is itemized as follows:

Real Estate	\$ 0	
Construction	\$ 1,000,000.	
Equipment	\$ 1,800,000	
Architect's Fee	\$ 100,000	
Other costs	\$ 301,000	
Total project cost	\$ 3,201,000.	000404
Total square footage	1,470	

*Construction (\$1,000,000) Equipment Cost (\$1,800,000) \$2,800,000
per square foot \$1,905

*Note See Additional Information Part A-11,B & D

PARKER POE

PARKER POE ADAMS & BERNSTEIN LLP

Attorneys and Counselors at Law

David B. Summer, Jr.

Partner

Telephone: 803.253.8910

Direct Fax: 803.253.8017

davidsummer@parkerpoe.com

1201 Main Street
Suite 1450

P.O. Box 1509

Columbia, SC 29202 1509

Telephone: 803.253.8000

Fax: 803.253.8017

www.parkerpoe.com

August 4, 2006

Via Hand Delivery

Ms. Victoria R. Tibshirany
Program Coordinator II
South Carolina DHEC
1777 St. Julian Place, Suite 201
Columbia, SC 29204

Re. SC-06-46

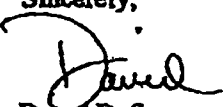
***Certificate of Need for the construction of an addition of one (1) fixed MRI
Coastal Carolina Medical Center***

Dear Ms. Tibshirany:

On behalf of Coastal Carolina Medical Center, this is to request authorization to utilize a mobile MRI at Coastal Carolina Medical Center until construction and installation of its fixed MRI, granted in the above-referenced CON application, is completed. In that regard, attached please find a copy of the proposed MRI Services Proposal/Agreement between Alliance Imaging, Inc and Coastal Carolina Medical Center for the utilization of a mobile MRI

If you have any questions or need further information or clarification, please do not hesitate to contact me. With best regards, I am

Sincerely,


David B. Summer, Jr

DBSjr/ccq
Enclosure

COL 62367v1

EXHIBIT

3

CHARLESTON SC
CHARLOTTE, NC
RALEIGH, NC
SPARTANBURG, SC



MRI Services Proposal/Agreement

**Coastal Carolina Medical Center
1000 Medical Drive
Hardeeville, South Carolina 29927**

***Prepared for: Eric Deaton, C.E.O.
Hollis Tessmer, Director of Imaging***

***Prepared by Kevin Smith, Area Sales Manager, Southeast Region
office number 1-800-743-4729 / mobile number 1-704-905-5131***

PROPOSAL

Date July 20, 2006

Unit Description

1.5T Mobile MRI Unit.

Service Schedule.

Full time perked

Term.

Thirty-six (36) months, provided, however, Client may elect to terminate this Agreement upon commencement of services with a Client solely owned, in house, fixed MRI system upon ninety (90) days prior written notice, provided, further, that such notice may be delivered no earlier than the sixth (6th) month following Commencement of this Agreement.

Personnel.

Option 1) Alliance shall be responsible for staffing the MRI system with appropriately trained technologist(s) based on Client's exam volume. Option 2) Client shall be responsible for staffing the MRI system with appropriately trained technologist(s) based on Client's exam volume.

Medical Supplies

Client shall be responsible for all film, film processing, data storage supplies, contrast, contrast supplies, utilities, suitable pad and power, permits, state and local taxes, etc.

Fees

Option A - staffed by Alliance
Flat monthly fee of \$65,000 00

Option B - staffed by Client.
Flat monthly fee of \$55,000 00

Commitment and Acceptance.

This proposal is subject to execution of a mutually acceptable agreement. This proposal is for informational purposes only and is not a binding legal obligation. This proposal is good for 30 days from receipt. Terms and conditions are subject to change after this 30-day timeframe.

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	2	Fees
	3	Scheduling
	4	Term

MRI SERVICES AGREEMENT

THIS MRI SERVICES AGREEMENT (the "Agreement") is made as of the first date written below between ALLIANCE IMAGING, INC., a Delaware corporation ("Alliance"), and

Coastal Carolina Medical Center
1000 Medical Drive
Hardeeville, South Carolina 29927

a South Carolina not for profit corporation (the "Client")

1 EQUIPMENT AND SERVICES

1.1 The Unit. Alliance shall provide a Magnetic Resonance Imaging ("MRI") system described in Schedule A of this Agreement (the "Unit")

1.2 Personnel. If Fee Option A is selected, Alliance shall provide the services of one (1) technical personnel to operate the Unit as appropriate for Client's exam volume. Client agrees not to hire or contract with any Alliance employee during the term of this Agreement, including renewals, and for a period of one (1) year after MRI services cease (collectively, the "Non-Solicitation Period"), without Alliance's prior written consent. Alliance and Client hereby agree that in the event of a breach of this provision damages shall be difficult to calculate and therefore agree Alliance shall be entitled to receive \$50,000.00. Alliance and Client agree that the aforementioned amounts are reasonable and shall constitute liquidated damages and not a penalty. Alliance shall ensure that all services provided by Alliance's technical personnel (including, but not limited to, any patient coordinator) shall be within the scope of his/her duties as technical personnel. Client agrees, for as long as Alliance remains a JCAHO-accredited organization, that Client shall not need to independently verify and shall not require any written documentation concerning the credentialing, education, training, evaluation, and competencies related to Alliance's technical personnel (including, but not limited to, any patient coordinator). In the event of a JCAHO survey of Client, Alliance shall have the personnel file of Alliance's technical personnel accessible upon request.

If Fee Option B is selected, Client shall provide the services of technical personnel to operate the Unit as appropriate for Client's procedure volume. Client's personnel shall be fully certified in the field of radiography by an institution recognized by the American Medical Association. Other conditions are as follows:

1. Client shall be responsible for any repairs of the Unit and ancillary equipment on the trailer that arise out of the actions or omissions of Client's employees or subcontractors.
2. Client shall be responsible for monitoring the Unit's cryogen level, and Client shall be responsible for any damage to the Unit arising from failure to maintain adequate cryogen levels.
3. Client shall comply with all checklists supplied to Client by Alliance personnel to operate the Unit, and Client shall be responsible for any damage to the Unit arising from failure to do so.
4. Client shall consult with Alliance's operations personnel no less than once per week concerning the operating condition of the Unit.

1.3 Maintenance. Alliance shall use reasonable efforts to cause the Unit to be maintained in good operating condition. Alliance may do so through the purchase of a maintenance contract from the MRI Unit manufacturer or otherwise, in its discretion. Alliance shall provide cryogens.

2 SCANNING ACTIVITIES.

2.1 Unit. Client shall prepare and maintain a safe and suitable site for the Unit which complies with the manufacturer's specifications (which shall be provided by Alliance) and all applicable laws and regulations. All site costs (for example, costs of tractor/trailer access and egress, power and telephone expenses) shall be Client's responsibility. The Unit shall be located at the address first above listed, (the "Unit Location"). Client represents and warrants to Alliance that it currently owns or has authorization to site the Unit at the Unit Location. Further, Client further warrants and agrees that, at all times during the term of this Agreement, Client shall maintain the authorization or ownership to site the Unit at the Unit Location. Client shall indemnify and hold Alliance harmless from any damages or liability arising out of breach of the representations and warranties in this Section 2.1. Client may request in writing to Alliance that the Unit Location be moved, in which case any such move shall be subject to Alliance's prior approval, all of the obligations under this Section 2.1 shall apply to the new Unit Location.

2.2 Power. Client shall provide electrical power, including a dedicated power line with 200 amps and 480 volts of three-phase power. Client shall promptly report any problems with power (for example, sags or surges) to Alliance. Client shall provide the power line, a lockable disconnect box and receptacle within twenty-five (25) feet of the electrical receptacle on the Unit. Client is responsible for damage to the Unit due to power that does not meet specification. Client is responsible for maintaining the power plug and keeping it in good operating condition with quarterly inspection.

2.3 Phone and Connectivity Client shall provide the Unit with a voice telephone line, a dedicated fax compatible telephone line and a RJ-45 ethernet broadband line with an automatic IP address assignment using Dynamic Host Control Protocol ("DHCP") and a proxy-less connection to the internet.

2.4 Operation The Unit shall be operated only by employees or subcontractors of Alliance or Client.

2.5 Medical Director Client shall appoint a qualified and licensed physician to act as Medical Director hereunder, along with another such physician to act in his absence (the "Medical Director"). Client shall be solely responsible for all activities which constitute the practice of medicine (for example, providing medical advice to patients in connection with MRI scans and the injection of contrast agents). Client shall obtain any written consents from patients that are required by the USFDA, state or local law or prudent medical practice. Client shall have full responsibility for all medical care and advice provided to patients. All medical care shall be provided under the ultimate supervision of the Medical Director.

2.6 Medical Supplies; Emergency Care: Client shall provide all medical supplies which may be required (including film and film processing, gowns, medications and contrast agents) and shall ensure the immediate availability at all times of equipment and personnel to treat patients who require emergency or other medical care (including a cardiac monitor, a fresh oxygen supply, an aspirator and a defibrillator).

2.7 Patient Handling. Client shall be responsible for the prompt and orderly pick up and delivery of patients to and from their designated areas.

2.8 Patient Log If Fee Option A is selected, Alliance shall maintain a log of all scans performed on the Unit. Client shall be provided with copies of the log upon request. If Fee Option B is selected, Client shall maintain a log of all scans performed on the Unit. Client shall be provided with copies of the log upon request.

2.9 Modifications Client shall not modify or alter the Unit without Alliance's prior written consent. Client shall not allow any portion of the Unit to become permanently attached to real property. Client agrees to execute any documents evidencing a first priority security interest or mortgage or assignment in favor of any party providing financing for the Unit.

2.10 Scheduling Client shall use all reasonable efforts to schedule its patients consecutively from the beginning of each service day to minimize unutilized scanning time and to prescreen patients for conditions unsuitable for MRI examination.

2.11 Notification of Physicians, Use of Service Client shall notify its staff of physicians of the availability of the Unit and shall use all reasonable efforts to encourage physicians to utilize the Unit for their patients' needs.

2.12 Exclusivity Client agrees to use Alliance solely for all of its MRI needs, except for an emergency where the use of Alliance's service is impractical. Client on behalf of itself, its subsidiaries and/or corporate affiliates (including but not limited to any entity in which Client has an ownership interest) agree during the term of this Agreement, not to own, permit, lease, manage, or invest in any MRI system or engage any entity besides Alliance to provide Client with MRI services.

2.13 Document Retention Alliance and Client agree to retain books, documents and records required under the Omnibus Reconciliation Act of 1989 and other applicable laws and regulations governing governmental reimbursement of medical care expense, in all cases for the periods specified in such laws and regulations.

2.14 Licenses. Client shall obtain and maintain all required licenses and regulatory approvals necessary to operate the Unit at Client's premises. Alliance shall reasonably cooperate to assist Client to obtain such licenses and approvals.

2.15 Taxes. All taxes, if any (for example, sales, use or similar taxes), on the services hereunder shall be the responsibility of Client.

2.16 Professional Interpretations. Client shall engage a radiologist to provide interpretations of MRI exams for Client's patients. Alliance shall not be responsible for providing any such interpretations.

3 FEES AND BILLING

Client shall pay Alliance fees in accordance with Schedule A. All fees for a billing period shall be due and payable within fifteen (15) days of the last day of such period. Alliance shall invoice Client twice each month. Client shall pay a late fee of one and one-quarter percent (1-1/4%) or the maximum legal rate, whichever is less, on all balances outstanding more than fifteen (15) days beyond the due date. Fees may be adjusted on each anniversary of the Commencement Date by the percentage increase for the Medical Care Services component of the Consumer Price Index for all Urban Consumers (CPI-U) as recorded by the Department of Labor Index for the then most recently available twelve month period. Client shall be responsible for all billings to Client Patients and/or third party payors for MRI.

exams performed on the Unit. Client's obligation to pay Alliance compensation in accordance with the provisions of Schedule A shall not be dependent upon Client's billing and collection of patient and/or third party payor accounts receivable. Alliance shall not bill, and Alliance shall not cause bills to be submitted to, any patient or third party payor for MRI exams performed on the Unit. Both parties agree that Alliance is providing its services set forth on this agreement "under arrangement" with Client, such that upon Client's receipt of payment from the Medicare program for MRI exams performed in the Unit, the liability of the beneficiary or any other person to pay for such services shall be fully discharged.

4 TERM

The term of this Agreement shall be as specified on Schedule A.

5 SCHEDULING

Alliance shall make the Unit available to Client according to the schedule specified in Schedule A.

6 INSURANCE, INDEMNITY.

6.1 Insurance.

a) Alliance. Alliance shall maintain insurance covering all risks of physical loss or damage to the Unit, comprehensive general liability and professional liability covering the conduct of its employees, all in amounts and subject to deductibles that are customary in the industry.

b) Client. Client shall maintain comprehensive general and professional liability insurance covering the Client, its employees, staff and physicians and shall require the Medical Director and other physicians who interpret or report on procedures performed on the Unit to maintain professional liability insurance. All such insurance shall be in amounts and with deductibles that are customary in the industry. Client shall bear the risk of loss or damage to the Unit from Client's negligent actions or omissions.

6.2 Indemnities. Each party hereto shall indemnify and hold the other party harmless from and against any and all liability, loss, damage, cause of action, cost or expense (including reasonable attorney's fees) arising out of, or in any way connected with, any negligent or intentional act or failure to act or any other wrongful conduct by the respective party, its members, agents, employees or subcontractors in the performance of its duties under this Agreement.

7 GENERAL.

7.1 Independence. Alliance is an independent contractor of Client, and this Agreement is a contract for services, not a lease. No agency, employment, partnership or joint venture is intended to be created by this Agreement. Neither Alliance nor Client shall take any action or position which is inconsistent with those descriptions of the relationship.

7.2 Remedies. Alliance shall not be responsible for failure to provide services as a result of conditions caused by Client. Alliance shall not be liable for consequential or special damages under any circumstances or any damages caused by conditions not within Alliance's reasonable control.

7.3 Waiver. Waiver of any breach shall not be deemed a waiver of the same provision in the future or the waiver of any other provision.

7.4 Notices. All notices and other communications shall be in writing and shall be given in person, by registered or certified mail, by overnight delivery, or by telecopy (in the case of telecopy, if written confirmation of sending is retained). The initial addresses and telecopy numbers of the parties are listed next to their signatures below. Notices to Alliance shall be sent to the attention of General Counsel. Either party may change its address or telecopy number for notice by notifying the other by a permitted method of giving notice. No objection may be made to a permitted method of giving notice. Under no circumstances shall any notice or communication be considered valid notice unless such notice or communication fully complies with the requirements of this Section 7.4.

7.5 Governing Law. This Agreement shall be governed by the law of the state where services are performed.

7.6 Entire Agreement, Amendment. This Agreement is the parties' entire understanding and supersedes all prior agreements, oral and written with respect to the subject matter of this Agreement. This Agreement may not be amended except by written agreement of the parties. No handwritten changes to this Agreement shall be enforceable unless such changes are initialed by both parties to this Agreement.

7.7 Successors and Assigns. Alliance may assign this Agreement. Client may not assign this Agreement without the prior written consent of Alliance. This Agreement shall be binding on and inure to the benefit of the parties' respective successors and assigns. Client agrees that this Agreement may be performed, in whole or part, by a subsidiary of Alliance and further consent shall not be required. Alliance may also assign the proceeds of this Agreement. Client shall require any successor (whether direct or indirect, by purchase, merger, reorganization,

consolidation, sale of property or stock, liquidation, or otherwise) to all or a substantial portion of its assets, by agreement in form and substance reasonably satisfactory to Alliance to expressly assume and agree to perform this Agreement

7.8 **Third Parties.** This Agreement does not convey any rights to any third parties

7.9 **Attorney Fees.** In any dispute arising out of this Agreement (whether litigation is involved or not) or in the event that either party must take action to collect fees or enforce rights, the prevailing party shall be entitled to reimbursement of its expenses, including court expenses and lawyers' fees.

7.10 **Certain Events.** Neither party shall be deemed in breach if its failure to perform under this Agreement is caused by conditions beyond its reasonable control (for example, fire, natural disaster, labor strikes, and so on)

7.11 **Confidentiality.** Client acknowledges and agrees that this Agreement is highly confidential and proprietary to Alliance and Client agrees that neither it nor any of its employees, physicians or representatives, shall disclose in any manner the terms, provisions, pricing or any other information contained in this Agreement (or any related proposal) to any third party

7.12 **Accreditation.** Alliance and Client agree to set standards of care and quality that comply with the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the American College of Radiology (ACR). Alliance and Client mutually shall cooperate in all phases of applying, scheduling, preparing and executing surveys or inspections by the JCAHO and ACR, as needed. Both parties agree to work cooperatively to implement changes, correct deficiencies or establish policies required and/or recommended by the inspecting agencies.

7.13 **Policies and Procedures.** Client agrees that Client shall comply with all of Client's Policies and Procedures, and Client agrees to indemnify and hold Alliance harmless from and against any and all liability, loss, damage, cause of action, cost or expense (including reasonable attorney's fees) arising out of, or in any way connected with, Client's failure to fully comply with Client's Policies and Procedures

7.14 **Change in Reimbursement.** In the event that health care reform causes a significant decline in Client's MRI reimbursement to a level that Client can demonstrate that it is impossible for Client to break even on the total MRI service utilizing the direct costs of the MRI service, Client may provide written notice to Alliance of such circumstance. Client and Alliance agree to then meet to decide upon a solution that shall be fair and equitable to Client and Alliance.

7.15 **Severability.** If any provision of this Agreement is held to be illegal, invalid, or unenforceable under present or future laws, that provision shall be fully severable and this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision never comprised a part of this Agreement. The remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance. Furthermore, a provision as similar in its terms to the illegal, invalid, or unenforceable provision as may be possible and be legal, valid, and enforceable shall be added to this Agreement automatically to replace the illegal, invalid, or unenforceable provision.

8 **TERMINATION**

8.1 **Termination**

a) **Default.** Alliance or Client may terminate this Agreement if the other materially defaults in the performance of any covenant, term or provision of this Agreement and the default is not cured within sixty (60) days following provision of notice to the defaulting party

8.2 **Termination, Alliance.** Alliance may terminate this Agreement or suspend service if:

a) **Payment Default.** Client fails to make any payment to Alliance when due and such failure continues for ten (10) days following notice to Client. In the case of any payment default, Alliance may without notice, cease providing services hereunder after three (3) days following a payment due date should it feel insecure with respect to Client's ability or willingness to make payment.

b) **Profitability.** Alliance is unable to realize a profit on the services provided hereunder, provided that the parties have negotiated in good faith to modify the terms of this Agreement to eliminate such condition and a period of sixty (60) days has elapsed since Alliance originally notified Client of such condition. In lieu of termination, Alliance may reduce the number of days of service provided.

c) **Bankruptcy.** Client commits or suffers (voluntarily or involuntarily) an act of bankruptcy, receivership, liquidation or similar event.

8.3 **Termination, Client.** Client may elect to terminate this Agreement upon commencement of services with a Client solely owned, in house, fixed MRI system upon ninety (90) days prior written notice, provided, however, that such notice may be delivered no earlier than the sixth (6th) month following commencement of this Agreement. Client agrees to give Alliance first right of refusal to provide such fixed services.

8.4 Client's Default. Upon Client's default, Alliance may (i) declare the entire balance of all fees and other amounts due including the sum of all fees and other amounts payable during the balance of the term of this Agreement, or (ii) take any action at law or in equity to collect payments then due and to become due, or to enforce performance of specific obligations. Alliance and Client hereby agree that, in the event of Client's default of this Agreement and Alliance's subsequent termination of this Agreement, damages shall be calculated by using the greater of: (i) the average monthly scan volumes by Client over the twelve-month period (or such lesser period if Alliance did not provide at least 12 months of service to Client prior to termination) immediately prior to termination of this Agreement, or (ii) the scan volume benchmarks set forth in Schedule A.

The foregoing remedies are in addition to any provided by law. Neither party shall have obligation to exercise any remedy and the exercise of the remedy shall not release the parties for any obligation hereunder. All remedies shall be cumulative, and action on one shall not constitute an election or waiver of any other right to which either party may be entitled. In addition, the defaulting party shall pay the other parties reasonable attorney's fees together with an amount equal to all expenses paid or incurred in the enforcement of any rights or privileges hereunder.

9 COMPLIANCE WITH LAWS

9.1 Compliance with Current Laws. The parties expressly agree that it is their understanding and intent that this Agreement, including any Exhibits or other attachments, complies as of the effective date hereof with applicable federal and state statutes and regulations, including the Stark Law, 42 U.S.C. Section 1395nn, and the Anti-Kickback Statute (collectively referred to as "Laws").

9.2 No Inducement. This Agreement has been negotiated in good faith through arms length negotiations. Nothing contained in this Agreement, including any compensation paid or payable, is intended or shall be construed (i) to require, influence or otherwise induce or solicit either party regarding referrals of business, or recommending the ordering of any items or services, of any kind whatsoever to the other party or any of its affiliates, or to any other person, or otherwise generate business between the parties, or (ii) to interfere with a patient's right to choose his or her own health care provider, or with a physician's medical judgment regarding the ordering of any items or services.

9.3 Change in Law. Neither party shall make or receive any payment or take any other action required or permitted hereunder, if any judicial decision, legislative action, regulatory or other administrative interpretation, whether federal or state, would render unlawful the conduct of either party hereunder ("Change in Law"). In the event of such a Change in Law, the parties shall be required to act in good faith to restructure the business arrangement between the parties to conform with then existing Laws. If the parties have not reached an agreement regarding the material terms of the restructured business arrangement within thirty (30) days following the date both parties are on

9.4 No Federal Health Care Program Exclusion. Each party represents and warrants to the other party that: (i) the representing party is not currently excluded, debarred, or otherwise ineligible to participate in the Federal health care programs as defined in 42 U.S.C. Section 1320a-7b(f) (the "Federal health care programs"); and (ii) the representing party is not aware of any circumstances which may result in the representing party being excluded from participation in the Federal health care programs. This shall be an ongoing representation and warranty during the term of this Agreement, and each party shall immediately notify the other party of any change in status of the representation and warranty set forth in this Section. In the event a party becomes excluded, debarred, or otherwise ineligible to participate in the Federal health care programs, that party shall be considered in default of this Agreement, and the other party may immediately terminate this Agreement for cause.

SCHEDULE A**1 UNIT DESCRIPTION**

ST mobile MRI system.

If the Unit described above is deemed to be unavailable, in Alliance's sole discretion, a reasonably comparable Unit may be substituted.

2 FEES

Option A – staffed by Alliance – six (6) days per week, Monday through Friday, 8:00am to 5:00pm and Saturday 8:00am to 12:00pm (noon). _____ Initial

Flat monthly fee of \$65,000.00

Option B – staffed by Client. _____ Initial

Flat monthly fee of \$55,000.00

3 SCHEDULING

Alliance shall make the Unit available to the Client and Client agrees to accept the Unit the following number of day(s) of each week, full time parked.

4. TERM

The initial term of this Agreement shall be for thirty-six (36) months commencing on the date on which services begin (the "Commencement Date") expected to be on or about September 2006, provided, however, Client may elect to terminate this Agreement upon commencement of services with a Client solely owned, in house, fixed MRI system upon ninety (90) days prior written notice; provided, further, that such notice may be delivered no earlier than the sixth (6th) month following Commencement of this Agreement. If delivery of the Unit is delayed notwithstanding Alliance using all reasonable efforts to prevent the delay, the Commencement Date shall be extended coterminously with the delay. The term of the Agreement shall also be extended coterminously with any period(s) services are suspended pursuant to Section 8.2. After each term, this Agreement shall automatically renew for successive terms, each of which shall be equal to the initial term, unless either party notifies the other to the contrary in writing at least 180 days prior to scheduled expiration. In the event this Agreement terminates and Client continues to accept services, the terms and conditions of this Agreement shall apply to the provision of services.

THIS AGREEMENT IS CONTINGENT UPON ALLIANCE'S BOARD OF DIRECTORS APPROVAL AND SUBJECT TO UNIT AVAILABILITY

Alliance and Client have duly executed this Agreement as of date and year written below

ALLIANCE IMAGING, INC.
a Delaware corporation

Signature: _____
Printed Name: Christopher J. Joyce
Title: Senior V.P., General Counsel & Secretary
Date: _____
Address: _____
1900 South State College Boulevard, Suite 600
Anaheim, California 92806
Telephone No (714) 688-7100
Facsimile No (714) 688-7111

COASTAL CAROLINA MEDICAL CENTER
a South Carolina not for profit corporation

Signature: _____
Printed Name: _____
Title: _____
Date: _____
Address: _____
1000 Medical Drive
Hardeeville, South Carolina 29927
Telephone No _____
Facsimile No. _____

Return Executed Agreement to: Contracts Administration, Alliance Imaging, Inc. 15 Massaria Drive, Suite 202, Berlin, Connecticut 06037

BOARD:
Elizabeth M. Hagood
Chairman

Mark B. Kent
Vice Chairman

L. Michael Blackmon
Secretary



C. Ed Hunter, Commissioner

Promoting and protecting the health of the public and the environment.

Edwin H. Cooper, III

Carl L. Broad

Steven G.

Coleman P. Buckhouse, MD

August 4, 2006

Re. SC-06-46
Construction for the addition of a 1.5 Tesla Magnetic Resonance Imaging (MRI)
unit
Coastal Carolina Medical Center
Hardeeville, South Carolina

David B. Summer, Jr.
Parker Poe Adams & Bernstein, LLP
1201 Main Street, Suite 1450
Columbia, SC 29202-1509

Dear Mr. Summer:

I am in receipt of your letter dated August 4, 2006 regarding the above-referenced project. According to this correspondence, Coastal Carolina Medical Center requests full-time use of a mobile MRI unit for the interim period in which the fixed MRI construction and installation will occur. This letter represents approval for temporary full-time use of a mobile MRI unit during the interim period of the fixed MRI construction and installation as outlined in your August 4, 2006 letter.

Should you have any questions, please contact me at (803) 545-4200.

Sincerely,

Victoria R. Tibshirany

Victoria R. Tibshirany
Bureau of Health Facilities and Services Development

BOARD
Elizabeth M. Hagood
Chairman

Mark R. Kent
Vice Chairman

L. Michael Blackmon
Secretary



C. End Hester, Commissioner

Promoting and protecting the health of the public and the environment.

Edwin H. Coof

Carl L.

Steven G.

Coleman R. Bucklow

August 4, 2006

Re: SC-06-46
Construction for the addition of a 1.5 Tesla Magnetic Resonance Imaging (MRI)
unit
Coastal Carolina Medical Center
Hartsville, South Carolina

David B. Summer, Jr.
Parker Poe Adams & Bernstein, LLP
1201 Main Street, Suite 1450
Columbia, SC 29202-1509

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Should you have any questions, please contact me at (803) 545-4200.

Sincerely,

Victoria R. Tibshirany

Victoria R. Tibshirany
Bureau of Health Facilities and Services Development

EXHIBIT

4

BOARD-
Elizabeth M. Hagan
Chairman
Edwin H. Cooper, III
Vice Chairman
Steven G. Kiser
Secretary



C. Earl Hanes, Commissioner
Promoting and protecting the health of the public and the environment

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Henry C. Scott
Paul C. Angbury, III
Glenn A. Mc
Coleman F. Buckhouse, Jr.

S.C. Board of Health and Environmental Control – Phone: (803) 898-3309 Fax: (803) 898-3393

January 8, 2007

Via U.S. Mail Certified and Electronic Mail

M. Elizabeth Crum, Esq.
Attorney for MRI at Belfair
McNair Law Firm, P.A.
Post Office Box 11390
Columbia, SC 29211

David B. Summer, Jr., Esq.
Faye A. Flowers, Esq.
Attorneys for Coastal Carolina Medical Center
Parker Poe Adams & Bernstein, LLP
Post Office Box 1509
Columbia, SC 29202

Via Inter-agency Mail Service

Ashley C. Biggers, Esq.
Nancy S. Layman, Esq.
SCDHEC – Office of General Counsel
2600 Bull Street
Columbia, SC 29201

RE Order of Remand – MRI at Belfair, Petitioner, v. South Carolina
Department of Health and Environmental Control and Coastal Carolina
Medical Center, Respondents, Docket No. 06-ALJ-07-0714-CC

Dear Counsel,

The S.C. Board of Health and Environmental Control appreciates the remand of this case to the Board by the Administrative Law Court. However, the Board will not be able to conduct a final review conference in this case because of the 60-day time limit provided in S.C. Code Section 44-1-60.

The Order of Remand provides, "for purposes of remand, Belfair is deemed to have filed its request for Board review under § 44-1-60(E) on September 8, 2006." Section 44-1-60(F) gives the Board only 60 days from the date of receipt of the request for final review to conduct a final review conference. Sixty days from September 8 is November 7. The Order of Remand was issued on October 18, and the next Board

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENT

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EXHIBIT

5

meeting was November 9, which was after the deadline for holding a final review conference in this case.

The Board conducted a meeting via conference call on November 17, 2006, to decide on the handling of pending cases. The Board decided at that meeting not to conduct a final review conference on the above-referenced matter. The minutes of the conference call meeting of November 17, 2006, are attached.

Sincerely,


Lisa Lucas Longshore
Clerk

BOARD:
Elizabeth M. Hagood
Chairman
Edwin H. Cooper, III
Vice Chairman
Steven G. Kisner
Secretary



C. Earl Henson, Commissioner

Promoting and protecting the health of the public and the environment.

BOARD
Hensr
Paul C. Aughton, II
Glenn A. McCall
Coleman F. Buckhouse, MD

S.C. Board of Health and Environmental Control Conference Call

November 17, 2006

The Board of Health and Environmental Control met on Friday, November 17, at 10:00 a.m. in the S.C. Department of Health and Environmental Control Boardroom, 2600 Bull Street, Columbia, S.C., via conference call. (Attachment 0-1)

The following members were in attendance via conference call

Elizabeth M. Hagood, Chair
Charleston

Edwin H. Cooper, III, Vice-Chair
Charleston

Steven G. Kisner, Secretary
Aiken

Henry C. Scott
Allendale

Glenn A. McCall
Rock Hill

Coleman F. Buckhouse, MD
Florence

Also in attendance were Mr. Carl Roberts, General Counsel, Ms. Lisa Longshore, Clerk, and Ms. Pamela G. Hawley, Executive Assistant to the Commissioner, and guests.

Mr. Roberts stated notice of this meeting has been provided to all persons, organizations and news media, which have requested notification, as required by section 30-4-80(e) of the South Carolina Code of Laws.

Item 1: Requests for Final Review by DHEC Board – 2006 Act No. 387

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Ms. Hagood stated that the Board members had reviewed the requests for review before the Board and that her recommendation would be for the Board to conduct Final Review Conferences in the following matters.

Docket No. 06-RFR-55, BB&L Landfill, and,
Docket No. 06-RFR-58, Friends of Congaree Swamp, SC Wildlife Federation and
Audubon South Carolina v SC Department of Health and Environmental Control
and S.C. Department of Transportation.

Mr. Cooper recused himself in Docket No. 06-RFR-55

After discussion, Dr. Buckhouse moved, seconded by Mr. McCall, to adopt the Chair's recommendation to hold a Final Review Conference on Board Docket Nos. 06-RFR-55 and 06-RFR-58 on December 14 at the monthly Board meeting and not to hold a Final Review Conference on Board Docket Nos. 06-RFR-56, -57, -59, -60, -61, -63, -64 and not to hold a review conference on the Order on Remand from the ALC in MRI at Belfair vs. SCDHEC and Coastal Carolina Medical Center. Approved.

Mr. Scott moved, seconded by Mr. Cooper, to adjourn. Approved.

All referenced attachments are made a permanent part of these minutes.

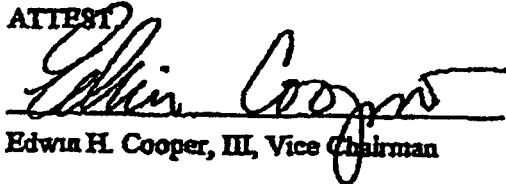
Respectfully submitted,



Steven G. Kisner, Secretary of the Board

Minutes approved this 14th day of December 2006

ATTEST



Edwin H. Cooper, III, Vice Chairman

Attachments

- 0-1 Agenda
- 1-1 Requests for Review - Docket Nos. 06-RFR-55, -56, -57, -58, -59, -60, -61, -63, -64 and Order on Remand, MRI at Belfair vs. SCDHEC and Coastal Carolina Medical Center

STATE OF SOUTH CAROLINA
BEFORE THE ADMINISTRATIVE LAW COURT

MRI at Belfair, LLC,	)	Docket No 04-ALJ-07-0399-CC
	)	
Petitioner	)	
	)	
v	)	
	)	
South Carolina Department of Health	)	
and Environmental Control and	)	
Coastal Carolina Medical Center,	)	
	)	
Respondents	)	
_____	)	

MRI at Belfair, LLC,	)	Docket No 07-ALJ-07-0389-CC
	)	
Petitioner,	)	
	)	
v	)	
	)	
South Carolina Department of Health	)	
and Environmental Control and	)	
Coastal Carolina Medical Center,	)	
	)	
Respondents	)	
_____	)	

**PREHEARING STATEMENT
OF PETITIONER MRI AT BELFAIR LLC**

In response to the Scheduling Order issued by the Honorable Ralph K. Anderson, III, dated March 11, 2009, Petitioner MRI at Belfair, LLC ("Belfair"), respectfully submits the following Prehearing Statement

FILED

MAR 16 2009

SC ADMIN LAW COURT

1 THE NATURE OF THIS PROCEEDING

This matter involves Belfair's request for a contested case hearing seeking administrative review of 1) the decision by the South Carolina Department of Health and Environmental Control ("DHEC" or "Department") dated November 22, 2004 ("Initial Decision") to approve a certificate of need ("CON") application of Respondent Coastal Carolina Medical Center ("CCMC") for a fixed magnetic resonance imaging (MRI) unit and construction to house the unit as part of the hospital adjacent to the Emergency Department ("ED") at a cost of \$3,201,000 ("Fixed In-house MRI Project"), and 2) the June 22, 2007 decision ("Second Decision") to determine that the change from the fixed MRI unit to a mobile unit housed permanently in a trailer ("Modular MRI Unit") behind the hospital and away from the ED does not constitute a substantial change ("Modular MRI Project") (collectively "Initial Project" and "Revised Project" are referred to as "MRI Project")

2 STATUTORY PROVISION(S) CONFERRING SUBJECT MATTER JURISDICTION TO THE AGENCY AND OTHER APPLICABLE STATUTES AND REGULATIONS

- a the South Carolina Administrative Procedures Act, S C Code Ann §§ 1-23-310 et seq (Supp 2008) ("APA"),
- b the State Certification of Need and Health Facility Licensure Act, S C Code Ann §§ 44-7-110 et seq (2002) ("CON Act"),
- c 24 A S C Code Regs 61-15 (Supp 2008) ("CON Regs"), and
- d the Rules of Procedure for the Administrative Law Court ("RPALC")

3 ISSUES PRESENTED FOR DETERMINATION

The issues presented for determination include

a) Whether CCMC's substitution of the Modular MRI Unit installed on a concrete pad out side of and behind the hospital for the Fixed In-House MRI Project constitutes a substantial change to CCMC's Project, resulting in the voiding of the MRI Project decision,

b) Whether the MRI Project complies with the project review criteria outlined in the Plan, and

c) Whether the sale of CCMC voided the CON for the MRI Project.

4 THE ACTION REQUESTED OF THE COURT, IF ANY

Belfair respectfully requests that this Court reverse the Department's Decision to allow CCMC to operate the Modular MRI Unit pursuant to the Second Decision

5 A BRIEF SUMMARY OF THE FACTS TO BE PRESENTED AT THE HEARING

CCMC filed its CON application ("Application") on May 7, 2004, for new construction and the addition of one (1) fixed MRI to be located at CCMC's hospital. The Application was filed under the 2003 South Carolina Health Plan ("Plan"). A project review meeting was held on September 28, 2004. Belfair opposed the Fixed In-house MRI Project at the project review meeting and on November 9, 2004, submitted written comments in opposition to the Initial Project. On November 22, 2004, DHEC issued its Initial Decision approving the Fixed In-house MRI Project.

On November 24, 2004, Belfair requested a contested case hearing before the Administrative Law Court ("Court" or "ALC") seeking administrative review of DHEC's decision to issue a CON to CCMC for the Fixed In-house MRI Project. This case was assigned Docket No. 04-ALC-07-0399-CC. On December 21, 2004, the Administrative

Law Judge ("ALJ") issued an Order for Prehearing Statements and each party filed their respective Prehearing Statements on January 20, 2005. On August 2, 2005, CCMC filed a Notice of Motion and Motion for Summary Judgment and Memorandum in Support at the ALC. On August 3, 2005, Belfair filed a Notice of Motion and Motion for Summary Judgment and Memorandum in Support at the ALC.

On August 12, 2005, this Court heard the summary judgment motions¹ and, on August 15, 2005, issued a verbal order granting partial summary judgment to CCMC and the Department and limiting the contested case hearing to whether MRI services were available to CCMC as the word "available" is used in the Plan.² The Court declined to issue a written Order granting partial summary judgment prior to the merits hearing, instead issuing it as part of the ALC Order after the merits hearing. The contested case was heard August 23-25, 2005 only on the issue of MRI service availability.

On November 10, 2005, this Court issued its Final Order and Decision denying Belfair's Motion for Summary Judgment, granting, in part, CCMC's Motion for Summary Judgment and approving the Department's Initial Decision to grant a CON to CCMC for the Fixed In-house MRI Project. Belfair appealed this Court's Final Order and Decision to the Board of the Department ("DHEC Board") on December 9, 2005, and the DHEC Board affirmed and adopted this Court's Final Order and Decision on May 25, 2006 ("Board Order"). Pursuant to Act 387 of 2006, Belfair appealed the Board Order, which it had received on June 2, 2006, to the South Carolina Court of Appeals.

¹ DHEC joined in the CCMC Motion for Partial Summary Judgment during the Motions hearing.

² Based on the Court's oral ruling, the remaining discovery conducted by the parties was only as to the issue of "availability" of MRI services to CCMC and the parties reserved the right to conduct additional discovery if needed.

On July 20, 2006, while the appeal of the Board Order was pending before the Court of Appeals, counsel for CCMC requested that DHEC issue the CON for CCMC for the Fixed In-house MRI Project³ On August 3, 2006, DHEC issued CON-06-46 to CCMC for the Fixed In-house MRI Project.

Then, on August 4, 2006, CCMC requested permission from DHEC to install and utilize a mobile MRI unit twenty-four hours a day seven days a week ("24/7"), during the implementation and construction of the Fixed In-house MRI Project On that same day, without notice to Belfair (despite the pending appeal and Belfair's status as an affected person in that appeal), DHEC issued its letter which approved CCMC for the "temporary full-time use of a mobile MRI unit during the interim period of the Fixed MRI construction and installation as outlined in [Mr Summer's] August 4, 2006 letter " ("Temporary Full-time Use MRI Project") Belfair appealed this DHEC decision and the matter was assigned Docket No 06-ALC-07-0714

During the pendency of Docket No 06-ALC-07-0714 and without notice to Belfair, on June 12, 2007, counsel for CCMC requested a determination from DHEC on whether its previous implementation of the Temporary Full-time Use MRI Project would constitute a substantial change to the Fixed In-house MRI Project No notice of this request was given to Belfair despite its affected party status in the two (2) pending cases On June 22, 2007, DHEC informed CCMC that DHEC did not believe CCMC's implementation of CON SC-06-46 through installation of the Modular MRI Project would constitute a substantial change from the Fixed In-house MRI Project On June 29,

³ Act 387 does not provide for an automatic stay during the pendency of an appeal from the ALC to the Court of Appeals Belfair did not seek a stay of the Court's Final Order and Decision

2007, Belfair requested a final agency review before the DHEC Board regarding the Department's decision that the change from the Fixed In-house MRI to the Modular MRI did not constitute a substantial change. The Board declined to hear the request for review by written memorandum dated July 26, 2007. On July 30, 2007, Belfair requested contested case review of the Department's decision and the matter was assigned Docket No. 07-ALJ-07-0389-CC. Discovery was begun on the case but was suspended by order of this Court dated February 27, 2008.

On June 28, 2007, DHEC issued E-07-67 for the change of ownership of CCMC, and CCMC was sold to Tenet Health Care ("Tenet"). Thereafter, new counsel was substituted for Tenet. On March 19, 2007, the South Carolina Supreme Court certified this matter for review pursuant to Rule 204(b), SCACR.

On February 7, 2008, the South Carolina Supreme Court heard oral arguments on this matter. On July 14, 2008, the Supreme Court issued its order in this matter, holding, inter alia

(1)

The Board determined that the first Plan standard for MRI services stating every hospital should have an available MRI unit meant that CCMC did not have to establish the project review criteria. This was error. Section 44-7-210(C) and the governing regulations are clear in establishing Plan standards and project review criteria as separate and distinct requirements that must be met as part of the CON application process. Because the Board held that CCMC did not have to prove compliance with the project review criteria by virtue of the first Plan standard, appellant was prohibited from presenting its case to challenge CCMC's compliance with the project review criteria. Again, CCMC's compliance with the project review criteria is an essential step in the CON process, and this prerequisite is independent of compliance with the State Health Plan. Accordingly, we remand this case to the ALC to determine whether

)

CCMC's application for a fixed, in-house MRI unit satisfies the project review criteria identified in the Plan

We reverse the CON award and remand for a determination on the sole issue whether CCMC's application complies with the project review criteria set forth in the Plan

MRI at Belfair v. SC Dep't of Health and Env'tl Control, 379 S.C. 1, 9-10, 664 S.E.2d 471, 475-476 (2008) (emphasis added) The South Carolina Supreme Court remanded this matter "to the ALC to determine whether CCMC's application for a fixed, in-house MRI unit satisfies the project review criteria identified in the Plan" (Appellate Order, p. 8) The CON award has been reversed and CCMC is operating in violation of the CON Act and CON Regs

Belfair is a free-standing imaging facility, located in Bluffton, Beaufort County, South Carolina, providing MRI services for Beaufort and Jasper Counties, South Carolina, and is an affected party as defined in the CON Act. Belfair is a South Carolina limited liability company which sought and received a CON to operate a 1.5 Tesla GE fixed MRI. The CON was issued on May 21, 2001, and the facility began operations on April 22, 2002. Belfair is one of several General Electric 1.5 Tesla MRI national show sites in the United States and also serves as an international show site for GE. Additionally, Belfair serves as a clinical evaluation site for General Electric's newly developed MRI products, giving it and the community it serves advanced access to life-saving technology 12-18 months ahead of every other MRI facility in South Carolina. Finally, Belfair or its medical director have been honored with the Community Service Award from the Volunteers in Medicine Clinic in 2002, 2003 and 2004 for providing the greatest amount of free care to the local indigent population.

The only CON application that has been filed with the Department for review is the CCMC Application and it established the proposed service area for CCMC's Project as including areas of Beaufort and Jasper Counties. CCMC is a thirty-one (31)⁴ acute bed hospital located in southern Jasper County, in Hardeeville, South Carolina, and is very close to the Beaufort County line. CCMC's parent company is Tenet which owns fifty-two (52) acute-care hospitals in twelve (12) states, including Hilton Head Hospital on Hilton Head Island, South Carolina.

There are approximately eleven (11) MRI units providing MRI services in Beaufort County that are accessible to the residents of Beaufort and Jasper Counties and the CCMC proposed service area. Based upon a five (5) day week and an eight (8) hour day, each MRI unit can conservatively perform three thousand (3,000) scans⁵ per year or some thirty-three thousand (33,000) scans per year on the existing MRI units. According to the 2004 State Health Plan, the ten (10) existing units only performed 10,715 scans in Fiscal Year 2002. There is a tremendous excess capacity already in the Beaufort-Jasper service area.

Belfair facts will show that

1 Although CCMC sought its CON for an MRI unit allegedly to provide emergency MRI scans for patients presenting at its ED, CCMC is using its Modular MRI Unit almost solely for outpatient MRI scans.

2 The Modular MRI Unit being utilized by CCMC is a refurbished MRI unit and the Fixed In-house MRI Unit was a new unit.

⁴ The hospital has thirty-one (31) acute beds and ten (10) rehabilitation beds.

⁵ The 3,000 number is extremely conservative and has been used in an abundance of caution.

3 There is an MRI unit within a twenty (20) to thirty-five (35) minute drive of all residents of Beaufort or Jasper Counties and within fifteen (15) minutes of Bluffton residents

4 Any increase in accessibility does not outweigh the adverse affect the Project will have on existing providers

5 The permanently installed Modular MRI Unit at CCMC does not promote cost-effectiveness and the alternative of shared mobile MRI service was not properly considered by CCMC or DHEC

6 DHEC violated the CON Act, the Plan and the Project Review Criteria, Reg 61-15 §§ 802 2 (Community Need Documentation), 802 3 (Distribution), 802 4 (Acceptability), 802 15 (Financial Feasibility), 802 16 (Cost Containment), and 802 23 (Adverse Effects on Other Facilities) in approving the MRI Project

7 The Department's decisions in this matter are contrary to law, exceed the agencies statutory authority, are arbitrary and capricious, or characterized by abuse of discretion or clearly unwarranted exercise of discretion, and clearly erroneous in view of the reliable, probative, and substantial evidence on the whole record

6 A LIST OF PROPOSED WITNESSES AND EXHIBITS

a) Proposed witnesses include

Joel C Grice
Former Director, Bureau of Health Facilities and Services Development
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Victoria R Tibshirany
Former Project Reviewer
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Elizabeth Lampkin
President
Hilton Head Regional Medical Center
25 Hospital Center Boulevard
Hilton Head Island, South Carolina 29926

Teresa Uguhart
CEO, Coastal Carolina Medical Center
1000 Medical Drive
Hardeeville, South Carolina

A Joseph Borelli, MD
President and Medical Director
MRI at Belfair, LLC
18 Clarks Summit Drive
Bluffton, South Carolina 29910

Belfair will call such other witnesses as may be identified in discovery or as are necessary. Belfair reserves the right to call any witnesses listed by the other parties hereto.

b) Proposed exhibits include

The Department's files in this matter. Other exhibits have not been identified at this time. Belfair will continue to supplement this Prehearing Statement as additional witnesses or exhibits are identified during discovery.

7 A STATEMENT REGARDING THE NECESSITY FOR DISCOVERY, IF ANY; AND

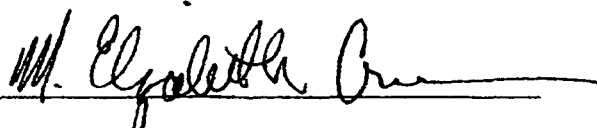
Belfair anticipates serving standard interrogatories, requests for production of documents and requests for admission. Belfair will depose one or more of

Respondents' witnesses Belfair anticipates that the parties will need more than three (3) depositions per party Due to the age of the case and the fact that discovery regarding the project review criteria had been begun in 2005 but had not been completed, the discovery will have to be updated and completed

8 THE ESTIMATED LENGTH OF HEARING

Belfair estimates that the hearing will take three (3) days

M Elizabeth Crum, SC Bar No 001486
Icrum@mcnair net
Ariail B Kirk, SC Bar No 71101
akirk@mcnair net
Kelly M Jolley, S C Bar No 72573
kjolley@mcnair net
McNAIR Law FIRM, P A
Post Office Box 11390
Columbia, South Carolina 29211
(803) 799-9800

By 
Attorneys for Petitioner MRI at Belfair, LLC

March 16, 2009

Columbia, South Carolina

**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

MRI at Belfair, LLC,	)	Docket No 07-ALJ-07-0389-CC
	)	
Petitioner,	)	
	)	
vs	)	
	)	MOTION FOR RECONSIDERATION
South Carolina Department of Health and	)	
Environmental Control and Coastal	)	
Carolina Medical Center,	)	
	)	
Respondents	)	
_____	)	

Petitioner MRI at Belfair, LLC ("Belfair") hereby moves this Honorable Court pursuant to Rule 29 (D) RPALC and Rule 59 SCRPC to reconsider and alter or amend its Final Order and Decision ("Order") filed October 23, 2009 and received by Petitioner on October 26, 2009

BACKGROUND

Belfair requested a contested case hearing to determine whether Coastal Carolina Medical Center's (CCMC) implementation of a magnetic resonance imaging (MRI) unit outside the hospital (Implemented Project) constituted a substantial change to the site-built, in-house MRI project (Original Project) that had been previously submitted to and approved by the South Carolina Department of Health and Environmental Control (Department), and whether the sale of CCMC voided the Certificate of Need (CON) issued for the Original Project. The Order ruled that the Implemented Project was not a substantial change from the Original Project, and determined that the issue of whether the sale of CCMC voided the CON for the Original Project was mooted by the Court's decision addressing the substantial change issue.

APPLICABLE LAW

24A S C Code Ann Regs 61-15 § 605 (Supp 2008) (Substantial Change Regulation or Section 605) provides that “[i]f an applicant amends or alters his project after receipt of a CON, the Department will decide whether or not the amendment is substantial and thereby constitutes a new project ”

ARGUMENTS

I THE COURT ERRED IN APPLYING THE PROJECT REVIEW CRITERIA TO DETERMINE WHETHER THE IMPLEMENTED PROJECT WAS A SUBSTANTIAL CHANGE FROM THE ORIGINAL PROJECT

Belfair respectfully submits that this Court should alter or amend the Order because it applied the incorrect standard for a determination pursuant to the Substantial Change Regulation. In particular, the Order’s application of the project review criteria found in 24A S C Code Ann Regs 61-15 § 802 (Supp 2008) to the Implemented Project is clear legal error The Order made the following ruling

Because the project review criteria are applied and analyzed when the Department initially grants a CON, presumably these same criteria must be re-examined to determine whether a project has substantially changed under Section 605 If the amendments to the project do not substantially change the project’s compliance with the relevant project review criteria, then the amendment is not substantial under Section 605

Order at p 8-9

The project review criteria are not the factors to be considered by the Court in making a determination whether a project amendment is a substantial change from the original project The primary flaw with that ruling was succinctly identified by Department witness Tibshrary She testified that an amended project that is determined to be a substantial change *could still receive a CON* (that is, could still satisfy the project

review criteria) after going through the new CON process envisioned by Section 605 (Tr p 253, ll. 8-12)

Ms Tibshirany's testimony demonstrates that the substantial change determination is a process completely separate from an application of the project review criteria. A Department and/or ALC determination under the Substantial Change Regulation must precede the application of the project review criteria to the amended project. Moreover, this testimony demonstrates that the substantive determination under the Substantial Change Regulation is entirely distinct from an application of the project review criteria. Finally, this testimony points out that any ruling finding only that an amended project meets the project review criteria ignores the substantial change determination (and the plain language of the Substantial Change Regulation) altogether.

Accordingly, application of the project review criteria to a determination under the Substantial Change Regulation is inconsistent with the provisions of the CON Act, S.C. Code Ann. 44-7-110, *et seq.* and the regulations promulgated thereunder (CON Regulations). Employing the project review criteria in making a substantial change determination blurs the clear, distinct, and separate application of the CON Regulations as required by the CON Act, creates conflicts with the plain language of the CON Act and the CON Regulations, and creates a number of procedural and substantive conflicts within the CON Act.

An application of the project review criteria in a Section 605 case does not determine whether the amended project is a "new project" —as required by the plain and unambiguous language of the Substantial Change Regulation — but rather administratively "leapfrogs" that question to determine whether the amended project

would be entitled to a CON if treated as a “new project.” The Substantial Change Regulation clearly requires that an amended project that constitutes a ‘new project’ must go through the CON application process—not that the CON application process can be bypassed by an application of the project review criteria immediately following a project amendment

Procedurally, consideration of the project review criteria in the context of the Substantial Change Regulation short circuits the statutorily mandated CON review process. S.C. Code Ann. § 44-7-210(C) requires the Department apply project review criteria only in connection with a properly filed CON application, which must adhere to the resulting notice and possible public hearing requirements. Accordingly, the ALC only has jurisdiction to consider the project review criteria after those criteria have actually been applied by the Department. Clearly DHEC could not and did not consider or apply the project review criteria per the CON Act in making a determination that the Implemented Project was not a substantial change from the Original Project.

Moreover, this improper application of the project review criteria in violation of the CON Act is significant because it may result in one or more irreconcilable procedural and substantive inconsistencies. If, following a project amendment, the ALC considers the project review criteria in order to make substantial change determination, then one of only two outcomes can possibly result. The ALC can either determine that the amended project meets the project review criteria, or it can determine that the amended project does not meet the project review criteria.

Where the ALC determines that the amended project *meets* the project review criteria and, therefore, does not constitute a “substantial change,” it denies “affected

parties” their statutory right to take part in the CON process for any “new project” that would have resulted from application of the Project Statute factors

Where the ALC determines that the amended project *does not meet* the project review criteria, and, pursuant to the Court’s current ruling, does constitute a “substantial change,” Section 605 requires DHEC and the applicant to treat the amended project as a “new project ” In this instance, the ALC’s “substantial change” ruling will have a preclusive effect on the applicant’s application for issuance of a CON for the new project This is because the ALC’s ruling that the amended project fails to meet the project review criteria prejudges that same review which must, by statute, take place again for the “new project ”

Application of the project review criteria at this stage, therefore, improperly and illegally reverses the proper procedure and interplay between the CON Act and the ALC’s role in hearing contested cases pursuant to the Administrative Procedures Act

II THE PROJECT STATUTE PROVIDES THE PROPER FACTORS FOR A DETERMINATION UNDER SECTION 605

The correct test for the Court’s determination under Section 605 was that proposed by Belfair in its proposed order (**Exhibit One**), and upon which Belfair based its case namely the factors set out in S C Code Ann § 44-7-230(A) (Project Statute), which provides in relevant part

The Certificate of Need, if issued, is valid only for the project described in the application including location, beds and services to be offered, physical plant, capital or operating costs, or other factors as set forth in the application, except as may be modified in accordance with regulations

Application of the Project Statute is consistent with the plain language of the Substantial Change Regulation, carries out the purpose of the Substantial Change Regulation (to ensure that all new projects are subject to the CON review process) and avoids the conflicts and inconsistencies that occur when the project review criteria are applied in the context of the Substantial Change Regulation. It is also consistent in every respect with the testimony of DHEC witness Tibshrary *who was in charge of making substantial change determinations for the Department at the time that CCMC made the request that is at issue here*

Application of the factors in the Project Statute creates two possible outcomes 1) the amended project is deemed to be a “new project,” resulting in a second CON review process, or 2) the amended project is not a “new project,” in which case the project may be implemented in accordance with the amended application

Application of the Project Statute factors therefore maintains the separate and distinct processes through which 1) the project review criteria are applied only in the CON review process pursuant to S C Code Ann § 44-7-210 and the CON Regulations, and 2) the Project Statute factors are considered to determine whether an application of the project review criteria to a “new project” will then be required. Importantly, application of the Project Statute factors neither prejudices a future consideration of the project review criteria, nor involves a consideration of the project review criteria in a circumstance that is otherwise prohibited by the CON Act

III THE COURT HAS NEVER APPLIED THE PROJECT REVIEW CRITERIA IN THE CONTEXT OF THE SUBSTANTIAL CHANGE REGULATION, AND INSTEAD HAS APPLIED THE FACTORS IN THE PROJECT STATUTE.

This Court has never applied the project review criteria in deciding a question under the Substantial Change Regulation, but instead has employed the factors set out in the Project Statute. In *Providence Hosp v SC Dep t of Health and Envtl Control and Palmetto Richland Mem Hosp* Docket No 02-ALJ-07-0155-CC, 2002 W L 31423801 (ALC September 11, 2002) (*Providence Hospital*), this Court applied the Project Statute factors in the context of a substantial change determination. The Court ruled as follows:

Therefore, in analyzing whether a substantial change has occurred, the court must determine the nature of the Project. S C Code Ann § 44-7-230(A) (Supp 2001) provides that the CON is 'valid only for the project described in the application including location, beds and services to be offered, physical plant, capital or operating costs, or other factors as set forth in the application, except as may be modified in accordance with regulations.

Id. pp 12-13

It is clear that the Court's consideration of Section 605 in *Providence Hospital* was based solely upon the Project Statute and not the project review criteria.

IV THE DEPARTMENT'S WITNESS TESTIFIED THAT THE DEPARTMENT RELIES ON THE PROJECT STATUTE FACTORS WHEN MAKING A DETERMINATION UNDER THE SUBSTANTIAL CHANGE REGULATION

Department witness Tibshrary directly testified that the Department relies upon, and is guided by, the Project Statute factors in determining whether a project amendment is a substantial change under Section 605. (Tr p 254 ll 15-18) Ms Tibshrary's

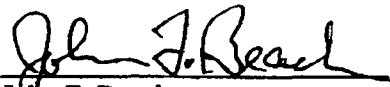
testimony decisively establishes that the project review criteria are not the appropriate criteria for making a determination under the Substantial Change Regulation

CONCLUSION

Consistent with the Petitioner's Proposed Order, Petitioner believes that the proper application of the Project Statute factors will result in a ruling by the Court that the Implemented Project did constitute a substantial change from the Original Project, pursuant to Section 605. Accordingly, Petitioner requests that this Court amend the Order to apply the factors set out in the Project Statute as described herein, reverse the Department's determination that the Implemented Project did not constitute a "substantial change," and grant such other relief as is just and proper.

Respectfully submitted,

ELLIS, LAWHORNE & SIMS, P.A

By 
John F. Beach
John J. Pringle, Jr.
1501 Main Street, 5th Floor
Post Office Box 2285
Columbia, SC 29202
Telephone (803) 343-1269
Facsimile (803) 799-8479
Attorneys for Petitioner

November 5, 2009
Columbia, South Carolina

EXHIBIT ONE

MRI at Belfair, LLC,
Petitioner,
v
South Carolina Department of Health and
Environmental Control and Coastal
Carolina Medical Center,
Respondents

DOCKET NO 07-ALJ-07-0389-CC

(Implemented Project) constitutes a substantial change to the site-built, in-house MRI project (Original Project) that had been previously submitted to and approved by the South Carolina Department of Health and Environmental Control (Department), and whether the sale of CCMC voided the Certificate of Need (CON) issued for the Original Project

A contested case hearing was held at the Administrative Law Court August 4-5, 2009. Upon carefully weighing all of the evidence and applying the applicable law, the Court finds that the Implemented Project constituted a substantial change from the Original Project, mandating that CCMC file a new CON application with the Department.

ISSUES PRESENTED FOR DETERMINATION

The issues presently before the Court are:

1. Has Belfair proven that the Department was incorrect in finding that the Implemented MRI Project was not a substantial change from the Original MRI Project, and, therefore, not a new Project pursuant to S.C. Code Ann. § 44-7-230(A) (Project Statute) and 24A S.C. Code Ann. Regs. 61-15 § 605 (Supp. 2008) (the Substantial Change Regulation)?

2. Did the sale of CCMC on or about July 1, 2007 void the CON for the Project, pursuant to S.C. Code Ann. § 44-7-230(E) and 24A S.C. Code Ann. Regs. 61-15 § 604 (Supp. 2008)?

EXHIBITS

Belfair offered Exhibit Numbers 1 through 6, CCMC offered Exhibit Numbers 1-25, with the exception of Exhibit Number 13, and Department offered Exhibit Number 1. All of these exhibits were admitted into evidence. Because each party designated the Department's file in this matter as its Exhibit 1, I will refer to that document as "Exhibit

1” or “Department Record” throughout this Order

APPLICABLE LAW

The Project Statute provides in relevant part, “The Certificate of Need, if issued, is valid only for the project described in the application including location beds and services to be offered, physical plant, capital or operating costs, or other factors as set forth in the application, except as may be modified in accordance with regulations” The Substantial Change Regulation requires that “[i]f an applicant amends or alters his project after receipt of a CON, the Department will decide whether or not the amendment is substantial and thereby constitutes a new project.” The Project Statute and the Substantial Change Regulation are silent as to the definition of “substantial,” as it relates to the degree of change constituting a new project

S C Code Ann § 44-7-230(E) provides that “[a] Certificate of Need or rights thereunder may not be sold, assigned, leased, transferred, mortgaged, pledged or hypothecated, and any actual transfer or attempt to make a transfer of this sort results in an immediate voidance of the Certificate of Need 24A S C Code Ann Regs 61-15 § 604 mandates that

- 1 A Certificate of Need is nontransferable A Certificate of Need or rights thereunder may not be sold, assigned, leased, transferred, mortgaged, pledged, or hypothecated, and any actual transfer or attempt to make a transfer of this sort results in the immediate voidance of the Certificate of Need. The sale or transfer of the controlling interest or majority ownership in a corporation, partnership, or other entity holding, either directly or indirectly, a Certificate of Need, results in the transfer and voidance of a Certificate of Need
- 2 Anyone having their Certificate of Need voided in this manner shall not be eligible to apply for a new Certificate for a period of one (1) year without Board approval

Therefore, any attempt to transfer the CON renders it void

FINDINGS OF FACT

Having observed the witnesses and exhibits presented at the hearing and closely passed upon their credibility, and considering the burden of persuasion by the parties, I make the following findings of fact by a preponderance of the evidence

1 Notice of the date, time, place and subject matter of the hearing was properly given to all the parties

2 CCMC is a forty-one (41) bed hospital located in Jasper County, South Carolina, which opened to the public in November 2004

3 Belfair is a free-standing imaging facility located in Bluffton, Beaufort County, South Carolina, providing MRI services for Beaufort and Jasper Counties, South Carolina, and is an "affected person" as defined in the CON Act

The Original Project

4 On May 7, 2004, CCMC submitted to the Department an application for a CON to construct an MRI suite and house a new MRI therein, all to be incorporated as an integral part of its existing hospital facility. The total project cost for the Original Project was \$3.2 million, with equipment costs of \$1.8 million, (Exhibit One, p. 000210). The MRI unit to be incorporated into the Original Project offered a maximum gradient amplitude of 33 millitesla per meter squared (Tr, p. 65). The MRI unit and associated equipment were to be located inside the hospital, adjacent to the emergency room, and in close proximity to other hospital services and facilities. Exhibit 1. The Original Project application provided that the MRI unit would be placed in an MRI suite (comprised of an MRI Room, MRI Control Room and MRI Equipment Room) where adequate space existed in order to allow patients to be safely and effectively transported to and from the MRI Room. (Exhibit One, p. 000133). According to the specifications of the Original

Project, the MRI unit would be located in an MRI Room that allowed space on all sides of the unit to provide reasonable access to patients being scanned (Exhibit One, p 000133) CCMC emphasized in its application for the Original Project the need for an MRI scanner that would be available “24 hours per day/7 days per week ” (Exhibit One, p 000056) CCMC’s application for the Original Project specifically articulated, on several occasions, the need for an MRI to serve “acutely ill” patients (Exhibit One, p 000041, 44, 56) CCMC’s Application for the Original Project specifically articulated a need for the MRI to serve “medically unstable” patients (Exhibit One, p 000056) CCMC’s Application for the Original Project specifically articulated a need for the MRI to serve “critically ill” patients (Exhibit One, p 000041) Accordingly, CCMC s Application for the Original Project described a need for an MRI to provide services to “acutely ill,” “critically ill,” and “medically unstable” patients CCMC’s Application explicitly rejected the use of any MRI unit other than an in-house unit (Exhibit One, p 000044)

5 On or about November 22, 2004, DHEC issued a CON approving the Original Project.

6 On August 4, 2006, CCMC requested permission from the Department to install and utilize a mobile MRI unit during the implementation and construction of the Original Project (“Temporary Project”) On that same day, without notice to Belfair, the Department issued a letter which approved CCMC for the “temporary full-time use of a mobile MRI unit during the interim period of the Fixed MRI construction and installation as outlined in [Mr Summer’s] August 4, 2006 letter ” (Exhibit One, p 000519)

The Implemented Project

7 On June 12, 2007, after issuance of the CON, but twenty-one (21) days

before the July 3, 2007 deadline for implementation, CCMC sought authority from the Department to implement the CON through permanent use of the MRI trailer unit located on a concrete pad outside of the hospital that CCMC had been leasing on a temporary basis (Exhibit One, p 000940) CCMC did not provide Belfair with notice of its request

8 On June 22, 2007, the Department concluded the changes to the project were not substantial and, therefore, did not require CCMC to file and pursue a new CON application. (Exhibit One, p 000958) The Department did not provide Belfair with notice of its determination On June 27, 2007, the Department informed CCMC that the Implemented Project was complete (Exhibit One, p 000962)

9 The total project cost for the Implemented Project was \$836,822, approximately \$2.3 million less than the Original MRI Project that DHEC had approved (Exhibit One, p 000921) Moreover, the estimated cost for the MRI equipment itself changed from \$1.8 million to approximately \$535,000 (Id.)

10 The MRI unit for the Implemented Project has a maximum gradient amplitude of 23 millitesla per meter squared, resulting in longer scan times than the 33 millitesla gradient available from the MRI unit approved in the Original Project CON (Tr, p 65-67)

11 The MRI suite as implemented is not located within the hospital and adjacent to the emergency room, but rather in a location outside the hospital that requires a several minute walk from the emergency room (Belfair Exhibit Five), (Tr, pp 45-46)

12 The Implemented Project MRI unit is a trailer that has been skirted, and connected via a non-enclosed walkway The Implemented Project MRI Suite has an external lift that raises patients up from the parking-lot level so that they can be wheeled

into the MRI trailer through the MRI Control Room (Belfair Exhibit Four)

13 The MRI Scan Room for the Implemented Project is too narrow to provide head-end access to the patient, creating safety problems (Tr , p 50)

14 The narrowness of the MRI Scan Room for the Implemented Project creates difficulty in detaching the MRI table and removing a patient from the MRI Scan Room in the event of an emergency (Tr , pp 50-51)

15 The confines of the MRI Control Room and the MRI layout for the Implemented Project create substantial safety issues in the event a patient in an emergency situation must be lowered from the MRI trailer on the lift, wheeled at parking lot level into the hospital, and then transported some distance away to the hospital emergency room (Tr , pp 49-51)

16 CCMC submitted certain of its "Policies and Procedures" to the Department as part of the Application for the Original Project (Exhibit One, pp 00003-000033) These "Policies and Procedures" contained no MRI-specific policies

17 Following approval of the Original Project, CCMC issued a number of policies and procedures applicable to its MRI (MRI Policies and Procedures) (Belfair Exhibit Three)

18 CCMC's MRI Policies and Procedures make clear that "MRI compatible monitoring equipment is not available for use in this facility " (Belfair Exhibit Three)

19 As described by Belfair witness Borelli, monitoring equipment is used to monitor a variety of vital signs and other aspects of a patient's condition. (Tr , pp 57-58)

20 Acutely ill patients require constant monitoring during the MRI procedure (Tr , p 57)

21 Unstable patients require constant monitoring during the MRI procedure (Tr , p 283)

22 Critically ill patients require constant monitoring during the MRI procedure (Tr , p 295)

23 Based upon CCMC's MRI Policies and Procedures for the Implemented Project, CCMC cannot and does not perform MRI scans on patients who require monitoring (Belfair Exhibit Three) This fact was confirmed by CCMC witness Moesch. (Tr , pp 97-98)

24 Therefore, as testified to by Belfair witness Borelli, without the ability to provide monitoring during the MRI procedure, CCMC cannot and does not perform scans on acutely ill patients, (Tr , pp 30-31), unstable patients (Tr , p 282), or critically ill patients (Tr , p 295)

25 Because it is located outside of, and physically disconnected from the hospital building, the Implemented Project requires a separate, MRI-specific "Code Blue" procedure that would not exist had the Original Project described in CCMC's Application been implemented (Belfair Exhibit Three), (Tr , pp 55-56)

26 This MRI-specific "Code Blue" procedure, necessary because the MRI trailer is located outside the hospital, materially impacts patient care and patient safety (Tr , pp 55-56)

27 Furthermore, the record demonstrates that CCMC performs few if any scans between the hours of 11 00pm and 7 00am. (Tr , p 107), (Belfair Exhibit Six)

28 The Implemented Project is a substantial change from the Original Project. As set out herein, several aspects of the Implemented Project represent a substantial change from the Original Project as described in CCMC's application

29 CCMC's Application described an MRI project that would provide scans to critically ill, unstable, critically ill, and acutely ill patients

30 Furthermore, in rejecting alternatives to an in-house MRI scanner, CCMC described in its Application that transferring patients to another location for an MRI scan would put its "emergent and acute care patients being transported to outside providers to obtain an MRI scan at risk" (Exhibit One, p 000055)

31 The Implemented Project clearly does not provide scans to those acutely ill, critical or unstable patients, however, as demonstrated by the fact that CCMC does not perform scans on those patients who require constant monitoring

32 CCMC's application described a Project with a need to provide scans on a 24-7 basis. The evidence of record demonstrates that CCMC provided no scans between the hours of 11 00pm and 7 00am during the period from September 1st of 2006 to December 31st of 2007 (Belfair Exhibit Six), and few if any scans following that time period

33 CCMC's Application described an MRI unit located inside the hospital, in a location adjacent to the emergency room (Belfair Exhibit Five)

34 The Implemented Project, however, is not adjacent to the emergency room. In fact, the significantly smaller MRI "suite" actually implemented is situated several minutes' transport from the emergency room, and in a trailer located on the surface of the hospital parking lot. (Tr , pp 45-46)

35 CCMC's Application described and demonstrated a layout for the Original MRI Project that provided adequate space to transport patients in and out of the scan room, as well as adequate space in and around the scanner itself, and in the MRI control room (Exhibit One, p 000133)

36 The rooms and layout of the Implemented Project offer limited space for scanning patients and transporting patients in and out of the MRI trailer

37 The use of a lift for the Implemented MRI Project, an aspect absent from the Original MRI Project, also raises safety concerns in the event of an emergency situation

38 CCMC's Application called for a 1.5 Tesla GE system with a high-performance high-speed gradient system for quick patient scanning, whereas the implemented system lacks the advanced gradient system and scans at a considerably slower rate than the system described in the Original Application. Based upon the expert testimony of Dr. Borelli, the higher gradient strength of the scanner proposed in the Application for the Original Project would have made it possible for that scanner to perform scans at a faster rate than the MRI unit that is part of the Implemented Project (Tr., pp. 65-67)

39 The Court finds the testimony of Dr. Borelli to be credible and compelling with respect to the changes from what was described in CCMC's Original Application to the Implemented Project

40 The Court recognizes that changes in CON projects do occur from time-to-time. When changes occur, the Department must determine whether changes are so substantial as to constitute a new project under the Project Statute and the Substantial Change Regulation. While cost is one standard metric in a substantial change assessment, the overarching concern here must be whether the Project alters the scope and capabilities of the entire Original Project as it was proposed by CCMC in its Application and approved by the Department. The extent and type of services offered in the Implemented Project, as well as numerous other aspects of the Implemented Project,

are significantly different than those set out in the Application for the Original Project. In particular, I find CCMC's description of the Original Project as set out in its Application with respect to providing MRI scans for critically ill, acutely ill, and unstable patients is substantially different from the Implemented Project. Therefore, I find that the changes to the Original Project were substantial and constitute a new project.

The Transfer of CCMC

41 CCMC's stock was transferred to Tenet Health System Medical on July 1, 2007 (Tr, p 168)

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, I conclude the following as a matter of law.

1 This Court has subject matter jurisdiction in this case pursuant to S C Code Ann § 1-23-310 et seq. (Supp 2008), S C Code §§ 44-7-110, et seq. (2002), and 24 A S C Code Regs 61-15 (Supp 2008).

2 The Administrative Law Judge is the fact finder in this matter for purposes of administrative and judicial review and does not sit in an appellate capacity. Brown v S C Dep't of Health and Envtl Control, 348 S C 507, 560 S E 2d 410 (2002). Furthermore, the burden of proof in a contested case hearing is upon the moving party. See 2 Am Jur 2d Administrative Law § 360 (1994), Alex Sanders, et al, South Carolina Trial Handbook § 9.3 Party With Burden Civil Cases (1999) (In civil cases, generally, the burden of proof rests upon the party who asserts the affirmative of an issue.) In the present case, Belfair has the burden of proving that the Department erred in deciding that the changes to CCMC's Original Project did not constitute a substantial change contrary to the Project Statute and the Substantial Change Regulation.

3 “The qualification of a witness as an expert in a particular field is within the sound discretion of the trial judge ” Smoak v Liebherr-America Inc., 281 S C 420, 422, 315 S E 2d 116, 118 (1984) Where the expert's testimony is based upon facts sufficient to form the basis for an opinion, the trier of fact determines its probative weight. Berkeley Electric Coop v Pub Service Comm'n, 304 S C 15, 402 S E 2d 674 (1991), See also Smoak supra Furthermore, a trier of fact is not compelled to accept an expert's testimony, but may give it the weight and credibility he determines it deserves Florence County Dep't of Social Services v Ward, 310 S C 69, 425 S E 2d 61 (Ct App 1992) He also may accept one expert's testimony over that of another S C Cable Television Ass'n v Southern Bell Telephone and Telegraph Co , 308 S C 216, 417 S E 2d 586 (1992)

4 The purposes of the CON Act are “to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State ” S C Code Ann. § 44-7-120

5 The purpose of the Project Statute and the Substantial Change Regulation is to ensure that every project is properly considered and reviewed pursuant to the requirements of the CON Act and the CON Regulations When a project changes substantially from what is described in the project application, the Project Statute and the Substantial Change Regulation require that the new project undergo the notice and review provisions set out in the CON Act.

6 It is appropriate to give due consideration to the Department's CON staff's utilization of its specialized knowledge and expertise in the application of the Act and

CON regulations See S C Code Ann § 1-23-330(4) (1976) However, the Department's Board, and not the Department's CON staff, is the policymaker for the Department and thus possesses the authority to establish its interpretation of its regulatory and statutory provisions Consequently, I find that neither the construction of the Act nor the CON regulations by individual members of the Department's staff is entitled to "most" respectful consideration

7 "The cardinal rule of statutory construction is to ascertain and effectuate the intent of the legislature " Hodges v Rainey, 341 S C 79, 85, 533 S E 2d 578, 581 (2000) The best evidence of legislative intent is the statute's actual language Id Therefore, where a statute's language is clear and unambiguous conveying a clear and definite meaning, no other meaning may be imposed Id However, if a statute is ambiguous, courts must ascertain legislative intent through statutory construction See Abell v Bell, 229 S C, 1, 91 S E 2d 548 (1956) An ambiguity arises when the language of a statute is capable of being understood by reasonably well-informed persons in either of two or more senses Southeastern Fire Ins Co v South Carolina Tax Comm'n, 253 S C 407, 171 S E 2d 355 (1969)

8 Another cardinal rule of statutory construction is that the statutory provisions do not stand alone but must be read in the context of the Code as a whole "A statute is passed as a whole and not in parts or sections and is animated by one general purpose and intent. Consequently, each part or section should be construed in connection with every other part or section so as to produce a harmonious whole " Sutherland Statutory Construction, 5th Ed , § 46 05, p 103 (1992) See also Keonig v SC Dep't of Public Safety, 325 S C 400, 480 S E.2d 98 (Ct. App 1996) Furthermore, the statutory language in question must also "be read in a sense which harmonizes with its subject

matter and accords with its general purposes ” Hitachi Data Systems Corp v Leatherman, 309 S C 174, 420 S E 2d 843, 846 (1992) (citing Multi-Cinema Ltd v SC Tax Comm'n, 292 S C 411, 357 S E 2d 6 (1987))

Substantial Change

9 Belfair contends that the changes embodied in the Implemented MRI Project are substantial and, therefore, the Department erred in not determining that the changes constituted a new Project requiring CCMC to file and notice, and the Department to approve, a new CON application. 24A S C Code Ann Regs 61-15 § 605 (Supp 2008) provides “[i]f an applicant amends or alters his project after receipt of a Certificate of Need, the department will decide whether or not the amendment is substantial and thereby constitutes a new project.” (emphasis added)

10 Therefore, in analyzing whether a substantial change has occurred, the Court must first determine the nature of the Project. The Project Statute provides that the CON “is valid only for the project described in the application including location, beds and services to be offered, physical plant, capital or operating costs, or other factors as set forth in the application, except as may be modified in accordance with regulations ” See also Regulation 61-15 § 605 The legislative purpose of the Act in the MRI context is that a CON limits a project based its location, the services it provides, the physical equipment and layout of the project, its costs, and other application-specific factors

11 The Department has historically defined a “substantial change” to an MRI project as an increase in the Tesla strength of the MRI unit, an increase in project cost of 10% or greater, or a change in the location of the MRI to a location not on the campus of the particular facility In the present proceeding, the Department takes the position that standard is appropriate (CCMC Exhibit Eight), (Tr , pp 178-185)

12 However, the Department's position is inconsistent with its own witness Tori Tibshirany's hearing testimony (Tr , pp 253-263), is too narrow, and does not encompass the potential substantial changes set out in the Project Statute that can take place within the context of an MRI project. The Substantial Change Regulation cannot conflict with the Project Statute. See South Carolina Coastal Conservation League v SCDHEC, 345 S C 525, 548 S E 2d 887 (S C Ct App 2001) ("Although a regulation has the force of law, it may not alter or add to a statute ") Additionally, as Belfair witness Borelli testified, Tesla strength is not a reliable indicator of the functions and capabilities of an MRI unit, especially when Tesla strength increases from 1.5 T to 3.0 T (Tr , pp 40-42) That point is illustrative of the fact that factors other than the Tesla strength of an MRI scanner must be considered in determining whether an MRI project has undergone a project change that is substantial

Moreover, the Department's construction of the Substantial Change Regulation as setting a cost ceiling that can not be exceeded and limiting Tesla strength incorrectly presumes that a project change resulting in a cost decrease (as occurred in this case) can *never* constitute a new project—ignoring the plain language of the Project Statute and the aspects that create a new project. In other words, a change in costs may not stand alone as a substantial change, but it must be considered as one of the factors specifically enumerated in the Project Statute as applicable to a substantial change analysis

Consistent with the plain language and purpose of the Project Statute, I conclude that in determining whether or not changes to an approved MRI project are substantial, the Administrative Law Court should consider

- a. whether the location of the project (within or outside the facility) has changed,
- b. whether the services upon which the Application was based have changed,

- c whether the equipment described in the Application and the area in which the MRI equipment is housed has changed,
- d whether the costs associated with the project have changed, and
- e whether other factors set forth in the application have changed

13 Location of the Project it is clear that the Implemented Project is sited in a different location from the Original Project. This change is significant, as the MRI is not conveniently located in the hospital and adjacent to the emergency room as originally proposed, but rather outside the hospital and several minutes from the emergency room. The location of the Implemented Project some distance away from the emergency room also calls into question the practicability of scanning those patients admitted to the emergency room.

14 Services Provided by the Project The services upon which the Application was based have also changed. CCMC does not scan unstable and critically ill patients, in contrast to the services to be offered as described in the Application for the Original Project.

15 Project Equipment and Layout While the MRI unit that is part of the Implemented Project may be similar in Tesla strength and other aspects to the MRI unit proposed in the Original Project, the area in which the installed MRI unit is housed is substantially different from that described in the application, raising a number of safety concerns. The trailer in which the MRI is housed offers limited space in and around the unit, in particular prohibiting access near the "head-end" of the MRI unit. The elevator lift may present difficulties in transporting a patient into and out of the MRI trailer. There is limited room to negotiate a stretcher into the MRI control room and the scan room.

16 Project Costs With respect to costs, it is undisputed that the Implemented Project cost substantially less than the amount described in the Application. However,

the Application also claimed that the \$3 2 million Original Project was the “most cost effective” means to accomplish CCMC’s needs (Exhibit One, p 000044)

17 Other factors set forth in the Application Unique to this case is the fact that the project described in the Original Application expressly rejected the mobile unit that the Implemented Project ultimately embraced The Department therefore must assess the factors that led to such a change in the Project by CCMC

18 Therefore, I find that Belfair has proven that CCMC’s Implemented Project constituted a “new project” when compared to the Original Project “described in the application,” pursuant to the Project’ Statute, and that the Implemented Project constitutes a substantial change to the Original Project within the meaning of the Substantial Change Regulation

Status of CON Upon Transfer

19 As a result of the substantial change from the Original Project, the Implemented Project necessarily constitutes a “new project” pursuant to the Project Statute and the Substantial Change Regulation

20 Accordingly, since the Court’s ruling means that the CON had not been implemented on or about July 1, 2007, I also find that the transfer of CCMC that occurred on or about that date voided the CON for the Original Project, pursuant to S C Code Ann § 44-7-230(E) and 24A S C Code Ann. Regs 61-15 § 604 (Supp 2008)

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is

IT IS HEREBY ORDERED that DHEC’s decisions that CCMC’s modifications were not substantial are overruled, and that CCMC shall file a new CON application for the Implemented Project

IT IS FURTHER ORDERED that CCMC'S Certificate of Need for the Original
Project was voided by the transfer of CCMC on July 1 2007

AND IT IS SO ORDERED

Ralph King Anderson, III
Administrative Law Judge

October _____, 2009
Columbia, South Carolina

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

MRI at Belfair, LLC,	)	Civil Action No 07-ALJ-07-0389-CC
	)	
Petitioner	)	
	)	
v	)	<u>COASTAL CAROLINA</u>
	)	<u>MEDICAL CENTER'S</u>
	)	<u>MEMORANDUM</u>
South Carolina Department of Health and	)	<u>IN OPPOSITION TO MOTION FOR</u>
Environmental Control and Coastal	)	<u>RECONSIDERATION</u>
Carolina Medical Center,	)	
	)	
Respondents	)	
	)	

Coastal Carolina Medical Center ("Coastal") hereby offers this memorandum in opposition to the motion for reconsideration and to alter and amend filed by MRI at Belfair, LLC ("Belfair")

ARGUMENT

I CONSIDERING WHETHER AMENDMENTS TO COASTAL'S MRI PROJECT SUBSTANTIALLY CHANGE THE PROJECT'S COMPLIANCE WITH THE PROJECT REVIEW CRITERIA IS NOT LEGAL ERROR

Belfair claims that considering the project review criteria as part of the substantial change analysis is legal error. Mem. at 2. Belfair's argument is based upon the notion that reexamining the criteria as part of substantial change analysis under section 605¹ is the same as applying the criteria to determine whether a project should be issued a Certificate of Need ("CON") under section 44-7-210.² Belfair contends that both of these analyses determine whether a project "meets the project review criteria," and thus allegedly duplicative use of the

¹ S.C. Code Ann. Regs. 61-15 § 605

² S.C. Code Ann. § 44-7-210

criteria causes a variety of legal problems Mem at 2-5 Belfair misunderstands the nature of the substantial change analysis

The substantial change analysis does not determine whether a project meets the project review criteria Instead, the substantial change analysis determines whether amendments to a project change the way the project was originally proposed to meet the criteria This analysis is limited by the scope and nature of the originally proposed project, and it is comparative Under section 605, DHEC or the ALC considers how the original project proposed in the CON application to comply with the criteria and then considers whether the amendments to the project will substantially change how the project will comply with the criteria

Under S C Code Ann § 44-7-210, on the other hand DHEC or the ALC applies the project review criteria to determine whether the project meets the criteria This analysis is not limited by any previous proposal, nor is it comparative For example, when Coastal applied in 2004 for a CON for an MRI to be located on its hospital campus, DHEC determined whether Coastal's project met the project review criteria Among other things, DHEC determined that there was a need for MRI services in Jasper County and parts of Beaufort County, and the project was needed by, and would increase accessibility for, Coastal's inpatients Because Coastal's project met need, accessibility and the other relevant criteria, a CON was issued

Assume that after receiving the CON, Coastal amended its MRI project to change the project's location from the hospital campus to a medical office building in Bluffton, 15 miles east of Coastal DHEC or the ALC would undertake the substantial change analysis and reexamine the project review criteria, including need and accessibility, to determine whether the new location substantially changes how Coastal proposed, in its CON application, to satisfy the criteria Because the Bluffton location would materially change the service area that would

generate the need for the project, and because it would not be accessible to Coastal's inpatients or patients from Jasper County, DHEC would presumably find that the amendment to the project substantially changes the way the project proposed to comply with the criteria, and the CON would be voided if the amendments were undertaken

Under section 605, DHEC could not determine that Coastal's amended project satisfies a need for MRI services in Bluffton and would increase accessibility to patients living in the eastern portion of Hilton Head Island. That the amended project may indeed satisfy this need and resolve this accessibility issue is of no moment in the substantial change analysis. DHEC would be limited, as the ALC was in this case, to determining whether the amendment substantially changes the way Coastal's project was originally proposed to comply with the criteria. Under section 605, DHEC could not determine, as Belfair argues, that Coastal's amended project would be entitled to a CON to serve a different service area, nor would a finding of substantial change preclude Coastal from submitting a subsequent CON application for a project located in Bluffton.

Because reexamination of the project review criteria pursuant to section 605 does not determine whether a project "meets" the criteria, Belfair's arguments about administrative "leapfrog[ing]" and "short circuit[ing]," the ALC's jurisdiction, violation of the CON Act, and preclusive effect on subsequent CON application decisions should be rejected.

II BELFAIR'S ARGUMENT REGARDING SECTION 44-7-230(A) IS FLAWED

Belfair argues that the items listed in section 44-7-230(A), rather than the project review criteria, provide the "test" that the ALC should apply to determine whether a project substantially changes under section 605. Mem at 5-6. Belfair's argument is flawed.

The purpose of section 230(A) is to make clear that CONs are project specific. Providers do not get CONs for generic projects whose scope, services, costs, and location will be determined later. Instead, a CON is issued to projects at a specific "location," that have specific "services to be offered," in a particular "physical plant," at an estimated capital cost.

S C Code Ann § 44-7-203(A) Section 230(A) then recognizes that proposed projects may change, and thus allows that projects can be "modified in accordance with regulations." *Id*

This clause takes us to section 605 that provides the regulatory authority for the substantial change analysis.

Coastal does not dispute that the items in section 230(A) are considered in the substantial change analysis. For example, changes in location, services, and costs are considered in the substantial change analysis. However, in order to consider these items, there must be a standard to apply to them. The standard comes from the reexamination of the project review criteria. For example, how could a change in location be analyzed in the absence of the project review criteria? Is a 200 yard, two mile, or 10 mile change substantial? Asking whether a change in location substantially changes the way in which the project complies with need and accessibility provides DHEC and the ALC with a substantive basis to determine whether the change is material.

III WHETHER THE ALC REEXAMINED THE PROJECT REVIEW CRITERIA, OR NOT, IN A PRIOR CASE IS OF NO MOMENT

Belfair claims that the substantial change issue in *Providence Hosp v S C Dep't of Health and Envtl Control and Palmetto Richland Mem. Hosp*, 02-ALJ-07-0155-CC 2002 WL 31423801 (Sept 11, 2002)(attached as Ex A) was resolved "based solely upon" section 203(A) "and not the project review criteria." Mem at 7. Belfair is mistaken.

First, this argument does not allege a legal error to be corrected. Even if *Providence* did not apply the project review criteria, it does not follow that the absence of this analysis in *Providence* means there is a legal error in the Final Order and Decision. As set forth above, reexamination of the project review criteria in the Final Order and Decision is not legal error.

That said, *Providence* contains a paragraph wherein the ALC reviews the project review criteria as part of determining the "nature" of the project. The ALC reviewed DHEC's findings regarding accessibility (the project "would provide increased access"), acceptability (the project "had physician and community support"), need (the project "would not be an unnecessary duplication"), and adverse impact (the project would not have a "negative effect upon existing services") *Providence* at *13. The ALC's consideration of whether the amendments to the project "impact the Department's assessment of the area being served by the project and any negative effects of affected persons" is clearly a reexamination of at least need, accessibility, and adverse impact. *Id.*

Though *Providence* is not cited in the Final Order and Decision, *Providence* and the instant case utilize the project review criteria similarly as the substantive standard in the substantial change analysis.

IV DHEC TESTIFIED THAT THEY REEXAMINE THE PROJECT REVIEW CRITERIA AS PART OF THE SUBSTANTIAL CHANGE ANALYSIS

Belfair alleges that Ms. Tibshirany conceded she "relies upon, and is guided by" section 230(A) to make substantial change determinations, and this "decisively establishes" that the project review should not be reexamined. Mem. at 7-8.

Ms. Tibshirany testified that some of the items in section 230(A) are reviewed as part of DHEC's substantial change determination. Tr. P. 254, L. 15-24 (attached as Ex. B). As set

forth above, Coastal agrees that location, cost, and services are considered in the substantial change analysis. However, Belfair again misses the point. Simply considering these items in a vacuum, without applying a standard to them, does not provide DHEC or the ALC with a health planning basis for the substantial change decision.

That basis is provided by a reexamination of the criteria, and that is what DHEC does. Mr. Grice testified that DHEC reexamines the project review criteria "to go back and look and makes sure that in no way would there be a substantial change in relation to what issues and criteria the Department used in making its original decision." Tr. at 183-184, *see also* Tr. at 231-36 (Ms. Tibshirany describing her reexamination of the project review criteria as part of DHEC's substantial change analysis for Coastal's MRI project). Belfair's argument should, therefore, be rejected.

CONCLUSION

For the reasons set forth above, the Court should deny Belfair's motion for reconsideration and to alter and amend.

Respectfully submitted,

NELSON MULLINS RILEY & SCARBOROUGH LLP

By


Travis Darhuff
Holly G. Gillespie
1320 Main Street, 17th Floor
Post Office Box 11070
Columbia, SC 29211
(803) 799-2000

Attorneys for Coastal Carolina Medical Center

Columbia, South Carolina

November 16, 2009

Westlaw

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Administrative Law Judge Division

State of South Carolina

*1 PROVIDENCE HOSPITAL, PETITIONER

vs.

SOUTH CAROLINA DEPARTMENT OF
HEALTH AND ENVIRONMENTAL CONTROL
AND PALMETTO RICHLAND MEMORIAL
HOSPITAL, RESPONDENTS

Docket No 02-ALJ-07-0155-CC

September 11, 2002

APPEARANCES

Harold W. Jacobs, Esquire, and Ralph W. Barbier
III, Esquire,
For Providence Hospital
M. Elizabeth Crum, Esquire, Francis P. Mood,
Esquire
Mary D. Shahid, Esquire, for Palmetto Richland
Memorial Hospital
Nancy S. Layman, Esquire, and Nancy L. Roberts,
Esquire for SC DHEC

FINAL ORDER AND DECISION

STATEMENT OF THE CASE

This matter arises from a request for a contested case hearing by Providence Hospital (Providence) filed on April 15, 2002, contesting three separate decisions issued on April 9, 2002 by Respondent South Carolina Department of Health and Environmental Control (DHEC or Department) relating to Palmetto Richland Memorial Hospital's (Palmetto) Certificate of Need (CON), SC-99-44, for the construction of a Heart Center (the Project).

First, Providence contests the Department's decision that Palmetto's redesign of its proposed Heart Center is not a substantial change from the Project as originally approved by the Department on November 5, 1999. Second, Providence contests the Department's decision that Palmetto achieved implementation of the CON prior to the CON's expiration on May 5, 2002. Third, Providence contests the Department's decision not to void the CON based upon the disclosure that Palmetto submitted inaccurate catheterization (cath) lab volumes in its CON application. In support of its request for a fourth cath lab, Palmetto moved to dismiss each of the three causes of action. By Order dated June 24, 2002, Palmetto's motion to dismiss Providence's cause of action regarding Palmetto providing the Department with inaccurate information in support of the fourth cath lab was granted, but the motions to dismiss the remaining causes of action were denied. A hearing on the merits was conducted on July 23, 2002 and July 24, 2002 at the offices of the Administrative Law Judge Division (ALJD or Division) in Columbia, South Carolina.

ISSUES PRESENTED FOR DETERMINATION

Providence asserted three causes of action in its request for a contested case hearing. As stated above, Providence's third cause of action was dismissed by Order dated June 24, 2002. The remaining issues are:

1. Has Providence proven that the Department was incorrect in finding that Palmetto achieved Project implementation prior to the expiration of the CON on May 5, 2002?

2. Has Providence proven that the Department was incorrect in finding that Palmetto's April 9, 2002 redesign of its Heart Center Project was not a substantial change, and, therefore, not a new Project as described under 24A S.C. Code Ann. Regs. 61-15 § 605 (Supp. 2001)?

DISCUSSION

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EXHIBIT

A

Providence, in what appears to be a case of first impression before the Division, has sought contested case review of the Department's application of its oversight regulations monitoring the implementation of an approved CON. The State Certificate on Need and Health Licensure Act (the Act), S.C. Code Ann. §§ 44-7-110 et seq. (Supp. 2001), requires that after the issuance of a CON the Department monitor and enforce the applicant's implementation of the CON to assure that the Project is within the scope of the approved CON and is effectuated in a timely fashion.

*2 DHEC issued a CON to Palmetto on October 22, 1999 finding that: (1) there was a need for the Project; (2) the Project would increase accessibility to cardiovascular services in the ten county Midlands area of South Carolina, and (3) the Project had physician and community support. After obtaining a CON for an addition or major renovation to an acute care hospital such as Palmetto, the applicant must have negotiated a valid construction contract for the Project within one year of the issuance of the CON or within the time frame specified by any extensions granted by the DHEC staff or Board pursuant to 24A S.C. Code Ann. Reg. 61-15 § 601 (Supp. 2001). Regulation 61-15 § 202 (2)(d)(10) also imposes a requirement on a CON applicant to "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." Under Regulation 61-15 § 601 (1), a "Certificate of Need becomes void if a valid construction contract is not properly negotiated."

Regulation 61-15 § 605 further requires that "[i]f an applicant amends or alters his project after receipt of a CON the Department will decide whether or not the amendment is substantial and thereby constitutes a new project." The applicable statutes and regulations are silent as to the definitions for "valid," as it relates to a construction contract, and "substantial," as it relates to the degree of change to a project.

FINDINGS OF FACT

Having observed the witnesses and exhibits presented at the hearing and closely passed upon their credibility, and considering the burden of

persuasion by the parties, I make the following findings of fact by a preponderance of the evidence:

1 Palmetto is a nonprofit hospital in Columbia, South Carolina. On March 17, 1999, Palmetto filed an application under the 1998 South Carolina Health Plan for a Certificate of Need to construct a Heart Center adjacent to the existing hospital in order to consolidate all heart services at Palmetto Richland Memorial Hospital.^(PNI) The Project called for the construction of a building on the northwest portion of the Palmetto campus, consolidation of the cardiovascular services (excluding surgical suites and cardiac rehabilitation) consisting of the relocation of 124 existing acute care beds, cardiac diagnostics, and the addition of a fourth cardiac cath lab and one electrophysiology lab. The new building would contain 257,017 square feet within five levels for a total Project cost of \$77,266,057.00. It was to consist of one underground floor with four floors above ground.

2 On October 22, 1999, DHEC notified Palmetto of its decision to issue the CON for the Heart Center. The Department formally issued the Certificate of Need on November 5, 1999. The CON was valid for one year because it was a major hospital construction Project. Afterwards, the Department granted two six-month extensions on Palmetto's CON and the DHEC Board subsequently granted a third six-month extension. Palmetto notified the DHEC Board that it would be seeking a fourth extension, but withdrew that request when Palmetto signed a construction contract prior to the Board's April 2002 meeting.

*3 3 During the DHEC review process of Palmetto's CON, Providence, as an "affected person" under the Act, had the right to be informed of the status of Palmetto's CON and to oppose Palmetto's application. However Providence did not oppose Palmetto's CON application and did not request a contested case hearing to challenge DHEC's determination to approve Palmetto's Certificate of Need for the Heart Center.

Project Implementation

4 In a letter dated April 9, 2002, Palmetto advised the Department that it had entered into a valid contract for the construction of the Heart Center with a commencement date of April 3, 2002.

Attached to this letter were American Institute of Architects (AIA) Forms A111 and A201, with exhibits, which had been executed by Palmetto and Rodgers Builders, Inc. (Rodgers) on April 3 2002. The Department determined the contract contained the signatures of the applicant and the contractor, described the Project, had commencement and termination dates, and a guaranteed maximum price (GMP) ^(FN2). The letter further stated that Palmetto had obtained a building permit from the City of Columbia for the Heart Center's foundation and parking and that "[t]he construction contract is in the amount of \$110,420.00 for preconstruction services and \$62,555,000.00 for construction." A copy of the building permit was also attached to this April 9, 2002 letter.

5 On April 2, 2002, Palmetto entered into a construction contract with Rodgers for construction of the Heart Center. Both parties signed the contract—Kester Freeman for Palmetto and Patricia Rodgers for Rodgers. The parties utilized two AIA forms to create the contract: B AIA documents A111 and A201, 1997 versions. Forms A111 and A201, issued by The American Institute of Architects, are approved and endorsed by The Associated General Contractors of America. AIA forms are used extensively in construction projects. Form A111 is the standard form of agreement between the owner and the contractor to determine the method of construction and payments. It also establishes the basics for any given project. Form A201 delineates the general terms and conditions of the contract for construction.

The A111 contract is defined as a "cost of work with a guaranteed maximum price" contract and is very commonly used in major medical construction projects. The A111 is normally used for "fast track" or "phased" construction contracts. "phased" construction contracts are prevalent in hospital construction. According to Patricia Rodgers, President of Rodgers Builders, the contract between Palmetto and Rodgers is a "phased construction contract with a guaranteed maximum price of \$62,555,000.00."

Under a "phased" or "fast-track" contract, the design team releases the project design schematics in phases under an agreed upon time schedule. The benefit of a phased contract is that work can proceed while the architect is still in the design

phase. Therefore, the contract allows the design team to work slightly ahead of the contractors rather than wait sixteen months for the design team to plan an entire project before starting a two year construction process. Consequently, such a contract theoretically permits the contractor to complete the project early and to assist the design team in making decisions that will keep the project within budget.

*4 6. Since the project design schematics are released as the project progresses, phased construction contracts commonly utilize a guaranteed maximum price. The GMP protects the parties by setting an upper limit for construction costs even though the design specifications have not been released. However, Providence contends that the contract does not contain a definite price or a definite method for determining the GMP. In Article 5.2.1 of the A111 Form, the parties agreed as follows:

The sum of the Cost of the Work and the Contractor's Fee is guaranteed by the Contractor not to exceed (\$). This amount shall be established no later than six weeks after the completion of schematic documents and drawings. The project construction budget is \$62,555,000 and the GMP shall not exceed this amount. See Exhibit "A" for a description of the Construction Budget. If Contractor's proposed GMP based on schematic drawings is greater than the Construction Budget the owner shall either increase the Construction Budget or redesign the Project as required to meet the Construction Budget. All redesign costs shall be at Owner's expense, subject to additions and deductions by Change Order as provided in the Contract Documents. Such maximum sum is referred to in the Contract Documents as the Guaranteed Maximum Price. Costs which would cause the Guaranteed Maximum Price to be exceeded shall be paid by the Contractor without reimbursement by the Owner.

(emphasis in original) Additionally, Exhibit B to the A111 Form lists the items included in the General Conditions Costs. Exhibit B further sets forth a "qualification" to the General Conditions Costs as follows:

Should the total project duration extend beyond 35 months from the Date of Commencement April 3 2002, then the General Conditions shall be renegotiated to accommodate any increased costs to Contractor.

As set forth above, Article 5.2.1 of the A111 Form states that the final GMP will be "established no later than six weeks after the completion of schematic documents and drawings." However, that article further states that "[t]he project construction budget is \$62,555,000 and the GMP shall not exceed this amount." While the final GMP may be lower, the parties have agreed that the contractor's GMP cannot exceed \$62,555,000.00. If, upon completion of the schematics, the contractor's construction budget exceeds the GMP, then the owner must either increase the GMP or redesign the Project to keep it within budget.

Furthermore, under Article 5.2.1 of the contract, if the contractor through its own fault, incurs additional expenses or exceeds the 35-month schedule in completing the Project as designed, the contractor may not obtain reimbursement for more than the GMP. On the other hand, if the owner changes the Project from that described in the contract, the owner must bear any additional costs resulting from the design changes. Ms. Rodgers explained that Article 5.2.1 of the contract is not an "escape clause." Rather, it is applicable when an owner makes design changes outside of the scope of the work defined by the contract, and permits the contractor to seek reimbursement for additional costs resulting from those changes. Therefore, though Article 5.2.1 provides a mechanism for increasing the GMP should the scope of the Project change, this type of contract clause is usual and customary in the construction industry and in other long term service contracts.

*5.7 Article 4.1 of the A111 Form provides that the date of commencement of the Project was April 3, 2002.

8 The substantial completion date of the Project is established by Article 4.3 of the A111 Form. In the contract, the parties inserted the underlined portion:

The contractor shall achieve Substantial Completion of the entire Work not later than days from the date of commencement, or as follows, to be determined no later than at completion of schematic drawings.

Therefore, a date for substantial completion has not been set. However, for DHEC purposes, final completion, not substantial completion, is the end date of the contract so that Palmetto will have all of the Project costs in order to submit the audited cost

report. In that regard, Section 7.1 and Exhibit B of the A111 Form provides for a Project duration of 35 months or less.

9 As of May 5, 2002, the City of Columbia had not issued a building permit for the construction of the CON Project. However, Rodgers has obtained permits from the City of Columbia for the demolition of the existing Ambulatory Care Clinic and for the foundation of the Heart Center.

10 Therefore, I find that the contract has a start date of April 3, 2002 with the completion date being 35 months from the start date. Though it is subject to change, the price of the Project set forth in the contract is \$62,555,000.00.

Substantial Change

11 Between February 2002 and April 2002, Palmetto redesigned its Heart Center. The stated reasons for the new design were to provide additional parking to the Palmetto campus and to streamline the Heart Center to flow more efficiently. On April 9, 2002, Palmetto requested the Department's approval of the design changes to the Project. The proposed changes were as follows:

- The original CON was for 257,017 gross square feet, which included 29,296 gross square feet of physician office space, or 227,721 square feet of CON-reviewable space. The proposed design is 180,000 gross square feet of CON-reviewable space and does not include physician office space.

- The proposed design has roughly 10,000 square feet less public space and 14,000 square feet less shell space than that approved in the original CON.

- Rather than move the three existing cath labs to the Heart Center, the proposed design has a 24,000 square foot reduction of new cath lab space resulting from keeping the three existing cath labs in the main hospital. This will leave the cath labs adjacent to surgery suites and will benefit patients with complications who need to be transported quickly to surgery.

- The new fourth cath lab will be built in renovated space in the main hospital.

- The revised site plan of the Heart Center will remain in the northwest corner of the campus but will not require the relocation of the Family Practice Clinic, although the clinic is being

relocated in a separate project due to its own needs

After reviewing the proposed changes in light of the CON Act and the 2001 South Carolina Health Plan, the Department concluded the changes were not substantial under Sections 605 and 606 of Regulation 61-15. The Department, however, reserved the right to review any future changes.

*6 12. The revised plan structurally retained the original concept of two floors of 124 patient beds and added a below grade parking area.^[FN3] However, the revised plan eliminated conversion of all semi-private rooms to private rooms, eliminated conversion of medical surgical beds to ICU and CCU beds, and eliminated clinical centers on each floor of the Heart Center and the accompanying clinical support space. The elimination of these architectural components resulted in a reduction from approximately 247,000 square feet to 198,000 square feet. Additionally the physician offices that were originally in the new structure were removed from the plan. Palmetto decided to keep the three existing cath labs in their present location in the main hospital and to move the proposed fourth cath lab adjacent to them. The stated rationale for keeping the cath labs in their present location as well as placing an additional cath lab next to them was their proximity to existing surgery suites. These changes would make the Project more cost-effective, provide additional parking and enable Palmetto to stay within the budget originally proposed:

13 L.G. "Skip" Lewis, Jr., a licensed engineer in South Carolina with more than 35 years of experience in preparing plans and specifications, along with building, managing, and administering construction projects, testified on behalf of Providence. Based upon his examination of Palmetto's original CON application as well as Palmetto's proposed April 9, 2002 redesign, he found that the changes in the Project were "substantial" from both a construction and design standpoint. I agree with Mr. Lewis' assessment from a construction and design standpoint. Nevertheless, he did not testify that the design changes to the Project amounted to a substantial change under the CON Act.

14 Changes in projects are common. When changes

occur, the Department must determine whether changes are so substantial as to constitute a new project.^[FN4] Here, the changes may indeed result in an increase in the cost-per-square-foot-per-bed. At the time the CON is reviewed, that cost has been used as an indicator in determining whether those costs-per-bed and costs-per-square-foot are comparable with other types of projects the Department has reviewed. Nevertheless, in this case, the Project did not alter the scope of the CON as it was originally approved by the Department. The number of beds and the types of cardiac services being provided before and after the building reconfiguration were identical to what was originally approved. The relocated cardiac cath labs are providing the same services and the change of the physical location of the cath lab from that conceptually approved in the CON does not constitute a substantial change to the Project. Furthermore, though the design changes resulted in a modification of the building footprint and floor plan, the Heart Center is still located in basically the same place within the northwest corner of the Palmetto campus. Consequently, the change in the footprint of the building did not constitute a relocation of the Heart Center but rather a simple repositioning at the same location. Finally, the total Project cost projected by Palmetto for construction of this Heart Center did not increase as a result of the revised design. Therefore, I find that the changes to this Project were not substantial.

CONCLUSIONS OF LAW

*7 Based upon the foregoing Findings of Fact, I conclude the following as a matter of law:

1 The Division has jurisdiction to hear this matter. The ALJD has been statutorily authorized to preside over cases appealing the Department's decisions. See S.C. Code Ann. § 1-23-600(B) (1986 & Supp. 2001). The Administrative Procedures Act (APA) provides that all parties must be afforded an opportunity for a contested hearing after proper notice. S.C. Code Ann. § 1-23-320 (1986 & Supp. 2001). The APA defines a contested case as "a proceeding, including but not restricted to licensing, in which the legal rights, duties or privileges of a party are required by law to be determined by an agency after an opportunity for hearing." S.C. Code Ann. § 1-23-310(2) (1986 & Supp. 2001). Furthermore, a party is a person

named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party" S.C. Code Ann. § 1-23-310(5) (1986 & Supp. 2001)

The State Certificate on Need and Health Licensure Act, S.C. Code Ann. Section 44-7-110, et seq. (Supp. 2001), requires that a person or a health care facility obtain a CON from the Department prior to, *inter alia*, the construction or establishment of a new health care facility. 25 S.C. Code Ann. Regs. 61-72 § 201 (A) (Supp. 2001) provides that "[a]ny person may request an adjudicatory hearing following actual or constructive notice of a final staff decision on a licensing matter as defined above, or following receipt of an administrative order" (emphasis added). An Order is "[a] written document, other than a license, which embodies a final staff decision imposing sanctions or requirements. It may be, but need not be, denominated an 'Order.' It includes, but is not limited to, administrative orders so denominated, a staff decision to deny a license, or any decision from which appeal may be taken pursuant to other applicable law or regulation." 25 S.C. Code Ann. Regs. 61-72 § 101(I) (Supp. 2001).

The Department's April 9 letter(s) constitute an Order pursuant to Regulation 61-72 § 201 (A). Additionally, since Providence is an affected person under the CON Act, it had "legal rights, duties or privileges" conferred upon it pursuant to the Act. Those "legal rights" were affected by an Order (the April 9 letters) which entitled Providence to request administrative review of the Department's decisions under the APA. Moreover, the determination of whether or not an amendment to a CON is substantial involves a "licensing matter."

Furthermore, the conclusion that a case is not an APA "contested case" does not automatically negate the necessity for an administrative hearing. "[D]ue process is flexible and calls for such procedural protections as the particular situation demands." *Stono River Envtl. Protection Ass'n v. S.C. Dep't of Health and Envtl. Control*, 305 S.C. 90, 94-406 S.E.2d 340, 342 (1991). The South Carolina Constitution provides that:

*8 No person shall be finally bound by a judicial or quasi-judicial decision of an administrative agency affecting private rights except on due notice and an opportunity to be heard and he shall have in all such instances

the right to judicial review

S.C. Const., Art. I Section 22. In *Rossv Medical Univ. of South Carolina*, 328 S.C. 51, 492 S.E.2d 62 (1997), the Supreme Court held that although an adjudicatory hearing may not be required pursuant to the APA, the constitutional due process provision of Section 22, apart from the APA, is sufficient to require the right to notice and an opportunity to be heard by an administrative agency prior to a final determination that affects "private rights." Therefore, under certain circumstances, an administrative hearing may be mandated by Article I, Section 22 of the South Carolina Constitution, even where there is no statute or regulation providing for such a hearing.

2. The Administrative Law Judge is the fact finder in this matter for purposes of administrative and judicial review and does not sit in an appellate capacity. *Brown v. S.C. Dep't of Health and Envtl. Control*, 348 S.C. 507, 560 S.E.2d 410 (2002). Furthermore, the burden of proof in a contested case hearing is upon the moving party. S.C. Code Ann. § 44-7-210(5) (Supp. 2001). See also 2 Am. Jur. 2d Administrative Law § 360 (1994). *Alex Sanders, et al., South Carolina Trial Handbook § 9.3 Party With Burden Civil Cases* (1999) (In civil cases, generally the burden of proof rests upon the party who asserts the affirmative of an issue.) In the present case, the Petitioner has the burden of proving that DHEC erred in affirming that Palmetto had timely negotiated a valid construction contract for the Project and that the changes to Palmetto's CON Project did not constitute a substantial change contrary to the Act and CON regulations.

3. The purposes of the CON Act are "to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State." S.C. Code Ann. Section 44-7-120 (Supp. 2001). S.C. Code Ann. Section 44-7-140 designates the Department of Health and Environmental Control as the sole agency for control and administration of the granting of Certificates of Need and licensure of health facilities and other activities necessary to be carried out under the Act. Furthermore, S.C. Code Ann. § 44-7-150(3) (Supp. 2001) mandates that the Department shall adopt substantive and procedural

regulations considered necessary by the Department to carry out its duties under the CON Act.

4 An Administrative Law Judge's review of a DHEC administrative decision to grant a CON application is governed by S.C. Code Ann. § 44-7-210(E) (Supp. 2001) which provides, in pertinent part:

The department's proposed decision is not final until the completion of reconsideration or contested case proceedings. The contested case hearing before the board or its designee is conducted as a contested case under the Administrative Procedures Act. The issues considered at the contested case hearing are limited to those presented or considered during the staff review and decision process

*9 (emphasis added)

Construction of the Department's Regulations

5 It is appropriate to give due consideration to the Department's CON staff's utilization of its specialized knowledge and expertise in the application of the Act and CON regulations See S.C. Code Ann. § 1-23-330(4) (1986 & Supp. 2001)

However, the Department's Board, and not the Department's CON staff, is the policymaker for the Department and thus possesses the authority to establish its interpretation of its regulatory and statutory provisions. Consequently, I find that neither the construction of the Act and CON regulations regarding what constitutes a substantial change from the approved CON nor what is a valid contract for CON implementation purposes by individual members of the Department's staff is entitled to "most" respectful consideration.

6. "The cardinal rule of statutory construction is to ascertain and effectuate the intent of the legislature." *Hodges v. Rainey* 341 S.C. 79 85 533 S.E.2d 578, 581 (2000). The best evidence of legislative intent is the statute's actual language. *Id.* Therefore, where a statute's language is clear and unambiguous, conveying a clear and definite meaning, no other meaning may be imposed. *Id.* However, if a statute is ambiguous, courts must ascertain legislative intent through statutory construction. See *Abell v. Bell*, 229 S.C. 1, 91 S.E.2d 548 (1956). An ambiguity arises when the language of a statute is capable of being understood by reasonably well-informed persons in either of two or more

senses. *Southeastern Fire Ins. Co. v. South Carolina Tax Comm'n*, 253 S.C. 407, 171 S.E.2d 355 (1969)

Another cardinal rule of statutory construction is that the statutory provisions do not stand alone but must be read in the context of the Code as a whole. "A statute is passed as a whole and not in parts or sections and is animated by one general purpose and intent. Consequently each part or section should be construed in connection with every other part or section so as to produce a harmonious whole." *Sutherland, Statutory Construction*, 5th Ed., § 46.05 p. 103 (1992). See also *Keonig v. SC Dept. of Public Safety*, 325 S.C. 400, 480 S.E.2d 98 (Ct. App. 1996). Furthermore, the statutory language in question must also "be read in a sense which harmonizes with its subject matter and accords with its general purposes." *Hitachi Data Systems Corp. v. Leatherman*, 309 S.C. 174, 420 S.E.2d 843, 846 (citing *Multi-Cinema Ltd. v. SC Tax Comm'n*, 292 S.C. 411, 357 S.E.2d 6 (1987)).

Valid Contract for CON Purposes

7 The Petitioner contends that neither the price of construction nor time for completion of the Project are established in Palmotto's contract, and therefore, there is no valid contract. "Contract" is not defined in either the Act or the CON regulations. For purposes of Regulation 61-15 § 601 (1), the Department's staff has interpreted a "valid contract" to be one that is signed by the parties, describes the Project, has a beginning and ending date, and a GMP. I find that a "valid construction contract" is more aptly defined by case law and legal resources.

*10 A contract exists where there is an agreement between two or more persons upon sufficient consideration either to do or not to do a particular act. *Carolina Amusement Co. Inc. v. Connecticut Nat'l Life Insurance Co.*, 313 S.C. 215 437 S.E.2d 122 (Ct. App. 1993). Essential terms include price, time of performance, and place of performance. *McPeters vs. Yeargin Construction Co. Inc.*, 290 S.C. 327, 350 S.E.2d 208 (Ct. App. 1986). Furthermore, a "valid contract" is defined as "a contract that is fully operative in accordance with the parties' intent." *Black's Law Dictionary* 326 (7th ed. 1999). That definition recognizes the general principle of contracts that a contract is sufficiently definite and certain if a court using the proper rules of construction can ascertain the terms and

conditions on which the parties intended to be bound. *Am. Jur. 2d Contracts* § 197 (2000). Reasonable, not absolute, certainty as to its terms is required. A contract will not be held unenforceable for indefiniteness because its performance is, as to particular details, left open to subsequent agreement of the parties. *Apern v. of South Carolina, Roof, 290 S.C. 442, 447, 351 S.E.2d 171, 173 (Ct. App. 1986)* (citing *Touche Ross & Co. v. DASD Corp.*, 162 Ga. App. 438, 292 S.E.2d 84 (1982)). "This is especially true where the contract provides the guidelines for the subsequent agreement." *Apern* at 173.

Here, Palmetto and Rodgers executed a written contract agreeing, in part, to: 1) construct the Heart Center and 800-car parking garage; 2) using phased construction with the architect releasing the schematic, design and construction drawings to the contractor in phases so that construction can begin on the initial phases without waiting on the drawings for the entire Project to be completed, and 3) a fee of 2.3% of the cost of the work.

8. Providence contends that the contract is not valid because the A111 and A201 Forms do not establish a GMP, or any price, for which Rodgers has agreed to construct the Heart Center. The contract provides that if, after completion of the design and development documents, the GMP is set by Rodgers at an amount exceeding Palmetto's \$62,555,000.00 construction budget, Palmetto will either have to increase its construction budget to accommodate the GMP or downsize the Project. If it chooses to do neither, it may abandon the Project without further obligation. As of May 5, 2002, neither the schematic documents nor the design development documents had been completed, nor had a definite GMP been established.

If a contract does not set a definite price, it must fix a definite method for determining the price in order for it to be valid. *Prestwick Golf Club Inc. v. Prestwick Ltd. Partnership*, 331 S.C. 385, 503 S.E.2d 184 (Ct. App. 1998). Here, the beginning date of the contract was on April 3, 2002 and the ending date is 35 months from that date. The contract also clearly sets a fee for Rodgers at 2.3% of the cost of the work. Therefore, Rodgers has a contract that clearly pays it for the work it performs even if the contract is ultimately voided. Furthermore, if, after completion of design and

development documents, Rodgers can perform the contract for no more than \$62,555,000.00, the contract is clearly binding. These provisions of the contract therefore set a definite method for determining the price for the contract.

*11 Nevertheless, if Rodgers determines that the GMP will exceed \$62,555,000.00 and Palmetto will not either increase its construction budget or downsize the Project, the contract is voidable. However, there is a significant distinction between "void" and "voidable" contracts. "A void contract is no contract at all, it binds no one and is a mere nullity." *Am. Jur. 2d Contracts* § 7 (2000). On the other hand, a voidable contract is a contract:

where one or more parties have the power by a manifestation of election to do so, to avoid the legal relations created by the contract, or by ratification of the contract to extinguish the power of avoidance. Accordingly, a voidable contract is valid and binding until it is avoided by the party entitled to avoid it.

Id. Applying the above reasoning, the contract for the construction of Palmetto's Heart Center on its face has language that grants the parties the authority to void the contract under certain conditions. Nevertheless, that language does not result in a "void" contract, but simply a "voidable contract." The contract is nevertheless a binding and valid contract until a party exercises its right to void the contract under the terms allowing that right.

9. The Petitioner also argues that the "substantial completion" date in the A111 Form was expressly left to be determined at a later date by Palmetto and Rodgers. Contracts that do not set an express duration or definite time for performance are unenforceable by the courts. *Carolina Cable Network v. Alert Cable TV Inc.*, 316 S.C. 98, 447 S.E.2d 199 (1994). "duration" is defined as "[a] period of existence or persistence." *The American Heritage College Dictionary* 3rd Edition, p. 427 (1993). Accordingly, the duration of a contract is the time period it is in existence or its beginning and end. Therefore, Providence contends that since the "substantial completion" date is an essential term and is missing from the contract, the contract meets neither the requirements of basic contract law nor the express requirement of 24A S.C. Code Ann. Regs. 61-15 § 202(2)(d)(10) (Supp. 2001).

A valid construction contract for major additions to

an acute care hospital, such as the Palmetto CON, must be properly negotiated within one year from the date of issuance of the CON or such later time approved through extension of the CON by the Department or the Board pursuant to the provisions of Regulation 61-15 § 601. The Board granted Palmetto an extension until May 5, 2002 to negotiate a construction contract for the Heart Center. Regulation 61-15 § 202(2)(d)(10) requires an applicant to "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." On April 9, 2002, Palmetto advised the Department that it had entered into a valid contract for the construction of Palmetto's Heart Center.

*12 In the present case, the parties do not disagree on the terms of their agreement or in their interpretation of those terms. In fact, the parties concur that Article 71 and Exhibit B to the A111 Form establish a 35 month completion date. Though these two provisions deal with establishing the "Costs of the Works," the parties interpreted those provisions as establishing a definite time period for the completion of the Project.

"Moreover, this court must consider the contract in its entirety and employ a construction that gives effect 'to the whole instrument and to each of its various parts and provisions.'" *Hardeev Hardee*, 348 S.C. 84, 92, 558 S.E.2d 264, 267 (Ct. App. 2001) (quoting *Yarborough v. Phoenix Mut. Life Ins. Co.*, 266 S.C. 584, 592, 225 S.E.2d 344, 349 (1976)). The fact that the exact meaning of the contract language cannot be ascertained by the reading of the agreement does not render it unenforceable. *Am. Jur. 2d Contracts* § 197 (2000). Where the parties have reduced their agreement to writing and the words used by the parties to express their agreement are susceptible to more than one reasonable interpretation, the court will examine evidence extrinsic to the written agreement to discover the intent of the parties in an effort to ascertain which of the parties' interpretations should prevail. *Jordan v. Security Group Inc.*, 311 S.C. 227, 428 S.E.2d 705 (1993). "The intention of the parties should be determined from the surrounding circumstances, as well as from the testimony of all witnesses; and subsequent acts are relevant to show

whether a contract was intended." *Cauldery Knox*, 251 S.C. 337, 345, 162 S.E.2d 262, 266 (1968).

Though the contract does not set forth a date for substantial completion, it does set forth a construction time period starting on April 3, 2002 and ending after 35 months. I do not find that a "substantial completion" date is an essential term of a contract. Rather, "substantial completion" is a term of convenience for the parties in seeking a date when the building may be occupied. Here, even though the 35-month term of construction is set forth in an unusual section of the contract, the parties interpret that term as the binding construction time period of the contract. Consequently, since Palmetto timely implemented the Heart Center Project by executing a valid construction contract with Rodgers Builders, I find that Palmetto complied with the provisions of Sections 202(2)(d)(10) and 601.

Substantial Change

10 Providence contends that the changes to the Heart Center as presented to the Department on April 9, 2002 by Palmetto are substantial and, therefore, the Department erred in not determining that the changes constituted a new Project requiring further CON approval. 24A S.C. Code Ann. Regs. 61-15 § 605 (Supp. 2001) provides "[i]f an applicant amends or alters his project after receipt of a Certificate of Need, the department will decide whether or not the amendment is substantial and thereby constitutes a new project." (emphasis added). Therefore, in analyzing whether a substantial change has occurred, the court must first determine the nature of the Project. S.C. Code Ann. § 44-7-230(A) (Supp. 2001) provides that the CON "is valid only for the project described in the application including location, beds and services to be offered, physical plant, capital or operating costs, or other factors as set forth in the application except as may be modified in accordance with regulations." See also Regulation 61-15 § 605. The legislative purpose of the Act is that a CON sets the upper limit of a project based upon the number of beds, the addition of health services regulated by the applicable State Health Plan, the square footage of new construction and the maximum estimated total project cost.

*13 In awarding the CON for the Heart Center, the

Department determined that the Heart Center would provide increased access to cardiovascular services in the ten county Midlands Area and the Project had physician and community support. The Department also necessarily determined that the Heart Center would not be an unnecessary duplication or have a negative effect upon the existing cardiovascular services at Providence. The Department's historic application of the law has been to define the "project" to encompass the location, number of beds, types of health services covered by the applicable State Health Plan, maximum square footage approved and total project costs of a proposed new health service or facility.

I find that in determining whether or not changes to an approved project are substantial the Administrative Law Judge should consider:

- a. Whether the total project cost has increased,
- b. Whether there is an increase in the number of beds,
- c. whether additional services for which criteria are proscribed in the State Health Plan have been added to the project;
- d. Whether there has been an increase in square footage of the project; and
- e. Whether there is a change in the location of the project so as to impact the Department's assessment of the area being served by the project and any negative effects of affected persons.

Here, though the cost-per-square-foot may have increased, the total Project cost and the number of beds has not increased. Furthermore, considering the Findings of Fact set forth above, the changes in design, space allocation, and repositioning of the Heart Center do not constitute a substantial change.

Moreover, the downsizing of the Project did not alter its character or essential services upon which the original CON was based. Therefore, I find that Providence has not proven that there has been a substantial change within the meaning of 24A S.C. Code Ann. Regs. 61-15 § 605 (Supp. 2001).

Building Permit

11 The Petitioner contends that on the May 5 2002 CON expiration date, Palmetto had not obtained a building permit for the CON Project, and the Department had not given Rodgers notice to proceed with the construction. Hence, Palmetto's Heart Center Project had not been implemented

and, thus, the CON expired by its terms on May 5 2002. 24A S.C. Code Ann. Regs. 61-15 § 202 (7) (Supp. 2001) requires that a CON application "[p]rovide a date that all necessary permits (grading, building, sewer, etc.) will be obtained." The Department determined on April 9 2002 that the building permit provided by Palmetto complied with its approved application.

At the time that DHEC determined to issue the CON for Palmetto's Heart Center, ALJD Rule 11 stated: "The request for a contested case hearing shall be filed with the affected agency within the time frame authorized by that agency." ALJD Rule 11 (2000).^[FNS] S.C. Code Ann. § 44-7-210(D) (Supp. 2001) provides that a decision of the Department's staff concerning a CON becomes final unless:

- *14 (1) a reconsideration by the staff of the department is requested in writing within the ten-day period by an affected person showing good cause for reconsideration of the proposed decision, or
- (2) a contested case hearing before the board, or its designee, regarding the grant or denial of the Certificate of Need is requested in writing within the ten-day period by the applicant or other affected person with standing to contest the grant or denial of the application.

Therefore, Providence was required to appeal the granting of the CON within ten (10) days of the Department's determination of whether or not to grant the CON if Providence objected to the language of the approved application. Accordingly, I find that since the Petitioner did not seek a contested case within those time limits, that issue is moot.

More importantly, upon the granting of the CON, the Department is the agency charged with the enforcement of the permit. In that regard, once a CON has been issued, it is the duty and responsibility of the Department to ensure that the permittee adheres to the provisions of the CON Act, and to bring an enforcement action if necessary. See S.C. Code Ann. § 44-7-140 (Supp. 2001). This Division does not have jurisdiction to oversee the Department's ministerial responsibility of insuring that the necessary permits are obtained.

Lifting of Stay

2002 WL 31423801 (S.C. Admin. Law Judge Div.)

Page 11

12. On May 30, 2002, I imposed a stay on the construction of the Heart Center Building, therapeutic cardiac cath lab, and any portion of the parking garage structure which may be subsequently utilized for patient and administrative offices. Having determined that the Decisions were properly made by the Department, I find that the stay should be lifted.

CON ALJD Rule 11 has subsequently been amended twice. The most recent amendment to Rule 11 was effective May 6, 2002. See ALJD Rule 11 (2002).

2002 WL 31423801 (S.C. Admin. Law Judge Div.)
END OF DOCUMENT

ORDER

IT IS HEREBY ORDERED that DHEC's decisions that Palmetto had timely implemented its CON and that Palmetto's modifications were not substantial are affirmed.

IT IS FURTHER ORDERED that the Stay issued May 30, 2002 is lifted.

AND IT IS SO ORDERED

Ralph King Anderson, III
Administrative Law Judge

FN1 Palmetto's proposed Heart Center is an expansion of an existing "health care facility" as defined in S.C. Code Ann. Section 44-7-130(10) (Supp. 2001) and therefore required CON approval.

FN2 For purposes of Regulation 61-15, the Department's staff considers a construction contract to be valid if it describes the Project, is signed by both parties, has a commencement date, has a guaranteed maximum price, and has a projected completion date.

FN3 A below-grade parking garage is a nonmedical project and is therefore exempt from CON review in accordance with S. C. Code Ann. § 44-7-170(B)(1) (Supp. 2001).

FN4 "If an applicant amends or alters his project after receipt of a Certificate of Need, the department will decide whether or not the amendment is substantial and thereby constitutes a new project." 24A S.C. Code Ann. Regs. 61-15 § 605 (Supp. 2001).

FN5 This is the language of Rule 11 that was in effect when DHEC originally granted Palmetto's

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1 STATE OF SOUTH CAROLINA
 2 ADMINISTRATIVE LAW COURT DIVISION
 3 Docket No 07-ALJ-07-0389-CC
 4
 5 MRI at Belfair LLC)
 6)
 7 Petitioner)
 8)
 9 v)
 10)
 11 South Carolina Department of)
 12 Health and Environmental Control)
 13 and Coastal Carolina Medical Center)
 14)
 15 Respondents)
 16)
 17)
 18)
 19)
 20)
 21)
 22)
 23)
 24)
 25)

ADMINISTRATIVE HEARING

Tuesday August 4 2009
 10 07 a m - 3:48 p.m.
 and
 Wednesday August 5 2009
 10 00 a m - 12 10 p m

The hearing before the Honorable Ralph King
 Anderson III was taken at the Edgar A Brown
 Building 1205 Pendleton Street Suite 224 Columbia
 South Carolina, on the 4th and 5th days of August
 2009 before Christine A Cortright Court Reporter
 and Notary Public in and for the State of South
 Carolina

1 JOEL GRICE
 2 MS BIGGERS DIRECT EXAMINATION 169
 3 MS GILLESPIE CROSS EXAMINATION 180
 4 MR PRINGLE CROSS EXAMINATION 188
 5 MS GILLESPIE RE-CROSS EXAMINATION 214
 6 TORI TIBBRAWAY:
 7 MS BIGGERS DIRECT EXAMINATION 218
 8 MS GILLESPIE CROSS EXAMINATION 228
 9 MR BEACH CROSS EXAMINATION 242
 10 MS GILLESPIE RE-CROSS EXAMINATION 264
 11 ALBERT J BORELLI JR M D
 12 MR PRINGLE DIRECT REPLY EXAMINATION 266
 13 MR DAYHUFF VOIR DIRE 270
 14 MR PRINGLE DIRECT REPLY EXAMINATION (CONT) 276
 15 MR DAYHUFF CROSS REPLY EXAMINATION 286
 16 MR PRINGLE RE-DIRECT REPLY EXAMINATION 294
 17 MR DAYHUFF RE-CROSS REPLY EXAMINATION 297
 18 CLOSING ARGUMENTS
 19 MR DAYHUFF 298
 20 MS BIGGERS 304
 21 MR PRINGLE 305
 22 Certificate 316
 23
 24 EXHIBITS
 25 (Petitioner Coastal Carolina Medical Center s Exhibit
 Numbers One through Six were admitted into evidence
 and are retained by the Administrative Law Court)
 (Respondent DHEC s Exhibit Number One was admitted
 into evidence and is retained by the Administrative
 Law Court)
 (Respondent s Exhibit Numbers One through Twenty-
 Five with the exception of Exhibit Number Thirteen
 were admitted into evidence and are retained by the
 Administrative Law Court)
 STIPULATIONS
 It is stipulated and agreed that this hearing
 is being taken pursuant to the rules of the
 Administrative Law Court and the South Carolina Rules
 of Civil Procedure

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8/4/2009 Administration Hearing

8/4/2009 Administration Hearing

1 APPEARANCES
 2 John J Pringle Jr Esquire
 3 John F Beach, Esquire
 4 ELLIS LAWYERS & SONS
 5 1501 Main Street 5th Floor
 6 Columbia South Carolina 29201
 7 Attorneys for the Petitioner
 8
 9 Ashley C Biggers Esquire
 10 SC DHEC
 11 2600 Bull Street
 12 Columbia South Carolina 29201
 13 Attorney for Respondent SC DHEC
 14
 15 Travis X Dayhuff Esquire
 16 Holly G Gillespie Esquire
 17 NELSON MULLINS RILEY & SCARBOROUGH
 18 1320 Main Street 17th Floor
 19 Columbia South Carolina 29201
 20 Attorneys for the Respondent Coastal Carolina
 21 Medical Center
 22
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1 THE COURT This is a hearing in the matter of MRI
 2 at Belfair LLC, Petitioner versus South
 3 Carolina Department of Health and Environmental
 4 Control and Coastal Carolina Medical Center
 5 Respondents The docket number is 07-ALJ-07-
 6 0389-CC That s the only docket number isn t
 7 it? There s no other docket number is it?
 8 MR DAYHUFF The other was dismissed, Your Honor
 9 THE COURT All right
 10 MR DAYHUFF Your Honor at this time we d like to
 11 move the admission of all the parties exhibits
 12 into evidence by agreement We provided
 13 notebooks to you
 14 THE COURT: Those exhibits are the numbers?
 15 MR DAYHUFF: Those exhibits are the numbers
 16 THE COURT: No
 17 MR DAYHUFF: No sorry
 18 THE COURT: Petitioner s One through what
 19 MR DAYHUFF: Oh good yes Coastal s Exhibits
 20 Respondent, would be One through Twenty-five
 21 And we want to exclude our Exhibit Thirteen
 22 from that list that s admitted into evidence at
 23 the request of Belfair We re not going to
 24 admit Thirteen into evidence.
 25 THE COURT All right One through

EXHIBIT

B

1 Q: Did you hear her talk about an email that you
2 sent to her regarding --
3 A I did
4 Q: -- your opinion? Could you pull that up
5 please? This is Petitioner's Exhibit Number
6 Eight
7 A Okay
8 Q This is the paragraph that Ms. Platt referenced
9 where you sent her your opinion. Could you
10 just look that over just for a minute --
11 A Okay
12 Q -- and then I'll ask you some questions
13 A: All right. Okay
14 Q: Okay. Do you still agree with -- first
15 summarize your opinion here in this. What were
16 you telling her?
17 A. Well, you know, I try -- I'll tell you, working
18 with the Department, we always get lots of
19 emails, you want to be sure that in an answer
20 and I would have never dreamed that we would be
21 looking at this email two years later, but I
22 would -- I always wanted to make it to try to
23 cover everything, cover all bases. And she was
24 really focusing kind of on change of site, but
25 I tried to include everything because you

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1 a project that was approved with an in-house
2 MRI that was inside the hospital and the change
3 would be that that unit would be located
4 adjacent to the hospital with a covered
5 walkway, but the same equipment accessibility
6 the same, it's right there at the hospital and
7 the cost was much less where we didn't even
8 have to worry about exceeding 10% of the
9 original approval.
10 Q Okay. So in this email, you're looking at
11 specific -- you referenced project review
12 criteria.
13 A: That's right.
14 Q: And you say that you would look at the proposed
15 project and then the actual project to make
16 sure that the actual project still meets the
17 project review criteria, is that an accurate --
18 A That -- yes, ma'am, that is correct. In other
19 words, want to make sure because this is like
20 I mentioned, the email is trying to answer
21 something that was -- it was brought and not
22 knowing specifically what it would be, but yes,
23 to go back and look and make sure that there
24 would in no way would there be a substantial
25 change in relation to what issues and criteria

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1 really -- it was a hypothetical question. So
2 what we're really saying here is that the
3 issues we'd have to look at involving the
4 impact of a site change, you know, it covers a
5 lot, it could be community need, documentation,
6 accessibility, projected expenses, financial
7 feasibility, cost containment, all of this.
8 And I also went on, you know, like adverse
9 effect on other facilities, zoning, utilities,
10 etcetera. A lot of times, a change in a
11 project, particularly with a site, if we talked
12 about, say, a brand new facility, locating, say,
13 rather than Bluffton, say, the town of Beaufort,
14 or something like that, you know, you have to
15 really look at that because in the original COM
16 review, you had affected people, maybe
17 commenting from the community where the
18 facility is located. So I tried to cover
19 everything here. And I also mentioned that
20 you know, our policy at the Department was that
21 that total project cost, you know, could not be
22 exceeded by more than 10%. So this was kind of
23 tried to cover everything, but I think it -- I
24 agree with this and it does cover. I think, the
25 project we're talking about today where we had

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1 the Department used in making its original
2 decision.
3 Q Mr. Fringle brought up, I think, when he was
4 questioning Ms. Platt, that when she asked you
5 this question, she was asking you about a change
6 in location. Would this analysis apply equally
7 to an MRI project?
8 A: In my opinion, yes, it applies. I tried --
9 even though I realized she was kind of focusing
10 on change of site, I tried to make this where
11 it covered just about anything because a lot of
12 times, applicants can't be too specific. When
13 they're writing, they ask a generic question.
14 We want to be sure we cover as much as we can
15 so that there's no misunderstanding in the
16 future. So yes, I mean, I -- to me, this
17 applies to almost anything that would be --
18 that would relate to a substantial change in a
19 project.
20 Q Okay. And when you were talking to Ms.
21 Biggers, you said that in analyzing, if an
22 applicant proposes to purchase one MRI unit but
23 they submit a request to purchase a different
24 MRI unit, the thing that the Department
25 considers is the Tesla strength, is that

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1 A Numerous I don't know that I could put a
2 number on it but
3 Q Okay So it's fair to say you have experience
4 in reviewing and making these substantial
5 change determinations?
6 A Yes
7 Q Okay
8 MS GILLESPIE: Could you pull up 6115 please?
9 Q I think Ms. Biggers already went through this
10 with you but Okay Is this the portion of
11 the regulation that you -- that is at issue
12 when you're making substantial change
13 determinations?
14 A: Yes
15 Q: Okay And how much guidance does this
16 regulation give you in determining what
17 constitutes a substantial change?
18 A This is about as far as it as the regulation
19 goes with it
20 Q: Okay So would you agree that DHEC has a great
21 deal of discretion in determining what
22 constitutes a substantial change?
23 A: Yes
24 Q: And do you see anything in this regulation that
25 outlines what an applicant should provide to

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1 planning standpoint
2 Q Okay How does the project review criteria
3 that is identified as being important in the
4 original COM application factor into your
5 substantial change determination?
6 A: They would still be relevant We're looking to
7 see that the changes that are being made to the
8 project don't affect the initial criteria that
9 were deemed to be important at the time of
10 review
11 Q: So with the changes does the applicant still
12 have to meet the same project review criteria
13 they did in the original application?
14 A Yes
15 Q Okay And listening to you go over the letter
16 -- could you pull up the letter 896 and 897?
17 This is Respondent Coastal's Exhibit One Bates
18 number 896 and 897 If you'll pull up the
19 second page Dan You went through the changes
20 with Ms. Biggers that Coastal requested to make
21 to their project and I think the three changes
22 I heard you say were location, cost and
23 machine?
24 A: Yes
25 Q: Is that accurate?

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1 DHEC in requesting whether a change is
2 substantial or not?
3 A No
4 Q: So it's left up to the Department and the
5 applicant to decide what is enough information
6 to determine whether a change --
7 A What is relevant to that particular project
8 yes
9 Q Okay And would you say that in reviewing a
10 project to determine whether changes are
11 substantial or not you view that from a health
12 planning perspective or a clinical perspective?
13 A A health planning perspective
14 Q: Okay And do you make any clinical
15 determinations when you're reviewing changes
16 as to whether they're substantial?
17 A: No
18 Q: And why is that?
19 A. Because my background and what I've been tasked
20 to do throughout my seven and a half years at
21 DHEC both as a COM reviewer and in making
22 these types of determinations has been based
23 on health planning issues not clinical issues
24 There would certainly be a clinical factor to
25 that but as a whole it's from a health

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1 A. Uh-huh (affirmative response)
2 Q: What project review criteria would location
3 relate to?
4 A I'm going to need to go back and -- is it okay
5 if I look through this file?
6 Q Sure Yes
7 A And are you asking me in relation to the
8 initial review of the COM or in general what
9 project -
10 Q: Their original COM
11 A Okay Accessibility
12 Q Okay And was accessibility identified as one
13 of the project review criteria in the original
14 COM?
15 A Yes
16 Q Okay
17 A It was one of the first
18 Q: So after analyzing the change in location that
19 Coastal planned to make would Coastal's
20 project still meet the accessibility project
21 review criteria that they did in the original
22 application?
23 A. Yes
24 Q Okay I heard you say cost was one of the
25 changes that they proposed to make What

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1 project review criteria does cost relate to?
 2 A: Cost containment
 3 Q: Okay And after the changes that Coastal
 4 planned to make would Coastal's project still
 5 meet the cost containment project review
 6 criteria?
 7 A: Even more so yes
 8 Q: Okay And why even more so?
 9 A: Because the amended project was substantially
 10 lower in cost than the initial project
 11 Q: Okay And the third change I heard you say was
 12 a different MRI unit What project review
 13 criteria would that relate to?
 14 A: It would -- well acceptability but it
 15 wouldn't necessarily relate to a specific
 16 criteria The point of it being that it is
 17 substantially the same unit that we approved in
 18 the initial application
 19 Q: Okay And after looking at the new unit that
 20 Coastal planned to implement did you determine
 21 that it was substantially the same unit that
 22 they proposed in their original application?
 23 A: Yes
 24 Q: Okay There are other project review criteria
 25 that were identified as important need,

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1 your analysis?
 2 A: The letters that were sent with the initial
 3 Certificate of Need application certainly
 4 covered what was being proposed because as I
 5 said, the project was not substantially
 6 changing The support for the original project
 7 served as support for the amended project
 8 Q: And do you typically see letters of support
 9 submitted with substantial change requests?
 10 A: I've never seen a letter of support submitted
 11 with a substantial change request
 12 Q: Okay How about financial feasibility? Did
 13 you consider financial feasibility in
 14 determining whether the changes were
 15 substantial and whether we still met that
 16 criteria?
 17 A: Yes Clearly if -- clearly if the initial
 18 project was financially feasible this project
 19 was -- the amended project was going to be
 20 financially feasible because the cost was
 21 greatly reduced
 22 Q: Okay And how about the final one adverse
 23 impact Did you consider adverse impact in
 24 your analysis?
 25 A: Yes and no for the same reasons that the

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1 acceptability; things that weren't identified
 2 as important but financial feasibility
 3 adverse impact Did you consider any of those
 4 project review criteria in your analysis?
 5 A: Yes
 6 Q: You did And can you tell me about your
 7 analysis of those project review criteria?
 8 A: Specifically financial feasibility?
 9 Q: Well you can start with need, did you consider
 10 need in determining --
 11 A: Yes Need had been demonstrated in the
 12 Certificate of Need application It was
 13 determined to be a relevant factor in approving
 14 that application And the project didn't
 15 change as a result of these changes -- of the
 16 proposed amendment, the need was still there
 17 and it was still being accomplished with the
 18 1.5T MRI unit located at the hospital
 19 Q: Okay So would you -- in your opinion was
 20 need still met in the proposed changes as it
 21 was in the original project?
 22 A: Yes
 23 Q: Okay And acceptability I didn't see any
 24 letters of support with our request for
 25 changes Did you consider acceptability in

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1 project was not substantially changing If
 2 adverse impact was not an issue to start with
 3 in the original CON application it wouldn't be
 4 an issue here simply because the project is
 5 substantially the same
 6 Q: Okay So in your opinion did the changes
 7 that Coastal proposed to make in the new
 8 project did they still meet all of the same
 9 project review criteria that we just went
 10 through as they did in the original CON
 11 application?
 12 A: Yes
 13 Q: And do you still agree with that opinion --
 14 A: Yes
 15 Q: -- today? Okay Let's look again at this
 16 letter Actually we went through the three
 17 changes we just went through them, location
 18 cost and the unit Do you see any other
 19 changes that Coastal proposed to make in this
 20 letter?
 21 A: If you don't mind, I am going to flip back to
 22 this letter in the book because I have a hard
 23 time reading on the screen
 24 Q: Sure It's Bates 896 and 897
 25 A: Okay I believe that the three factors you

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1 in Mr. Summer's --
 2 A: They would have to go through CON review
 3 Q: Okay. Mr. Summer's June 12, 2007 letter then
 4 they would have to go -- it would be treated as
 5 a new project and they'd have to go through a
 6 new CON?
 7 A: Correct.
 8 Q: So if you determined that it was a substantial
 9 change, the amended project could still receive
 10 the CON if it goes through that process, am I
 11 correct?
 12 A: Yes.
 13 Q: Okay. Dependent upon whether it meets --
 14 A: Certain review criteria.
 15 Q: Okay. Thank you. Let's look at a statute that
 16 we haven't spent much time on over the last day
 17 and a half. It's 44-7-230(A), and I have it up
 18 on the screen right now. And you can
 19 familiarize yourself with it.
 20 A: Okay.
 21 Q: Okay. Thank you. Are you familiar with this
 22 statute?
 23 A: Yes.
 24 Q: Okay. If you would please, just read the first
 25 sentence into the record.

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8/4/2008 Administration Hearing

1 A: "The Certificate of Need, if issued, is valid
 2 only for the project described in the
 3 application, including location, beds and
 4 services to be offered, physical plant, capital
 5 or operating costs or other factors as set
 6 forth in the application, except as may be
 7 modified in accordance with the regulations."
 8 Q: Okay. Great. Now, from the Department's
 9 perspective, what is the purpose of that part
 10 of section A?
 11 A: To clarify or specify that the CON is only
 12 valid for the project that was reviewed, and
 13 that substantial changes to the project would
 14 invalidate the Certificate of Need.
 15 Q: Okay. So based on that, does the Department
 16 rely on that language in order to carry out
 17 Regulation 61.15, Section 603?
 18 A: Yes.
 19 Q: Okay. And would you agree that many of the
 20 factors that you look at in determining whether
 21 a project amendment is a substantial change or
 22 in executing 605 are actually set forth in
 23 section A?
 24 A: Yes.
 25 Q: Okay. And those factors are location, beds, and

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1 services to be offered, physical plant, capital
 2 or operating costs, and other factors as set
 3 forth in the application.
 4 A: Yes.
 5 Q: If you would, let's take a look at the work
 6 location there. Now, in reviewing CONs, and
 7 I'm going to call it a substantial change
 8 request, if that's all right with you, just
 9 because it's easy for me to refer to it as
 10 that, did you review the location within or
 11 outside of the hospital of the originally
 12 proposed in-house MRI suite?
 13 A: Yes.
 14 Q: Okay. And where was it to be located?
 15 A: The initial unit was to be in an addition that
 16 was to be constructed on one side of the
 17 hospital. I believe it's the opposite side of
 18 the hospital from which the mobile unit ended
 19 up being located.
 20 Q: Okay. And just to be clear, I think it was
 21 adjacent to the emergency room?
 22 A: Yeah.
 23 Q: All right. Now, in reviewing CONs
 24 substantial change requests, did you also review
 25 the location for the proposed modular or mobile

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8/4/2008 Administration Hearing

1 MRI unit?
 2 A: Yes.
 3 Q: Okay. And that was actually one of the
 4 questions that you asked Mr. Summer in your
 5 June 21, 2007 letter to him, correct, to --
 6 A: Yes.
 7 Q: -- clarify the location issue? All right.
 8 Now, would you agree with me that the
 9 Department considers that term, location, as it
 10 is used here, to include patient access?
 11 A: Yes, it can include location -- I mean, patient
 12 access.
 13 Q: Patient access to the unit?
 14 A: Yes.
 15 Q: Okay. So in reviewing this CON's substantial
 16 change request, did your department consider
 17 how the proposed -- I have a hard time not
 18 saying mobile unit, but I'm not trying to make
 19 it sound like anything other than just what I
 20 know it as.
 21 A: Sure.
 22 Q: But the unit, the proposed unit, changed the
 23 patient access that CON's original in-house
 24 MRI suite would have provided? In other words,
 25 did you look at the question or consider how --

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**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

MRI at Belfair, LLC,	)	Docket No 07-ALJ-07-0389-CC
	)	
Petitioner,	)	
	)	
vs	)	SCDHEC'S MEMORANDUM IN OPPOSITION TO PETITIONER'S MOTION FOR RECONSIDERATION
	)	
South Carolina Department of Health and Environmental Control and Coastal Carolina Medical Center,	)	
	)	
Respondents	)	
	)	

Respondent South Carolina Department of Health and Environmental Control ("DHEC" or "Department") respectfully submits this Memorandum in Opposition to Petitioner's Motion for Reconsideration

In its Motion for Reconsideration, Petitioner MRI at Belfair, LLC ("Belfair") argues that the Court applied an incorrect standard for determining whether or not Respondent Coastal Carolina Medical Center ("CCMC") substantially changed its MRI project. Belfair contends that the Court should have applied the factors set forth in S C Code Ann. § 44-7-230(A), rather than the project review criteria found in 24A S C Code Ann Regs 61-15 § 802 For the following reasons, Belfair's argument lacks merit

**I THE COURT PROPERLY CONSIDERED WHETHER OR NOT CCMC'S
IMPLEMENTED PROJECT MET APPLICABLE REVIEW CRITERIA IN
SUBSTANTIALLY THE SAME WAY AS ITS ORIGINALLY APPROVED
PROJECT DID**

Belfair contends that it is improper to consider the project review criteria set forth in 24A S C Code Ann Regs 61-15 § 802 in the substantial change analysis, as the project review criteria are only relevant if the change results in a new project requiring a new CON review

Such an argument overlooks the way in which the Court analyzed the project review criteria, however

The following project review criteria were relevant in reviewing CCMC's initial CON application (1) need, (2) accessibility/distribution, (3) cost containment, (4) acceptability, (5) financial feasibility, and (6) adverse impact. 24A S C Code Ann Regs. 61-15 § 802 CCMC's original project met those criteria, and the project was approved

If the change to CCMC's project had been substantial, it would have been considered a new project and would have required a new CON review. During that new CON review, the Department would once again consider whether or not the project met those review criteria. In those circumstances, the project review criteria would be relevant to determine whether or not the new project could be approved for a CON.

In the case of a substantial change review, however, the issue is not whether or not the project, as amended, meets the relevant project review criteria and can be approved for a CON. Rather, the issue is whether the amended project meets those same project review criteria it originally met in substantially the same way.

In its Final Order and Decision, the Court analyzed CCMC's project's compliance with the above-listed project review criteria, both as originally approved and as amended. (Order pp. 6-7) It found no substantial changes between the two. The Court concluded that "[t]he amended MRI project satisfies need, accessibility/distribution, acceptability, cost containment, financial feasibility, and adverse impact in substantially the same way that the original project satisfied these criteria." (Order p. 9) (Emphasis added). That finding supported the Court's ultimate conclusion that the changes to the project were not substantial changes.

The regulatory provision regarding substantial change to a CON project does not specify how a substantial change analysis shall be conducted. It states only that “[i]f an applicant amends or alters his project after receipt of a CON, the Department will decide whether or not the amendment is substantial and thereby constitutes a new project.” 24A S C Code Ann Regs 61-15 § 605 (Supp 2008) There is no mandatory requirement that the Department or the Court apply S C Code Ann § 44-7-230(A), nor is there a prohibition from considering project review criteria Belfair is therefore incorrect in arguing that consideration of the project review criteria in this instance constitutes a legal error

The Court s analysis of the project review criteria was relevant to the issue of the case It did not violate any statutory or regulatory provision It was therefore proper, and there is no error

II. THE COURT PROPERLY CONSIDERED ADDITIONAL FACTORS BEYOND THE PROJECT REVIEW CRITERIA, INCLUDING CLINICAL AND OPERATIONAL ISSUES, IN FINDING THAT THERE ARE NO SUBSTANTIAL CHANGES TO THE MRI PROJECT

The project review criteria analysis was not the only analysis conducted by the Court in determining whether or not CCMC’s project changes were substantial The Court also compared the operational functions of the MRI as originally proposed with the operational functions of the implemented MRI After weighing the evidence submitted by both sides, it found that there are no substantial clinical or operational differences between the original project and the amended project. (Order pp 4-6, 9) The Court concluded that “the MRI will operate in substantially the same manner, provide substantially the same services, and serve substantially the same patients ” (Order p 9)

The statute that Belfair argues should control the substantial change analysis, Section 44-7-230(A), provides that “[t]he [CON], if issued, is valid only for the project described in the application including location, beds and services to be offered, physical plant, capital or

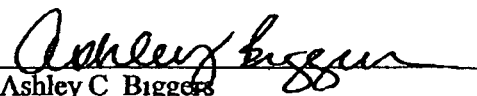
operating costs, or other factors as set forth in the application, except as may be modified in accordance with regulations ” S C Code Ann. § 44-7-230(A) (2002) Belfair seeks application of that statute, but fails to demonstrate how its application would change the result of the case

The Court analyzed the differences in the location of the MRI as set forth in the original application and as implemented, and found that the MRI is still “built to be an integral part of the hospital” as originally planned. (Order pp 3-4) The Court considered cost issues as part of its analysis of the cost containment and financial feasibility project review criteria, and found the project as amended to be more financially feasible and to better contain costs (Order p 6) And as part of its overall analysis of the clinical and operational issues raised by Belfair at the hearing, including differences in maximum gradient amplitude, monitoring equipment, “Code Blue” procedures, and patient access to the unit itself, the Court took into consideration any differences in the services to be offered, the physical plant, and other factors set forth in the application (Order pp 4-6)

The Court’s analysis as described above covers the factors listed in Section 44-7-230(A) that are relevant to the MRI project, and it takes into consideration the differences in the project which Belfair challenged at the hearing Belfair s argument that an application of the Section 44-7-230(A) factors would result in a different ruling by the Court therefore fails

For the foregoing reasons, Petitioner’s Motion for Reconsideration should be denied.

Respectfully submitted,


Ashley C. Biggers
Staff Attorney, SCDHEC
2600 Bull Street
Columbia, South Carolina 29201

November 18, 2009

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THE STATE OF SOUTH CAROLINA
In the Court of Appeals

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APPEAL FROM ADMINISTRATIVE LAW COURT

Ralph King Anderson, III, Administrative Law Judge

Case No 2007-ALJ-07-0389-CC

South Carolina Department of Health and Environmental Control and
Coastal Carolina Medical Center,

Respondents,

v

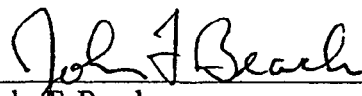
MRI at Belfair, LLC,

Appellant

NOTICE OF APPEAL

MRI at Belfair, LLC appeals the Amended Final Order and Decision of the
Honorable Ralph King Anderson, III dated November 24, 2009 Appellant received
written notice of entry of this order on November 25, 2009

December 23, 2009


John F. Beach
John J. Pringle, Jr
ELLIS, LAWHORNE & SIMS, P A
1501 Main Street, 5th Floor (29201)
Post Office Box 2285
Columbia, South Carolina 29202
Telephone (803) 343-1269
Facsimile (803) 799-8479
Attorneys for Appellant

Other Counsel of Record

Travis Dayhuff, Esquire
Holly G Gillespie, Esquire
Nelson Mullins Riley & Scarborough LLP
1320 Main Street, 17th Floor
Columbia, SC 29201
(803) 799-2000

Ashley C Biggers, Esquire
SCDHEC
Office of General Counsel
2600 Bull Street, 3rd Floor
Columbia SC 29201
(803) 898-3350
Attorneys for Respondents

RECEIVED

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

NOV 25 2009

Ellis, Lawhorne
& Sime, PA

MRI at Belfair LLC

Petitioner,

vs

South Carolina Department of Health
and Environmental Control and Coastal
Carolina Medical Center,

Respondents

Docket No 07-ALJ-07-0389-CC

AMENDED FINAL ORDER
AND DECISION

APPEARANCES John J Pringle, Jr, Esquire and John F Beach, Esquire, for MRI at Belfair LLC,
Travis Dayhuff, Esquire and Holly G Gillespie, Esquire, for Coastal Carolina Medical Center,
Ashley C Biggers, Esquire, for South Carolina Department of Health and Environmental Control

STATEMENT OF THE CASE

This matter comes before the Administrative Law Court (ALC or Court) pursuant to a request for a contested case hearing under the Administrative Procedures Act filed by MRI at Belfair, LLC (Belfair) Belfair claims that the Certificate of Need (CON) Coastal Carolina Medical Center (Coastal) obtained for a magnetic resonance imaging (MRI) unit on its hospital campus should be voided because Coastal substantially changed its MRI project.¹ Respondents assert that the amendments to the MRI project are not substantial because they did not change the project's compliance with the relevant project review criteria A hearing was held before me on August 4 2009 at the offices of the ALC and a Final Order and Decision was issued on October 23 2009 Following that decision, Petitioner timely filed a Motion for Reconsideration on November 5, 2009 In response to the issues raised in that Motion, I am issuing this Amended Final Decision and Order

¹ Belfair also claims that if the changes are found by the Court to be substantial, the 2007 sale of the hospital would also void the MRI CON

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SC ADMIN LAW COURT

BACKGROUND

Belfair previously challenged the decision of the South Carolina Department of Health and Environmental Control (Department) to issue a CON to Coastal for the acquisition of a 1.5 tesla MRI and construction of an addition to its hospital. On November 10, 2005, the Administrative Law Court (ALC) granted partial summary judgment for Coastal and the Department and determined after an evidentiary hearing, that a CON for Coastal was appropriate because an on-site MRI was necessary to make MRI services "available" to Coastal's inpatients and emergency patients under the applicable State Health Plan standard. MRI at Belfair, LLC v. S.C. Dept. of Health & Envtl. Control and Coastal Carolina Med. Ctr., 04-ALJ-07-0399-CC (November 10, 2005).

After the Department's Board affirmed the ALC's order issuing the CON to Coastal, Belfair appealed the Board's decision to the Court of Appeals. However, Belfair did not move the ALC or Court of Appeals to stay the decision to grant the CON to Coastal. Accordingly, the Department issued the CON for the on-site MRI to Coastal on August 3, 2006.

On June 12, 2007, Coastal requested a determination from the Department that converting the mobile MRI Coastal was temporarily operating, pursuant to its approval, into a fixed unit was an acceptable implementation of Coastal's CON. More particularly, Coastal sought a determination that this proposal would not constitute a substantial amendment to the originally approved project. 24A S.C. Code Ann. Regs. 61-15 § 605. In support of this request, Coastal submitted information regarding the MRI unit, the location the MRI would occupy on the hospital campus, and the revised cost of the project.

The Department determined that Coastal's plan to convert its mobile MRI to a fixed MRI was not a substantial change to its CON project. It made this determination because the location of the MRI project did not change, the cost of the project decreased, and the 1.5 tesla mobile MRI is substantially the same as the 1.5 tesla MRI proposed in the CON application. After receiving that determination, Coastal purchased the 1999 refurbished 1.5 tesla General Electric MRI housed in a trailer and affixed it to a concrete pad adjacent to the hospital. Coastal thereafter submitted a final completion report to the Department for the project and the Department closed its file on the CON on June 27, 2007.

Belfair subsequently requested the DHEC Board to review its staff's decision that the amendments to the MRI project were not substantial. After the Board declined to conduct a final review, Belfair filed for contested case review of this final agency decision.

On July 14, 2008, the Supreme Court remanded the original case, Docket No. 04-ALJ-07-0399-CC, to the ALC to permit Belfair the opportunity to put up its evidence that the MRI project did not satisfy the project review criteria set forth in the State Health Plan. MRI at Belfair, LLC v. S.C. Dept. of Health & Environmental Control, 379 S.C. 166, 564 S.E.2d 471 (2008). After the remand, the ALC consolidated contested cases 04-ALC-07-0399-CC and 07-ALJ-07-0389-CC. On July 9, 2009, upon the motion of Belfair and with the consent of Coastal and DHEC, the ALC dismissed contested case 04-ALC-07-0399. With this motion, Belfair conceded its claim that the MRI project set forth in the CON application did not satisfy the relevant project review criteria. Therefore, the issue remaining for determination is whether the amendments to the MRI project are substantial.

FINDINGS OF FACT

Having observed the witnesses and exhibits presented at the hearing and taking into consideration the burden of persuasion and the credibility of the witnesses, I make the following findings of fact by a preponderance of evidence:

Coastal is a forty-one (41) bed hospital located in Jasper County, South Carolina, which opened to the public in November 2004. Belfair is a free-standing imaging facility, located in Beaufort County, South Carolina, providing MRI services for Beaufort and Jasper Counties. Albert J. Borelli, Jr., M.D., a radiologist, is the owner of Belfair, which competes with Coastal for MRI services.

The Original Project versus the Implemented Project

The original CON approved new construction at the hospital to house the fixed MRI unit.

The MRI unit and associated equipment were to be located inside the hospital, adjacent to the emergency room in an MRI suite (comprised of an MRI Room, MRI Control Room, and MRI Equipment Room). The MRI suite as implemented is not located within the hospital and adjacent to the emergency room, but rather in a location just outside the hospital. The MRI unit is in a trailer that has been skirted, and connected via a non-enclosed walkway. The MRI Suite has an external lift that raises patients up when

necessary so that they can be wheeled into the MRI unit. Though it requires a several minute walk from the emergency room it is nevertheless built to be an integral part of the hospital

Clinical and Operational Issues

Basically the operational functions of Coastal's MRI and the proposed MRI are quite similar. Coastal's MRI and the proposed MRI both

- Have 1.5 tesla² magnets
- Were manufactured by GE and are similar models
- Are short bore³ systems
- Have patient tubes that are the same diameter
- Are four channel⁴ systems
- Run similar software
- Have the same coils⁵

Dr. Borelli nevertheless contends that the implemented project is substantially different from the original⁶. He points out that the MRI unit to be incorporated into the Original Project offered a maximum gradient amplitude of 33 millitesla per meter squared whereas the MRI unit for the Implemented Project has a maximum gradient amplitude of 23 millitesla per meter squared. The lower gradient strength is noteworthy because the higher the gradient strength, the faster the MRI completes a scan. Nevertheless, in terms of the actual operation of the units, the gradient strength in this case is not a significant difference. For example, given the ten (10) millitesla per meter difference in gradient strength, an MRI of a knee would take approximately sixty seconds longer on Coastal's MRI than the proposed MRI. This certainly would not increase the wait time for patients.

² Tesla is the measure of the magnetic field strength generated by the MRI's main magnet.

³ The bore describes the length of the tube where the patient lies to be scanned.

⁴ The number of channels affects the speed of the scan.

⁵ A coil is essentially a radio frequency antenna placed on or around the body part to be scanned. In this instance, Coastal's MRI in fact has additional coils making it superior to the proposed unit.

⁶ In addition to the arguments below, Dr. Borelli testified that the proposed MRI has an MRI-safe wheelchair, MRI-safe IV stand, and a 3-D workstation, and suggested that these items may not be present with Coastal's MRI. However, Coastal's MRI has an MRI-safe wheelchair, an MRI-safe IV track. Moreover, no evidence was offered as to whether Coastal's MRI has a 3-D workstation. Dr. Borelli also testified that it is more difficult to access the back of the magnet on Coastal's MRI while the Original Project did not present that concern. There was no persuasive evidence offered that the access to the magnet would result in substantial clinical or operational differences between these MRI units. Therefore, these contentions will not be addressed further.

since Coastal's volume is approximately four scans per day. Moreover, despite its lower gradient strength, there was no evidence that the proposed MRI would produce substantially better images than Coastal's current MRI.

Dr. Borelli also testified that Coastal does not have MRI-safe monitoring equipment and thus cannot scan patients who require constant monitoring.⁷ Indeed, Coastal does not have MRI-safe monitoring equipment and thus Coastal does not scan patients too unstable to be removed from monitoring equipment. However, the lack of this equipment is not a substantial change because MRI-safe monitoring equipment was not present in the Original Project application, nor did that application state that patients on constant monitoring will be scanned. Moreover, the lack of that equipment does not preclude Coastal from scanning unstable patients.⁸ Coastal does provide MRI scans to unstable patients if the radiologist and the patient's physician determine that the patient can be safely removed from monitoring during the MRI scan.

Dr. Borelli further objected that because the Implemented Project is located outside of the hospital building, it requires a separate, MRI-specific "Code Blue" procedure that would not exist had the Original Project described in CCMC's Application been implemented. When a code blue is called at a hospital, a code blue team, normally consisting of an Emergency Room physician and certain staff, rush to the patient who is in distress. The Original MRI would have utilized a phone connected to the hospital intercom to call a code blue, while Coastal's MRI requires an MRI technician to press a code blue button, and then the hospital operator announces the code blue over the hospital intercom. This difference, however, did not make Coastal's MRI less safe than the proposed MRI.

Dr. Borelli also noted other differences between the projects that he believed raised safety concerns. For instance, 1) the Implemented Project requires the use of a lift to access and leave the unit, which is more limited in space than the Original Project, and 2) the Implemented Project is not adjacent to the emergency room as was the Original Project. Dr. Borelli believes the limited space on the lift will make it more difficult to

⁷ Monitoring equipment is used to monitor a variety of vital signs and other aspects of a patient's condition. MRI safe monitoring equipment is non-ferrous and it does not produce radio frequency interference that harms image quality.

⁸ These patients may also be referred to as acutely ill patients or critically ill patients.

remove patients from the Implemented Project MRIs with lift openings similar in size to Coastal's have been approved by the Department to operate all over South Carolina, and meet the recognized quality of care and safety standards. Moreover, the evidence did not establish that the size of the lift opening of Coastal's MRI has caused any actual incidents or problems with the removal of patients. Additionally, the change in the proximity to the emergency room also does not raise safety issues. In fact, the evidence did not reflect that distance between the emergency room and the Coastal's MRI unit would reduce the standard of care of emergency room patients at this hospital or is even distinct from the distances of other approved hospitals.

Project Review Criteria

The amendments to the MRI project did not substantially change the project's compliance with the following project review criteria: (1) need, (2) accessibility/distribution, (3) cost containment, (4) acceptability, (5) financial feasibility, and (6) adverse impact. 24A S.C. Code Ann. Regs. 61-15 § 802. More specifically, the need for the project did not change because the CON application projected that the proposed MRI would be utilized by inpatients, outpatients, and emergency patients from certain Jasper and Beaufort county zip codes. Furthermore, the actual utilization of Coastal's MRI is substantially the same as the projection. Likewise, compliance with the geographic accessibility/distribution criterion did not change because the Original Project was, and Coastal's MRI is, located on the hospital campus. Compliance with financial accessibility also did not change because Coastal's MRI serves the same variety of payors that the proposed MRI was projected to serve.

The proposed MRI also established the acceptability criterion through letters of support from physicians, patients, and others in the service area. Recent interviews with physicians of varying specialties as well as the actual utilization data establish that Coastal's MRI is supported by the physicians and patients in the service area.

The MRI project as amended meets the cost containment criterion significantly better than the more costly original MRI project. The original CON approved new construction at the hospital to house the fixed MRI unit. The total project cost for the Original Project was \$3.2 million, with equipment costs of \$1.8 million. The total project cost for the Implemented Project was \$836,822, approximately \$2.3 million less than the

Original MRI Project that DHEC had approved. Moreover, the estimated cost for the MRI equipment itself changed from \$1.8 million to approximately \$535,000. The changes to the project thus resulted in significant savings of health care dollars. Obviously, compliance with the financial feasibility criterion did not change because the proposed MRI was projected to be financially feasible, and analysis of the contribution margin of Coastal's MRI reveals that it is even more financially feasible.

Finally, the MRI project would not adversely impact MRI providers in the area, and the project as implemented is not causing adverse impact. For example, despite Coastal beginning operation in 2006, Belfair's MRI scan volume has continued to grow. In 2007, Belfair's MRI performed 6713 scans, as compared to 993 scans for Coastal. In 2008, Belfair's MRI performed 7019 scans, as compared to 845 scans for Coastal. Belfair has thus not suffered adverse impact from the operation of the MRI project.

Conclusion

There are not substantial clinical or operational differences between Coastal's MRI and the Original Project. In other words, the MRI will operate in substantially the same manner, provide substantially the same services, and serve substantially the same patients. I therefore find that Coastal's MRI and the Original Project are substantially the same from a clinical and operational perspective.

Additionally, the amendments to the MRI project do not substantially change the project's compliance with need, accessibility/distribution, acceptability, cost containment, financial feasibility, and adverse impact. I therefore find that the changes to the MRI project do not alter its compliance with those project review criteria.

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact, I conclude the following as a matter of law:

General Conclusions

The Administrative Law Court has jurisdiction over this contested case proceeding pursuant to S.C. Code Ann. § 44-1-60(F) (Supp. 2008) and § 1-23-600(A) (2005). In contested case hearings, the Administrative Law Judge is the fact finder. Brown v. S.C. Dept. of Health & Env't'l Control, 348 S.C. 507, 560 S.E.2d 410 (2002). The ALC review of matters it heard from the Department is de novo. Marlboro Park Hosp. v. S.C. Dept. of

Health & Envtl Control, 358 S C 573, 595 S E 2d 851 (Ct App 2004) Furthermore, Petitioner bears the burden of proving its case by a preponderance of the evidence Leventis v S C Dept of Health & Envtl Control, 340 S C 118 132-33 530 S E 2d 643, 651 (Ct App 2000), Anonymous v State Bd Of Med Exam'rs, 329 S C 371, 375, 496 S E 2d 17, 19 (1998) Thus, Belfair must prove by a preponderance of the evidence that the changes to CCMC's MRI project are substantial enough to warrant voiding the CON

Change to the Original Project

2 In this case, Coastal requested the Department to determination that proposed amendments to the MRI project are not substantial ones that would void Coastal's MRI CON, pursuant to 24A S C Code Ann Regs 61-15 § 605 DHEC issued a determination that the proposed amendments are not substantial Belfair challenges that determination

The Department administers the CON program for South Carolina pursuant to the State Certification of Need and Health Facility Licensure Act, S C Code Ann §§ 44-7-110 et seq (2002) Under the Act, before an entity can operate certain health care facilities and services in South Carolina, the Department must issue a Certificate of Need to that entity, subject to certain statutory exemptions See S C Code Ann. §§ 44-7-160 & 44-7-180 (2002) The CON program is also administered under the guidelines of 24A S C Code Ann. Regs 61-15 (Supp 2003) Additionally, Section 44-7-210(C) provides that, "[t]he Department may not issue a Certificate of Need unless an application complies with the State Health Plan Project Review Criteria, and other regulations' See also, MRI at Belfair, LLC v S C Dept of Health & Envtl Control, 379 S C 1, 664 S E 2d 471 (2008) In considering the State Health Plan, the Department's decision must be based on the currently approved State Health Plan in effect at the time such application is accepted See Regulation 61-15 § 504

The Act was enacted to "promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities" in South Carolina. S C Code Ann § 44-7-120 (2002) Here, Coastal is a health care facility as defined by the CON Act S C Code Ann § 44-7-

130(10) (2002) Furthermore, Belfair is an affected party as defined in the CON Act See S C Code Ann § 44-7-130(1) (2002)

A CON is "valid only for the project described in the application except as may be modified in accordance with regulations S C Code Ann § 44-7-230(A) (2002) Once a CON is issued an applicant may not substantially amend or alter the project 24A S C Code Ann Regs 61-15 § 605 If the project is substantially amended or altered, it constitutes a new project Id Review of this issue requires a comparison of the amended project to the original project proposed in the CON application to determine whether the amendment is substantial A CON is "valid only for the project described in the application

except as may be modified in accordance with regulations' S C Code Ann § 44-7-230(A) (2002) Once a CON is issued an applicant may not substantially amend or alter the project 24A S C Code Ann Regs 61-15 § 605 If the project is substantially amended or altered, it constitutes a new project Id Review of this issue requires a comparison of the amended project to the original project proposed in the CON application to determine whether the amendment is substantial In making that determination, I find that consideration of the project review criteria is relevant In other words, whether the amendments to the project substantially change the project's compliance with the relevant project review criteria is pertinent in determining whether amendments to this permit were substantial under Section 605

The evidence established that there are not substantial clinical or operational differences between Coastal's MRI and the Original Project In other words, the MRI will operate in substantially the same manner, provide substantially the same services, and serve substantially the same patients Furthermore, the amendments to the original MRI project did not substantially change the project's compliance with the project review criteria The amended MRI project satisfies need accessibility/distribution, acceptability, cost containment, financial feasibility and adverse impact in substantially the same way that the original project satisfied these criteria Coastal's amended MRI project also retained the character and essential services upon which the original CON was based Therefore, the amendments to Coastal's MRI project do not constitute substantial amendments to a CON project under section 605, and thus Coastal's MRI CON is not void

Sale of Hospital

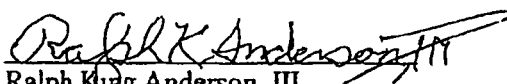
On July 1 2007 the hospital was purchased by Tenet HealthSystem Medical, Inc Belfair contends that the sale of CCMC voided the CON for the Project S C Code Ann § 44-7-230(E) provides that "[a] Certificate of Need or rights thereunder may not be sold assigned, leased, transferred, mortgaged, pledged or hypothecated, and any actual transfer or attempt to make a transfer of this sort results in an immediate voidance of the Certificate of Need " Belfair nevertheless recognized that this claim is dependent upon a determination that Coastal's amendments to its MRI project were substantial under Regulation 61-15 § 605 In other words, on June 26, 2007, Coastal completed its MRI project and submitted a final completion report to DHEC DHEC determined the project was complete and closed its file on Coastal's MRI project the following day If the changes to the Original Project were not substantial then the project was completed before the date of sale However, if the changes to the Original Project were substantial then the project was not completed before the date of sale and the CON is thus voided as a result of that sale This Court's decision that the changes to the project were not substantial therefore renders this contention moot

ORDER

Based upon the above Findings of Fact and Conclusions of Law

IT IS HEREBY ORDERED that the changes to CCMC's MRI project are not substantial and do not warrant voidance of the CON

AND IT IS SO ORDERED


Ralph King Anderson, III
Chief Administrative Law Judge

November 24, 2009
Columbia, South Carolina

CERTIFICATE OF SERVICE

This is to certify that the undersigned has this date served this order in the above entitled action upon all parties to this cause by depositing a copy hereof, in the United States mail postage paid or in the Interagency Mail Service addressed to the party(ies) or their attorney(s)

This 24th day of November, 2009
By: Charles M. Scott
Judicial Law Clerk

**Transcript of the Testimony of
MRI AT BELFAIR, LLC VS. SC DHEC ET AL.**

Date: August 4, 2009

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Fax (803) 799-5668
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STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT DIVISION
Docket No 07-ALJ-07-0389-CC

MRI at Belfair, LLC,

Petitioner,

v

South Carolina Department of
Health and Environmental Control,
and Coastal Carolina Medical Center,

Respondents

ADMINISTRATIVE HEARING

Tuesday, August 4, 2009

10 07 a m - 3 48 p m

and

Wednesday, August 5, 2009

10 00 a m - 12 10 p m

The hearing before the Honorable Ralph King
Anderson, III was taken at the Edgar A Brown
Building, 1205 Pendleton Street, Suite 224, Columbia,
South Carolina, on the 4th and 5th days of August,
2009, before Christine A Cortright, Court Reporter
and Notary Public in and for the State of South
Carolina

APPEARANCES

John J Pringle, Jr , Esquire
 John F Beach, Esquire
 ELLIS LAWHORNE & SIMS
 1501 Main Street, 5th Floor
 Columbia, South Carolina 29201
 Attorneys for the Petitioner

Ashley C Biggers, Esquire
 SC DHEC
 2600 Bull Street
 Columbia, South Carolina 29201
 Attorney for Respondent SC DHEC

Travis X Dayhuff, Esquire
 Holly G Gillespie, Esquire
 NELSON MULLINS RILEY & SCARBOROUGH
 1320 Main Street, 17th Floor
 Columbia, South Carolina 29201
 Attorneys for the Respondent Coastal Carolina
 Medical Center

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	EXHIBITS		
15	(Petitioner Coastal Carolina Medical Center's Exhibit		
16	Numbers One through Six were admitted into evidence		
	and are retained by the Administrative Law Court)		
17	(Respondent DHEC's Exhibit Number One was admitted		
18	into evidence and is retained by the Administrative		
	Law Court)		
19	(Respondent's Exhibit Numbers One through Twenty-		
20	Five, with the exception of Exhibit Number Thirteen,		
21	were admitted into evidence and are retained by the		
	Administrative Law Court)		
22	STIPULATIONS		
23	It is stipulated and agreed that this hearing		
	is being taken pursuant to the rules of the		
24	Administrative Law Court and the South Carolina Rules		
25	of Civil Procedure		

1 THE COURT This is a hearing in the matter of MRI
2 at Belfair, LLC, Petitioner, versus South
3 Carolina Department of Health and Environmental
4 Control and Coastal Carolina Medical Center,
5 Respondents The docket number is 07-ALJ-07-
6 0389-CC That's the only docket number, isn't
7 it? There's no other docket number, is it?

8 MR DAYHUFF The other was dismissed, Your Honor

9 THE COURT All right

10 MR DAYHUFF Your Honor, at this time, we'd like to
11 move the admission of all the parties' exhibits
12 into evidence by agreement We provided
13 notebooks to you

14 THE COURT Those exhibits are, the numbers?

15 MR DAYHUFF Those exhibits are the numbers

16 THE COURT No

17 MR DAYHUFF No, sorry

18 THE COURT Petitioner's One through what?

19 MR DAYHUFF Oh, good, yes Coastal's Exhibits,
20 Respondent, would be One through Twenty-five
21 And we want to exclude our Exhibit Thirteen
22 from that list that's admitted into evidence at
23 the request of Belfair We're not going to
24 admit Thirteen into evidence

25 THE COURT All right One through Thirty-five with

1 the exception of Thirteen

2 MR DAYHUFF One through Twenty-five with the

3 exception of Thirteen for Coastal

4 THE COURT One through Twenty-five Okay They're

5 admitted

6 MR PRINGLE Okay And Petitioner, MRI at

7 Belfair's trial Exhibits One through Six

8 THE COURT Okay Are admitted without objection?

9 MS BIGGERS Without objection

10 THE COURT Okay

11 MS BIGGERS And DHEC Exhibit One

12 THE COURT Oh, very simple But I bet that's a

13 thick one Okay And it's admitted without

14 objection?

15 MR DAYHUFF Correct

16 MR PRINGLE Without objection

17 THE COURT All right That's done What's next?

18 Any motions or stipulations the parties wish to

19 make?

20 MR DAYHUFF None from Coastal

21 THE COURT All right I'll hear your opening

22 statements

23 MR PRINGLE Actually, there is one matter, Your

24 Honor, I' guess a carryover from last week

25 regarding the motion for -- motion for partial

1 summary judgment

2 THE COURT I said I was going to rule on the record
3 on that I tell you what, I'd like to go ahead
4 and get into the case right now

5 MR PRINGLE Okay

6 THE COURT And I'll -- but I can go ahead and say
7 on the record that that motion was denied I
8 was going to offer more explanation for that
9 But, so with that said, let's just proceed
10 ahead and I'll go get my notes so I can give a
11 full explanation of that later on if you need
12 it All right?

13 MR PRINGLE Yes, Your Honor

14 THE COURT Okay

15 OPENING STATEMENT BY MR PRINGLE

16 MR PRINGLE I've just put on the board, and I know
17 Your Honor is already familiar with it, Section
18 605, project changes after receipt of
19 Certificate of Need which is for purposes of
20 the substantial change claim that MRI at
21 Belfair has made, it's what's before the Court
22 today And you can see it's probably halfway
23 down the page there

24 THE COURT Right in front of me over here, so

25 MR PRINGLE Perfect, perfect And I don't need to

1 give you too much background since you've had
2 the case But in a nutshell, CCMC filed an
3 application with DHEC for a CON for an MRI, a
4 \$3 2 million project, that was approved by DHEC
5 and then litigated before Your Honor During
6 that -- in that application process as well as
7 in the hearing before Your Honor, CCMC
8 repeatedly emphasized that that \$3 2 million
9 project, which was to be an in-house suite
10 located adjacent or very close to the emergency
11 room in the hospital, in the hospital proper,
12 was absolutely necessary for its provision of
13 MRI services in terms of all of the project
14 review criteria, including need and the various
15 other criteria In addition to the steadfast
16 assertion that that project and that project
17 only was necessary and appropriate, CCMC
18 repeatedly eschewed or denied that an
19 alternative of a mobile MRI was appropriate in
20 terms of cost, in terms of ability to provide
21 services, in terms of a host of factors

22 THE COURT Where I can be clear, the mobile MRI
23 issue, though, was it not one that would be
24 there periodically or was it --

25 MR PRINGLE That was certainly one of the -- one

1 of the claims made by CCMC, but I think it went
2 beyond just the fact that a mobile might not be
3 there all the time There are issues as to,
4 and testimony that spoke of mobile MRIs as
5 being inferior to fixed in-house MRIs in terms
6 of capabilities and services and the like, so
7 And one of the main bases for the approval of
8 this fixed in-house MRI suite was, and I went
9 through the DHEC record this morning and
10 counted that at least 19 times where they
11 specified that they needed this MRI unit to use
12 to treat acutely ill patients that were
13 otherwise too unstable for transport from their
14 facility to another facility It's throughout
15 and it's throughout the hearing It's even
16 referenced and mentioned prominently in the
17 stay motions that Your Honor heard just several
18 months ago, is that this specific unit was
19 necessary for the provision of MRI services to
20 acutely ill patients and those that were
21 otherwise too unstable in their view for
22 alternatives And you may recall that there
23 was even further discussion that CCMC was
24 located on the I-95 corridor and that there
25 would be numerous traffic wrecks that would

1 require CCMC to use an MRI for these purposes

2 Then and flash forward to --

3 THE COURT I don't remember that, but I'll take
4 your word I thought I remembered that there
5 was testimony, and y'all I haven't this word
6 for word, but there was testimony that the type
7 of wrecks that would occur on I-95 were those
8 that would be of the nature that may be for apt
9 to require immediate services, is that it?

10 MR PRINGLE Sure Immediate services for acutely
11 ill patients, for trauma patients

12 THE COURT Yeah

13 MR PRINGLE For those who had to have these things
14 on a very immediate basis, so

15 THE COURT Okay But I don't remember there being
16 a large number of them I just thought it was
17 there was a reference that that's the type of
18 trauma that occurs at high speed

19 MR PRINGLE I think that's correct and it was
20 certainly a basis for the need that they
21 attempted to demonstrate

22 THE COURT Okay

23 MR PRINGLE Flash forward to 2007, in June of
24 2007, while this, the case in which they were
25 granted CON was on appeal, CCMC sought a

1 determination from DHEC without providing
2 notice to my client even though my client was
3 an affected person in the CON docket, and an
4 interested person for purposes of the CON,
5 requesting a determination that making the
6 temporary mobile MRI that they had put in place
7 in 2006, as I left that out in the time line,
8 that that would be the project That that
9 would replace the \$3 2 million project with a
10 \$1 8 million MRI with a project that was
11 somewhere in the -- the figures have changed a
12 little bit -- somewhere at most an \$830,000
13 project with the MRI unit being \$535,000 So,
14 you know, a reduction in costs, you know, I
15 think probably at least three times and
16 probably more Very little documentation was
17 filed with that request DHEC did not review
18 or request much additional documentation in
19 connection with it, and in fact issued a
20 determination that the skirted or this, you
21 know, essentially tractor-trailer MRI that was
22 located next to the hospital was not a
23 substantial change from the \$3 2 million
24 project that was so essential and so crucial to
25 the CCMC just a couple of years before So

1 what we are going to show today is that in
2 terms of a substantial change determination
3 involving an MRI, that there are a number of
4 things that DHEC should have considered,
5 aspects that DHEC did not consider, and that in
6 fact if you consider those factors, aspects of
7 the MRI unit, the type of services that it's to
8 provide, where it's located and comparing the
9 --

10 THE COURT You're on the 802 criteria now, right?

11 MR PRINGLE Right Comparing the two, that indeed
12 there was a substantial difference and a
13 substantial change that took place in the
14 subsequent application and that CCMC is
15 required to file a CON application in order to
16 meet those criteria and demonstrate that this
17 completely different project is entitled to a
18 CON

19 THE COURT Who's got the computer screen in front
20 of me? Which party?

21 MR DAYHUFF We do Well, it's their exhibit, but
22 it's our equipment

23 THE COURT It's not working or if it's supposed to
24 have that in front of me, it keeps flashing up
25 and I mean every now and then I'll see a flash

1 and then --

2 MR PRINGLE That's what ours did and we turned

3 ours off, so we'll see if we can fix that

4 THE COURT Okay

5 (Off the Record)

6 MR BUPP My apologies, Your Honor

7 THE COURT That's fine It's now working Okay,

8 Mr Dayhuff

9 OPENING STATEMENT BY MR DAYHUFF

10 MR DAYHUFF Your Honor For the record, my name

11 is Travis Dayhuff I'm here with Holly

12 Gillespie Dan Bupp is working out computer

13 for us today and we represent Coastal Carolina

14 Medical Center There is Coastal Carolina

15 Medical Center Coastal Carolina Medical

16 Center is a 41 bed hospital It has an ER, an

17 ICU and it has imaging services to include MRI

18 Another view of the hospital To the right of

19 the hospital as you're facing it is our MRI and

20 this shows the location of the hospital It's

21 at the intersection of I-95 and 278 To the

22 right of the hospital is the MRI that we're

23 here about today You can see perhaps from the

24 picture that it's connected to the hospital by

25 the green awning and then the white square

1 structure is the MRI That is the MRI that we
2 have installed, have implemented as part of our
3 CON project It is a 1 5T GE MRI It's a 1999
4 refurbished MRI that has been --

5 THE COURT The one originally was 2 3 and this is -
6 - is that right?

7 MR DAYHUFF The original one, the one proposed in
8 the CON application was a 1 5T GE MRI

9 THE COURT So both of them are 1 5?

10 MR DAYHUFF Correct It was the same Tesla, the
11 same manufacturer This one -- the one
12 proposed was a new one, a new 2004 GE MRI The
13 one we implemented is a 1999 refurbished MRI,
14 1 5T Now, we obtained the CON, as I think Mr
15 Pringle mentioned, in 2004 And upon obtaining
16 the CON, Belfair began what has been a five
17 year campaign to prevent us from having an MRI
18 and to remove that from our hospital campus
19 The latest round of this case that we're here
20 about today arose from an appeal to the Supreme
21 Court Belfair appealed to the Supreme Court,
22 asked the Supreme Court to allow Belfair to
23 offer evidence on project review criteria that
24 our MRI did not satisfy the project review
25 criteria in the original CON After several

1 months of discovery, and the Supreme Court
2 granted them that right, after several months
3 of discovery, MRI at Belfair abandoned those
4 claims, conceded that there are no claims on
5 the project review criteria And so that has
6 left us with two issues The first issue is
7 substantial change, or 605 in the DHEC reg is
8 what DHEC applied to analyze the substantial
9 change issue and what this Court will now
10 apply If a change to the project, to a CON
11 project, is considered substantial, it's
12 considered a new project that you would have to
13 obtain a new CON for Now, Belfair contends
14 that the change between the original CON
15 application with a 1.5T MRI that was to be
16 located in new construction on the left side of
17 the hospital is substantially different than
18 the MRI that we implemented in 2007, the 1.5T
19 that sits to the right of the hospital The
20 evidence you will hear at trial, Dr Borelli is
21 going to offer evidence on behalf of MRI at
22 Belfair We have taken his deposition He
23 focuses the substantial change inquiry on what
24 I would call highly technical clinical issues
25 He is going to talk, if he follows the script

1 of his deposition, about things like gradient
2 strength, RF channels and purported differences
3 in safety between the original CON, the
4 original project, the proposed project and the
5 actual We're going to offer the testimony of
6 Dean Moesch in response to Dr Borelli Dean
7 Moesch is a radiologist He works at Coastal
8 Carolina He will testify that these
9 differences highlighted by Dr Borelli have no
10 clinical significance to him And that opinion
11 is important because, as you will hear, Dr
12 Moesch supervises the scans at Coastal and he
13 reads those scans to provide diagnoses to
14 patients And these changes highlighted by Dr
15 Borelli, these differences, are meaningless to
16 him from a clinical perspective Now, with all
17 due respect to the radiologists that are here
18 to offer testimony, I think focusing on
19 clinical issues obscures the appropriate
20 inquiry that DHEC undertook and this Court
21 should undertake to decide the issue of
22 substantial change That inquiry should be an
23 inquiry based on analysis of health planning
24 concepts Section 605 is obviously a part of
25 Regulation 61-15 that was promulgated pursuant

1 to the CON Act We all know that the CON Act
2 is a statutory system that regulates the
3 construction of facilities, healthcare
4 facilities in South Carolina And they
5 regulate those facilities by applying
6 healthcare planning concepts, things like cost
7 containment, need, financial feasibility When
8 you seek to build a project in South Carolina,
9 certain projects, you obtain a CON and you make
10 a case on the project review criteria
11 Substantial change, whether or not something is
12 a substantial change, needs to be analyzed
13 under those same criteria albeit perhaps in a
14 more truncated form than the original CON
15 application But I think it's those healthcare
16 planning concepts that need to be addressed

17 THE COURT 801 and 802?

18 MR DAYHUFF Correct You will hear from Kathy
19 Platt, our healthcare planner, Mr Grice and
20 Ms Tibshrany They're going to address those
21 relevant healthcare planning concepts and those
22 concepts are the very familiar ones that --

23 THE COURT Tibshrany?

24 MR DAYHUFF Ms Tibshrany, yes She's the DHEC
25 reviewer of the substantial change analysis

1 that granted the substantial change or that
2 made the finding that our change was not a
3 substantial change So these are the project
4 review criteria that will be analyzed by those
5 folks They will look at whether the change
6 from 2004, the proposed one, to the actual
7 affects need, distribution, acceptability, cost
8 containment, financial feasibility and adverse
9 impact

10 THE COURT What numbers are those, do you know the
11 reg? You can find out later on for me

12 MR DAYHUFF I can certainly find that out

13 THE COURT I know need is the first one, so

14 MR DAYHUFF That's correct The first thing --

15 THE COURT Matter of fact, it's one, two and three
16 to start off with

17 MR DAYHUFF I think that's right, Your Honor And
18 the first four -- need, distribution,
19 acceptability and cost containment -- were the
20 four highlighted in the State Health Plan as
21 being the most relevant to the MRI analysis in
22 the 2003 State Health Plan

23 THE COURT Okay

24 MR DAYHUFF All right The other issue we have is
25 Belfair's void for sale issue 604 applies to

1 that Belfair alleges that if we were to go
2 back in time to 2007, that if DHEC would have
3 done the right thing in their opinion and found
4 that our MRI constituted a substantial change,
5 then we couldn't have implemented, DHEC
6 couldn't have closed the file, and the sale of
7 the hospital in July of 2007 would have voided
8 our CON Now, I believe that claim fails for
9 three reasons The first is you will evidence
10 that no one from Belfair raised this issue with
11 DHEC, not to the DHEC staff, not to the DHEC
12 Board They failed to exhaust administrative
13 remedies The second reason this will fail is
14 it will become moot as a result of your
15 decision on the substantial change So to sum
16 up, our --

17 THE COURT Conversely you could argue -- are you
18 saying that this is an element of the
19 consideration of substantial change or it's not
20 or it's just simply going to be moot as a
21 result of the decision?

22 MR DAYHUFF I think substantial change will make
23 it moot, if I understand the theory under which
24 Mr Pringle brings his claim So we would ask,
25 Your Honor, that you affirm the findings of

1 DHEC in this matter, that this was not a
2 substantial change, and find that the sale of
3 the hospital in July of 2000 did not void our
4 MRI CON Thank you

5 THE COURT All right Ms Biggers?

6 OPENING STATEMENT BY MS BIGGERS

7 MS BIGGERS Thank you, Your Honor The changes
8 that Coastal Carolina Medical Center sought to
9 make to this project after the CON was issued
10 were analyzed by DHEC pursuant to Section 605
11 of Regulation 61-15 The changes included
12 using a refurbished MRI unit rather than a new
13 unit, relocating from a site within four, the
14 four walls of the hospital to one immediately
15 adjacent but outside and connected to the
16 hospital, and decreasing the total project
17 cost When the Department reviewed these
18 changes, the Department determined that the
19 same magnet strength still existed, that the
20 MRI would still have the same capabilities and
21 services and would serve the same population,
22 and there would be no increase in capital cost
23 The Department, therefore, determined there was
24 not a substantial change to this project We
25 believe that after you hear the evidence here

1 today you'll find Petitioners will not be able
2 to prove that there are any substantial changes
3 to the project and that there is no reason to
4 void the CON And we believe that you'll find
5 that this CON should not be voided

6 THE COURT All right Mr Pringle?

7 MR PRINGLE Your Honor, MRI at Belfair calls Dr
8 Joseph Borelli

9 ALBERT J BORELLI, JR , M D , having been duly
10 sworn, testifies as follows

11 COURT REPORTER And will you please state your full
12 name?

13 MR BORELLI Albert Joseph Borelli, Jr , M D

14 COURT REPORTER Thank you

15 MR PRINGLE May I approach the witness and hand
16 him a copy of the trial exhibits?

17 DR BORELLI - DIRECT EXAMINATION BY MR PRINGLE

18 Q Dr Borelli, by whom are you employed and in
19 what capacity?

20 A I'm employed by MRI at Belfair I'm its
21 president and the medical director and have
22 been so since its founding in, seven years ago,
23 2002

24 Q Okay What do you do at MRI at Belfair?

25 A I am in charge of the entire facility

1 clinically Mr Ableman in the courtroom here
2 is in charge with non-clinical operational
3 activities and I make all the decisions

4 Q Okay Tell the Court a little bit of -- I
5 guess your CV is already entered into evidence,
6 but if you could briefly go through your
7 educational background and some of your
8 training

9 A I attended the University of Pennsylvania
10 undergrad, went to medical school at Hahnemann
11 in Philadelphia as well Did my residency
12 training at the University of Oklahoma and then
13 at the University of Pittsburgh for MRI
14 fellowship, trained under Emanuel Kanal, one of
15 the foremost instructors worldwide in MR And
16 following that --

17 THE COURT In what?

18 A Excuse me?

19 THE COURT You said MR --

20 A In MRI MRI I should say And that's my
21 educational background

22 Q Okay Tell me about beyond after your medical
23 training background what kinds of professional
24 experience you've had

25 A I began working at a freestanding MRI facility

1 in Johnstown, Pennsylvania which served five
2 hospitals Those hospitals ranged in size from
3 approximately 50 beds to 250 beds One of them
4 was a level two trauma center and we were the
5 only MRI facility that served all those
6 hospitals I did that for seven years The
7 following two years I developed a freestanding
8 facility in association with that larger trauma
9 hospital, the 250 bed hospital We developed
10 a freestanding MRI It was a joint venture
11 between the radiologists and the hospital
12 These were all non-profits And we also had a
13 mobile MRI at the hospital on an interim basis
14 that served those patients as well So I have
15 experience both with a lot of freestanding
16 facilities and with a mobile MRI attached to a
17 trauma hospital, developing them and operating
18 them I developed that facility and I
19 developed MRI at Belfair as well

20 Q Okay What certifications or professional
21 designations do you hold in addition to an M D
22 degree?

23 A I do work with the American College of
24 Radiology I served, I have served on the
25 Committee on MRI Accreditation for a number of

1 years I still serve as a reviewer for MRI
2 accreditation The accreditation program is
3 part of the Commission on Quality and Safety of
4 the American College of Radiology and we
5 oversee, we write the standards and enforce the
6 standards of quality and safety for
7 approximately 8,000 facilities nationwide For
8 a two year period beginning in 2006, I was
9 actually the chairman of that committee and I
10 was personally responsible for developing the
11 new MRI Accreditation Program It's a brand
12 new program that replaced the program that was
13 13 years old And the brand new program, it's
14 much more specific and detailed and it covers
15 different body parts now rather than just an
16 overall MRI accreditation I'm very proud of
17 that

18 Q Okay Have you been published in certain
19 contexts?

20 A Yes Most recently I published an article for
21 General Electric in their trade magazine that
22 goes out to about 50,000 radiologists and
23 technologists worldwide -- and I think may have
24 been a larger number -- on techniques for
25 musculoskeletal imaging It will look at the

1 joints and cartilage better, basically using a
2 novelty that I created and that GE is now
3 publishing that nationally in training sites on
4 the use of that technique, just as an example
5 I stay up on the latest technology and quality
6 and safety trends

7 Q Okay You mentioned GE Can you tell the
8 Court a little bit more about your relationship
9 with GE?

10 A Yeah, my relationship with GE started back in
11 Johnstown many years ago About 12 years ago,
12 we developed the Johnstown, the Laurel
13 Highlands MRI That was a regional show site
14 for General Electric So GE would bring
15 customers in the Pennsylvania area there and I
16 would demonstrate the capabilities of the
17 system to the customers That then expanded to
18 a national show site for MRI at Belfair And
19 I flew out to Milwaukee to GE headquarters and
20 proposed that MRI at Belfair be a national show
21 site They agreed it would be an excellent --
22 it'd be a win-win in all ways and that facility
23 has been a show site since that time and we're
24 now one of four national show sites for the 1.5
25 Tesla product line So I'm very, very familiar

1 with GE's 1.5 Tesla product line I actually
2 went out just a few weeks ago to scan on a new
3 scanner that is going to be released and it
4 actually was just released to the public about
5 a month -- a week ago, FDA approved And I
6 provide consultation services to GE pursuant to
7 their development of new MRI technology

8 THE COURT Hold on one moment Mr Borelli talks
9 fast so I have to try to keep up with him

10 A Shall I slow down, Your Honor?

11 THE COURT No So your facility is a show site for
12 the 1.5 Tesla?

13 A That's correct

14 THE COURT Okay I want to make sure I got that
15 right Go ahead

16 Q Okay Have you ever been qualified as an
17 expert testifying in a case before?

18 A Yes, I have

19 Q Okay What kind of expertise did you offer?

20 A There was a malpractice case many years ago in
21 Colorado I was offered as an MRI expert

22 Q Okay And what kind of expertise did you offer
23 in that case?

24 A A woman had had an MRI scan The radiologist
25 that interpreted the study did not -- did not

1 have MRI specific training, did not have an MRI
2 fellowship, failed to detect an obvious
3 aneurysm and it was a malpractice claim And
4 I've also been an expert in a billion dollar
5 arbitration case with MedQuest down in Phoenix
6 That was a couple of years ago

7 Q Okay And what kind of expertise did you offer
8 in that case?

9 A MRI operations, radiologist duties, MRI -- not
10 just MRI facilities, imaging center operations
11 in general It was claim -- it was a contract
12 issue with radiologist staffing about 13
13 facilities, all of which included MRI

14 Q Okay Okay So what kind of expertise are you
15 going to offer in your testimony today?

16 A I'm going to offer my expertise regarding a
17 whole gamut of MRI operations, clinical and
18 safety matters

19 Q Okay And you've already talked about all
20 this, but does your experience and background
21 qualify you to give opinions in those areas?

22 A Yes, based on my training, my 17 years, I
23 believe, of experience in MR, dedicated MR, my
24 experience operating multiple MRI facilities,
25 developing two, yes, I believe I'm very well

1 qualified And my background with the
2 Commission on Quality and Safety with the ACR,
3 chairing the Committee on MRI Accreditation has
4 qualified me very well

5 Q Okay

6 MR PRINGLE Your Honor, I'd offer Dr Borelli as
7 an expert in the area of MRI operations,
8 safety, quality and management

9 THE COURT Mr Dayhuff?

10 MR DAYHUFF No objection, Your Honor

11 MS BIGGERS No objection

12 THE COURT He is so qualified

13 MR PRINGLE Okay

14 Q Dr Borelli, let's start with sort of the --
15 before we get into the specifics of these two
16 competing or these applications to talk a
17 little bit about based upon your review of the
18 documents in this case and your involvement,
19 the kinds of things that should be considered
20 in making a determination of whether a
21 substantial change has taken place

22 A I think overall the most important factor to
23 look at is to answer the question, has the
24 project changed in a way such that the services
25 that were outlined and proposed as needed, are

1 they provided by the actual -- by the new
2 project And I think in this particular case
3 this project fails that test by a huge margin

4 Q Okay Let's look at a document just to start
5 going through the DHEC record, and I think --
6 I hope you can see that on your screen

7 A Yes, I can.

8 Q It's a document labeled number 39 of the DHEC
9 record Can you just, and this has already
10 been discussed some, but just to set the table
11 a little bit about some of the information
12 about the original in-house MRI project?

13 A Yes I think we see the type of construction,
14 it's an addition to the existing facility, so
15 it's actually going to become a part of the
16 hospital but ultimately is within the hospital
17 Mr Dayhuff had said it's on the left side
18 No, it's in the hospital I disagree with that
19 characterization Whereas the mobile MRI
20 implemented is outside the hospital Those are
21 big differences We see that the movable
22 equipment, \$1 8 million, that means the MRI
23 scanner itself In the current case, the total
24 project cost, according to Ms Dayhuff, was
25 \$530,000 That would tell me the scanner

1 itself is probably in the \$300,000 range The
2 movable equipment would be in the 300 to 350
3 range I'm looking at a five to sixfold
4 differential And then we see the total
5 project cost of 3 2 million versus the 570 of
6 Ms Dayhuff Those are substantial changes by
7 anyone's measurements

8 Q Okay And we'll talk about this more
9 specifically But in your view, what is --
10 what does -- what is the significance of a
11 decrease in cost in an MRI situation like this?
12 What do you -- what does that -- questions that
13 create in your mind, if any?

14 A Well, I think, you know, even from a layman's
15 perspective, if you were to say this project
16 cost 3 2 million, this one cost 570,000, but
17 they both can do the same things, I think
18 that's a specious argument right on its face
19 I mean that can't be true Otherwise, why
20 would -- why would facilities be preparing
21 projects for DHEC in the multi-million dollar
22 range when the needs can be satisfied for one-
23 fifth or one-sixth that cost just on its face
24 But when you look deeper and you see yes, there
25 are ramifications The ramifications are on

1 the quality of the imaging and patient safety

2 --

3 Q Okay

4 A -- and the types of services that can be
5 provided and it impacts accessibility and need

6 Q Okay On those points, let's talk a little bit
7 about -- a little bit about some of the
8 original application and some of the things
9 that emphasized in the original application by
10 CCMC as far as the need and the use of the
11 original fixed in-house MRI If you'd take a
12 quick look at that and especially to the third
13 paragraph

14 A I'll read it It says, "With the increased use
15 of MRI services and increased population
16 growth, Coastal Carolina finds it necessary to
17 expand the services to include on-site MRI
18 services MRI services are routine diagnostic
19 services that provide needed -"

20 THE COURT Hold on Slow down The court
21 reporter's got to get this

22 A Okay

23 THE COURT Go ahead

24 A "Diagnostic services that provide needed
25 insight for physicians treating the critically

1 ill, acute care patients In-house MRI
2 services in hospitals have become the standard
3 of patient care " The next paragraph, "Without
4 in-house MRI services at Coastal Carolina,
5 patients will experience an inconvenience in
6 having to travel to an outside provider as well
7 as delays in diagnosis, decision making and
8 treatment Coastal Carolina's emergency room
9 and acutely ill patients would need to be
10 transported by ambulance to freestanding sites
11 for their diagnostic services "

12 Q Okay What are acutely ill patients?

13 A An acutely ill patient, that would be a patient
14 that needs to be in the hospital If they
15 weren't acutely ill, they could go home So
16 they need continued monitoring to make sure
17 that their condition does not rapidly decline
18 to the point where there could be a fatality

19 Q Okay

20 A So acutely ill is someone that really frankly
21 needs to be in a hospital

22 Q Okay And what does this language say about
23 the proposed fixed in-house unit and performing
24 MRI scans on acutely ill patients?

25 A They say it's absolutely mandatory to have an

1 in-house unit to serve the needs of those in-
2 house patients

3 Q Okay

4 A Those acutely ill patients, I'm sorry

5 Q Okay Let's move ahead to, if you'd look at
6 the alternative language and disposition and
7 just read that very quickly

8 A "Alternative number one Do not construct an
9 addition for a fixed in-house MRI and utilized
10 mobile services Disposition one Reject
11 Without an in-house MRI, Coastal Carolina's
12 acutely ill and emergent patients would need to
13 be transported to an outside provider which is
14 costly, risky and stressful All patients
15 would incur delays in diagnosis and treatment
16 as well "

17 Q Okay And go ahead and not quickly read but
18 read alternative number two and disposition
19 number two

20 A "Alternative number two Construct an addition
21 to the facility to house one fixed MRI
22 Disposition number two Accept This is the
23 most cost efficient, convenient and safest
24 option for the patients of Coastal Carolina "
25 I would add emphasis to cost efficient and

1 safest in my opinion "Not having to transport
2 the acutely ill and emergent patients of
3 Coastal Carolina to an off-site MRI scanner
4 will provide these patients with the highest
5 standard of care in the most safe and cost
6 effective manner In-house MRI services at
7 Coastal Carolina will avoid the inconvenience
8 of traveling to an outside provider and
9 avoiding delay in diagnosis, decision making
10 and treatment "

11 Q Okay

12 THE COURT That said page 44 It was page 44 out
13 of what exhibit?

14 MR PRINGLE That's out of the DHEC record which is
15 DHEC Exhibit Number One

16 THE COURT Okay

17 MR PRINGLE And I believe that all of the Bates
18 stamped numbers with -- will be the DHEC record
19 probably, but, we'll keep pointing that out

20 THE COURT Okay

21 Q Okay I'll show you another document here
22 Can you tell me what this document is?

23 A Could you scroll down a little bit, please?

24 Q Oh, sure

25 A Oh, I see it now I see, this is the original

1 CON equipment quotation

2 Q Okay And was this document submitted to DHEC
3 with the original application for the fixed in-
4 house MRI?

5 A Yes, it was

6 Q Okay Without perhaps going into too much
7 detail, describe this unit and in the process
8 of doing so, point out the things that you
9 believe are important in terms of substantial
10 change that relate to the MRI unit and what it
11 can do

12 A Comparing this unit to the as-built?

13 Q Sure, yes

14 A Well, frankly, they are both 1.5 Tesla GE
15 systems They're both short bore systems
16 Actually, they're fairly similar I'd say
17 they're quite similar There are some
18 substantial differences, though One has to do
19 with the gradients That's the speed with
20 which the magnetic fields that are superimposed
21 on the main magnetic field are switched on and
22 off and that correlates very closely with
23 scanning speed So, for example, this scanner
24 here compared to what has been implemented can
25 produce scans, I would say, five to forty

1 seconds faster for each series of a scan And
2 we may do a minimum of six to seven series up
3 to fifteen twenty series on a patient So
4 we're looking at several minutes longer to scan
5 a patient with this scanner than with the
6 other And that's down where you see under the
7 high-performance high-speed grading system
8 The system that was implemented has gradients
9 an amplitude of only twenty-three
10 Additionally, I think there's a question as to
11 whether this system proposed here is an eight
12 channel system versus a four channel system
13 It took us some time to get documentation of
14 that That occurred maybe about a last minute
15 document that turned up that purported to show
16 that this perhaps is a four channel system, but
17 I called into question and I think Ms Platt
18 agreed there's a question as to whether this
19 system was an eight channel system or a four
20 channel system I think at the very least DHEC
21 should have inquired because that has a major
22 impact on scanning speed as well, possibly
23 doubling the scanning speed for many
24 applications And that's important when you're
25 trying to scan an acutely ill patient But

1 frankly, otherwise, in terms of the actual MRI
2 scanner itself, they're similar

3 Q Okay While we're on the subject of channels,
4 describe to the Court a little bit about what
5 channels are and your view on their importance
6 relative to other measures that they may be
7 used to compare MRIs

8 A I would say, for example, I did note that
9 DHEC's policy, I believe, is to say that 1 5
10 Tesla scanners are equivalent, and actually
11 that a 3 Tesla scanner would be a substantial
12 change from a 1 5 And I would argue strongly
13 that the number of channels is far more
14 important than the field strength I think
15 DHEC --

16 MR DAYHUFF Your Honor?

17 THE COURT Yes

18 MR DAYHUFF Could I object for lack of foundation
19 I didn't hear Dr Borelli say clearly that
20 there is a difference in channels between the
21 actual and proposed If there's not a
22 difference in channel, then I'm not sure that
23 we need to discuss the differences in channels
24 If the actual and proposed are both four
25 channel, I don't think we need to hear

1 testimony about that

2 A I didn't say they were both four channels

3 THE COURT All right You can't respond

4 MR PRINGLE I think he's raised the issue of the
5 question of whether there's eight or four
6 channels

7 THE COURT He's raised the question that it may be
8 and that he's heard that there's some document
9 that may resolve that issue, but there's
10 nothing in the record at this point in time to
11 establish that there is a difference But
12 here's my ruling If you -- you're allowed to
13 present his testimony in this regard if you
14 assert to the Court that you will link it up
15 If you can make that assertion as an officer of
16 the Court, I will allow it to go in and then if
17 you don't fulfill that promise, I will strike
18 that testimony and disregard So now my
19 question is to you, can you make that
20 assertion?

21 MR PRINGLE I'm not sure, I think we can make that
22 assertion or we can certainly make the
23 assertion that there's a question about whether
24 it's an eight or a four But let me also
25 mention that the reason, one of the reasons for

1 offering this testimony is to provide a
2 backdrop in perspective on the kinds of things
3 that are important in making substantial change
4 determinations And talking about perhaps that
5 the issue of Tesla strength is not as
6 significant as say the issue of channels or
7 some of the other issues that we're going to
8 discuss

9 THE COURT All right Mr' Dayhuff, do you want to
10 respond to that?

11 MR DAYHUFF Your Honor, if they don't lay the
12 foundation that there is a difference here,
13 four and eight channel, if that's not Dr
14 Borelli's testimony, I don't think there's any
15 need to go into the difference between four and
16 eight channels

17 THE COURT Okay Well, I'm going to let him go
18 into it Like I said, can I have the rules of
19 evidence? You would think they would give you
20 the rules of evidence, but the specific
21 provision in the rules of evidence that allow
22 you to go -- present testimony that you assert
23 it will be linked up and then if you don't do
24 it, I'll -- the judge is to strike it Now, if
25 there was a jury, I don't think I'd let you do

1 it based on what you said I'm not going to be
2 so swayed by this if I don't think it's
3 properly linked up, so I'm going to let you go
4 into it Mr Dayhuff, that is, though, I
5 didn't mean to interrupt you, but if he doesn't
6 link it up, I'll strike it from the record,
7 understand?

8 MR DAYHUFF Thank you, Your Honor

9 THE COURT All right Ms Biggers, I never asked
10 you Do you have a position on this?

11 MS BIGGERS Your Honor, I don't think it's
12 relevant because I don't think they'll be able
13 to show that it's linked up

14 THE COURT Okay

15 MR PRINGLE And just for clarification, you mean
16 by linked up, linked up in that it is an eight
17 channel?

18 THE COURT You have to -- I think that is the
19 phrase that they use in the Rules of Evidence
20 When I come back in here, I'm going to have the
21 Rules But link up exactly, establish that
22 that is a -- that there is a differentiation
23 between the two MRI units

24 MR PRINGLE Okay

25 THE COURT Otherwise, obviously if there is no

1 difference, it's irrelevant So --

2 MR PRINGLE And I understand Your Honor's ruling,
3 except that we wanted to explore the bases for
4 DHEC's determination and the things that DHEC
5 emphasizes That's the only -- but I hear you
6 and I'll move on

7 THE COURT Go ahead

8 Q Now --

9 A Now, I want to finish answering the question

10 Q Okay Okay Sure

11 A So, Your Honor, the point isn't that one is
12 four and one is eight My point is that DHEC
13 has stated that 1 5 equals 1 5 They've also
14 stated 1 5 does not equal 3T and my argument
15 is, the point I'm trying to make here is that
16 if you take that simplistic of approach, you'll
17 be wrong And why has DHEC done that
18 historically? Over the years as MRIs developed
19 from lower field strength units to high field
20 strength units, going from 2 Tesla to 5 to 7
21 to 1 2, to 1 5, there was, and I would agree,
22 a linear proportional increase in quality of
23 the scans with an increase in field strength
24 However, once you get to 1 5T going to 3T, the
25 physics change completely And no one today

1 will tell you that a 3T scanner is uniformly
2 better than a 1.5T scanner as they would say a
3 1.5T scanner is uniformly better than a 1T
4 scanner, all other things being equal. Once
5 you get to 3T, and I'm going to give you a
6 little bit of explanation why, the wavelength
7 of the radio frequencies that the scanner uses
8 at 3T are now roughly the size of the human
9 body and that creates standing waves inside the
10 body. So literally you'll have a picture of
11 the body and you have a black area and you
12 won't be able to see the abdomen because of the
13 problem with 3T and those problems so far have
14 been insurmountable. So right now, 3T is not
15 better than 1.5T. We even submitted an article
16 into evidence from one of the leading 3T
17 researchers in the world that says, sorry guys,
18 we can't say 3T is better, still work to be
19 done, we may not be able to solve the problems.
20 So my point is channel count is actually more
21 important than field strength, especially if
22 you're going from 1.5 to 3T, irrespective of
23 whether channel count comes into play in this
24 case. But I'm just pointing out that looking
25 at the field strength and saying, hey, if it's

1 a 3T, it's substantially different than a 1 5T,
2 I don't agree with that I think the 1 5T is
3 going to trump the 3T most of the time If
4 there's a substantial change, it may be in the
5 other direction in favor of 1 5T That's the
6 only point I'm making

7 THE COURT Let me respond to you on that point that
8 he made where you'll understand If DHEC
9 failed to make an analysis about channel eight
10 versus four, that also, I believe, would be
11 irrelevant here because this is a de novo
12 hearing And the analysis that needs to be set
13 forth is to me whether there's a substantial
14 change I'm not here to -- I've said this over
15 and over, I'm not here to determine whether
16 DHEC was right or wrong or challenge whether
17 they properly considered the case or not I'm
18 here to determine the issues on de novo again
19 So I'm just not so sure of the import that that
20 will have on my ultimate decision, but I've set
21 that forth for your clarification as this case
22 goes forward

23 MR PRINGLE I understand, Your Honor

24 Q Dr Borelli, tell me a little bit about or tell
25 me what ancillary equipment is

1 A Pursuant to an MRI equipment quote, ancillary
2 equipment would be equipments other than the
3 scanner itself For example, the coils that
4 are placed on the patient to scan various parts
5 of anatomy There's a coil for the knee, for
6 example What are coils? They're basically
7 radio frequency antennae So the knee coil
8 goes around the knee, head coil goes around the
9 head, body coil goes around the torso Other
10 ancillary equipment would be, for example, a
11 work station to analyze blood vessels for
12 stroke patients, for example And we see in
13 this project, the project submitted with the
14 CON, versus the project that was implemented
15 that there's a difference and a substantial
16 difference One has this 3D work station to
17 look at blood vessels in stroke patients, the
18 other doesn't have the 3D work station to look
19 at blood vessels for stroke patients It's
20 called an AW work station and it costs about
21 \$100,000 That's a substantial change The
22 other ancillary equipment that we see that was
23 present in the original CON but not present in
24 the current, we see a non-magnetic IV stand
25 What's the importance of a non-magnetic IV

1 stand? Well, it's very important If you
2 don't have a non-magnetic IV stand, you can't
3 safely bring or you can't hang an IV bag in the
4 MRI magnet? room If you use a standard IV
5 pole, that will fly in as a missile object into
6 the scanner and can kill the patient We see
7 an MRI --

8 THE COURT Non-magnetic, what was it, work stand?

9 A IV stand, intravenous It's basically a stand,
10 looks like a coat hanger that you hang an IV
11 bag on

12 THE COURT I understand

13 A They're typically made out of metal and if you
14 were to bring that into the MR environment, it
15 would be hazardous and potentially fatal
16 That's in this quote but not in the as-built as
17 far as all the information I've seen to date
18 We see the MR wheelchair That is an MRI
19 compatible wheelchair It's made out of non-
20 ferrous metal or fiberglass It's in this
21 proposal but not in the as-built Frankly, I
22 don't know how they get non-ambulatory patients
23 into that trailer without an MRI compatible
24 wheelchair Maybe they have one and they just
25 didn't tell DHEC or didn't tell us But it

1 makes a big difference on patient care

2 Q Okay

3 A And it's not a really expensive item either

4 Q Let's move to another Let's talk a little bit
5 about location And I'm referring you to, and
6 I don't know how well this shows up, but I'm
7 referring you to the Exhibit Five Is that a
8 layout of the hospital?

9 A That's been presented to us as a layout of the
10 hospital, yes

11 THE COURT Whose Exhibit Five?

12 MR PRINGLE It's the Petitioner's Exhibit Five

13 Q Can you tell me -- can you orient yourself with
14 that and point out various parts of the
15 hospital and the in-house fixed unit versus the
16 temporary or the mobile installed unit?

17 A This is the main entrance to the hospital here
18 This is the ambulance entrance to the emergency
19 room which sits here And this is the as the
20 on-site in-house MRI that was originally
21 proposed we see right next to the emergency
22 room Over here, we see a walkway here I
23 believe this is the walkway to the MRI scanner
24 This is an indication and this was indicated by
25 Ms Urquhart as the location of the trailer-

1 based MRI and that is sitting on the complete
2 other side of the hospital And I would hazard
3 a guess, it probably takes a couple of minutes
4 even for an ambulatory patient to walk from
5 here over to the emergency room for treatment,
6 if there were an emergency with the patient in
7 the ER suite -- excuse me, the MRI suite

8 THE COURT Treatment? You mean diagnosis?

9 A No For example, let's say a patient has a
10 problem in the scanner They need to take that
11 patient and bring the patient all the way back
12 to here to the emergency room for treatment
13 And also if you have a patient in the emergency
14 room that is acutely ill, that patient has to
15 go all the way through here, all the way
16 outside, around and into that trailer, quite
17 some time

18 Q Okay Let's talk a little bit about you
19 mentioned that you have some -- or, tell me, do
20 you have some concerns about safety within the
21 skirted tractor-trailer mobile unit relative to
22 the fixed MRI unit that was proposed?

23 A Yes There are many substantial changes in
24 terms of how patients are scanned, how patients
25 are accessed, how patients are monitored The

1 mobile -- a trailer based MRI has no room
2 around the outside of the magnet I think we
3 have an exhibit if you could pull that up,
4 would that be helpful to show that picture?
5 Yes And then maybe if we have the diagram
6 from the top, the top view, there we go Your
7 Honor, notice that the -- this is the magnet
8 itself and this is a diagram of what is
9 installed or very similar to what is installed
10 This is an Ellis and Watch trailer That's the
11 same type of trailer that is installed now
12 And this is the control room where the
13 technologist sits
14 THE COURT Wait a second I was writing Where is
15 it again?
16 A This is the control room --
17 THE COURT Okay
18 A -- where the technologist sits This is the
19 lift that brings the patient from the ground
20 level up to the door which is a couple, several
21 feet up in the air These are stairs There's
22 two doors here There's a door here and this
23 is the actual scanner room itself Now, notice
24 that there is no room on either side to get
25 behind the scanner This is a substantial

1 change from the original proposed project The
2 original project, if we can go back to the
3 picture if we want to, we can, but MR suites
4 typically have several feet of room on either
5 side of the scanner And why is that?

6 MR DAYHUFF Your Honor, could I offer an
7 objection? This is an expert opinion that
8 wasn't offered to us in discovery, so I would
9 ask that it be -- not allowed to be offered at
10 trial

11 MR PRINGLE Dr Borelli offered in his opinions
12 regarding space and limited space within the
13 MRI, that it was a cramped environment and that
14 as opposed to the fixed MRI, that it caused
15 problems in being in such a smaller
16 environment

17 MR DAYHUFF Dr Borelli mentioned something about
18 the smaller environment in the MRI truck but
19 did not mention anything about the need to be
20 able to go around behind the MRI

21 MR PRINGLE Again, I think it goes to the issues
22 that he's raised and the opinions he has that
23 in the smaller environment that certain things
24 can't be done as effectively and patient care
25 and safety is compromised

1 THE COURT Mr Dayhuff, did he testify about there
2 being limited space?

3 MR DAYHUFF He testified generally about limited
4 space in the truck compared to the proposed
5 I guess my position would be that's not a fair
6 disclosure of this, what appears to be a newer
7 expanded opinion about going behind the MRI

8 THE COURT What would your prejudice be as far as
9 being able to respond to this?

10 MR DAYHUFF I could certain cross-examine him,
11 Your Honor

12 THE COURT Okay Objection is overruled

13 A I did, in my deposition, did mention that --

14 THE COURT No need to go into that

15 Q Just continue with the discussion that you --

16 A The tight confines of the mobile MRI create
17 safety problems There's a number of them
18 One of them is that you cannot get around the
19 outside of the magnet to get to the head end of
20 the patient If the patient were to go in head
21 first, which is what is typically done, the
22 head of the patient will be, potentially be in
23 here or over here and in terms of monitoring an
24 acutely ill patient, that can't be done
25 adequately in my opinion Additionally, if

1 there's a problem with the patient, there's a
2 substantial change in the way that a patient is
3 accessed and extracted from the scanner
4 environment In this particular case, the
5 table would have to be detached, and the table
6 would have to be detached and brought out
7 through this opening here This is generally
8 a two-person operation but it can be done with
9 one person, but you have to -- because this
10 room is so small, you have to work this table
11 kind of back and forth to get it out through
12 there, okay In a larger room, it's much
13 easier just to drive it out In a tight space,
14 it's going to create some problems there More
15 importantly is what you do with the patient
16 once the patient's in this control room now
17 So now you're outside the magnetic field Your
18 patients are now safe from magnetic field
19 interactions, what have you, you can treat the
20 patient with electronic devices, what have you
21 You bring the patient out here, you then have
22 to jiggle that table to get it onto this lift
23 This lift measures 88 inches in width and it
24 has a railing around it, so you don't fall off
25 The table itself measures precisely 88 inches

1 I measured ours It's the same They're the
2 same tables You can imagine how difficult it
3 would be to move a patient on this table,
4 particularly a patient that's having a problem,
5 potentially a life threatening problem, and try
6 to wiggle them onto this lift and do that
7 quickly maybe while you're trying to perform
8 CPR and lower the table That's a substantial
9 change from the original application The
10 patients wouldn't have to do that The
11 facility that I designed with a mobile MRI, we
12 went to the trouble and it wasn't a substantial
13 cost, we built a ramp up to the mobile so you
14 got rid of this lift This lift is a big
15 problem, a big safety issue And I don't think
16 -- I think it's a big compromise to try to scan
17 acutely ill patients and get them on and off
18 that lift if something bad happens to them So
19 they should have built a ramp so they wouldn't
20 have the issue with the lift

21 Q Okay Let's talk about have you had a chance
22 to review what I've put up in front of you and
23 what is actually Petitioner's Exhibit Number
24 Three, and I'll call this CCMC MRI procedures?

25 A Yes, I have

1 Q Okay And what, based upon your review, what
2 opinions do you have about CCMC's provision of
3 scans for acutely ill patients?

4 A The policies and procedures have some
5 inconsistencies within them which we can
6 review This particular procedure, the code
7 blue procedure, points out the substantial
8 changes between the proposed project and the
9 as-built, which I'd be happy to elaborate on

10 Q Well, just briefly, what kinds of changes?

11 A Well, the existence of this policy, of this
12 procedure here that's specific for a trailer
13 based MRI highlights that there are substantial
14 -- there has been a substantial change This
15 says code blue procedure in the MRI trailer
16 That wouldn't exist if it had been an in-house
17 magnet It wouldn't say -- it would say code
18 blue procedure in the MRI trailer These are
19 specific procedures that differ -- that in my
20 opinion would differ than if it was in-house
21 For example, we look at, you know, number one,
22 push the code blue button Now, I'm not sure,
23 but I suspect that that button is there because
24 the scanner is outdoors, it's not in the
25 hospital, it's outside the hospital The

1 second step, the MRI tech will call 784-5555
2 That may not be necessary if it was an in-house
3 system They may just have an intercom on an
4 in-house system And by the way, I called that
5 number It's non-operative

6 MR DAYHUFF Your Honor, I don't think the witness
7 can speculate He can give his expert opinions
8 but the last two have been this may be the
9 case, I can speculate about that That's not
10 appropriate expert testimony

11 THE COURT Well, opinion is often speculated but
12 then there's a certain point where the opinion
13 is so speculative that the probative value of
14 it diminishes to the point of not being worthy
15 of being offered So I assume that's what
16 you're saying

17 MR DAYHUFF I like that objection better than the
18 one I --

19 MR PRINGLE Can you give me a response, too?

20 THE COURT Well, I just said that's the appropriate
21 consideration I'm not giving objections here

22 MR PRINGLE I would just say in response that
23 it's, you know, his, as an MRI practitioner and
24 operator, you know, opinions about what's going
25 on in the trailer and that touch on the issues

1 there that are before us here

2 THE COURT Okay Mr Dayhuff, do you want to
3 respond to that?

4 MR DAYHUFF I think this opinion is getting close
5 to without enough foundation to be offered I
6 don't think Dr Borelli is an expert in code
7 blue procedures in hospitals And I'll ask him
8 on cross examination whether he has a code blue
9 procedure at his facility I doubt that he
10 does

11 THE COURT Well, you can voir dire him on that
12 right now if you wish, but I've got to make the
13 evaluation at this point in time So, because
14 I mean this is kind of quasi-relevant versus
15 whether he's qualified to go into this and what
16 we're getting at here

17 MR DAYHUFF I could ask a couple of questions, if
18 Your Honor would let me, on code blue

19 DR BORELLI - VOIR DIRE BY MR DAYHUFF

20 Q Dr Borelli, do you have a code blue system at
21 MRI at Belfair?

22 A Freestanding centers do not generally

23 Q Okay So do you at MRI at Belfair?

24 A No, but I have experience within hospitals

25 Q All right Have you examined the code blue

1 system at Coastal Carolina?

2 A No, I have not

3 Q All right

4 MR DAYHUFF No further questions, Your Honor

5 THE COURT All right Any response to that?

6 MR PRINGLE I think he's pointing out the

7 differences between the systems and practices

8 in a mobile MRI versus a fixed MRI and --

9 THE COURT All right I'm going to rule you can

10 point them out as far as this document is

11 concerned As far as an explanation, I think

12 we need a foundation laid for his ability to go

13 into explaining it

14 MR PRINGLE Okay

15 THE COURT In other words, he can go into this

16 document certainly And I think his testimony

17 was when the objection was being made that the

18 code blue procedure reflects a difference in

19 the MRI or the procedures for the hospital

20 versus the MRI trailer So proceed

21 DR BORELLI - CONTINUATION OF DIRECT EXAMINATION BY

22 MR PRINGLE

23 Q And there is a difference in your opinion

24 between -- or these code blue procedures are

25 something that would not have existed in the

1 fixed MRI suite?

2 A They would be different They would be
3 substantially different and it would impact
4 patient care and patient safety, yes

5 Q Okay Let me move to another page of this and
6 get you to talk about another issue And I'm
7 now on, I think you can see it on your screen
8 Why don't you tell me about this part of the
9 policies and procedures?

10 A Okay This is a policy and procedure -- can
11 you scroll up so I can read the title?

12 Q Oh, sure

13 A Says title, Prevention of Burns in the MR
14 Department, and then to prevent burns from
15 coils in/on the MRI equipment And we see in
16 bold about midway down, emphasis included in
17 the document, not added by us, "MRI compatible
18 monitoring equipment is not available for use
19 in this facility " But that's a big problem

20 Q Tell me what MR compatible monitoring equipment
21 is

22 A To monitor a patient within the MRI
23 environment, you need equipment specifically
24 designed to not produce radio frequency
25 interference which will ruin the quality of

1 images It needs to be equipment that will not
2 fly into the magnet, that will be drawn into
3 the magnet because it's ferro-magnetic There
4 is specific equipment designed to monitor
5 patients in the MRI environment If you have
6 an acutely ill patient, by definition you need
7 to be monitoring that patient during the
8 procedure Based on this policy, they cannot
9 safety scan acutely ill patients

10 Q Tell the Court a little bit about some examples
11 of everyday monitoring equipment and what it
12 might monitor

13 A For example, you want to monitor the patient's
14 pulse You want to know whether the patient's
15 heart is still beating while in the scanner
16 You want to know whether the patient is
17 breathing It's called a respiratory belt
18 You want to know the patient's blood pressure
19 Patients that are acutely ill, that is one of
20 the more common reasons that they pass is
21 because their blood pressure drops You want
22 to monitor the electrocardiogram in patients
23 that have cardiac disease They're usually on
24 a monitored bed in the hospital You want to
25 monitor -- did I mention heart rate? You need

1 to monitor vital signs You need to monitor
2 the oxygenation of the blood

3 Q With respect to the fixed unit --

4 A And I apologize, and I want to say there are
5 devices that are in common use, we have them at
6 our facility, that allow you to monitor
7 patients, monitor all of those parameters and
8 more

9 Q Okay Why would the provision of MR monitoring
10 equipment be important for CCMC in its
11 operations?

12 A Because they have made the strong argument that
13 they need the MRI for acutely ill patients
14 Whether they're trauma patients or ER patients
15 or otherwise acutely ill, those patients need
16 to be monitored They need to be monitored at
17 all times and you can't pull off the monitoring
18 during the 45 minutes or so they're going to be
19 in the MRI scan That's unacceptable As a
20 matter of fact, the Joint Commission sent out
21 a Sentinel Event that had recommendations in
22 the Sentinel Alert in 2008 that spoke to that
23 matter directly

24 MR DAYHUFF Objection, hearsay

25 MR PRINGLE We'll move on

1 THE COURT Okay Sustained

2 Q Is, in your opinion, the lack of MR compatible
3 monitoring equipment in the installed MRI a
4 substantial change from the original
5 application in view of the uses and needs
6 expressed by CCMC in its original application?

7 A As I stated earlier, overall we look at the
8 service that's being provided Has that
9 changed substantially from my standpoint,
10 possibly from a health planning standpoint?
11 And because this implemented project based upon
12 this in bold document saying that they don't
13 have MRI compatible monitoring equipment, they
14 cannot provide the services that they
15 emphasized in their original application, i e ,
16 providing services to -- MRI services to
17 acutely ill patients

18 Q Okay Talk a little bit about -- you've talked
19 about these policies Let me show you one
20 that's on another diagram and let you look at
21 that And this is actually drawn from one of
22 Respondent's exhibits, that would be 272 Let
23 me just point that out for Your Honor This
24 would be in Respondent's Exhibit Seventeen or
25 Respondent CCMC's Exhibit Seventeen Tell us

1 what that is

2 A This is a -- this is a document from Ellis and
3 Watts They're the manufacturer of the tractor
4 trailer And they provide this document for
5 siting purposes

6 Q Okay Based upon your review of this document,
7 what have you gleaned from this?

8 A I did notice in the top left, and maybe you can
9 zoom in here, but I see an emergency escape
10 hatch

11 Q Okay Is there any significance to that?

12 A I don't think the proposed project would have
13 had, the original CON project would have had an
14 emergency escape hatch associated with it
15 That's a substantial change in my opinion

16 Q Okay Tell me --

17 A And I don't think you could get a trauma
18 patient out through that emergency escape
19 hatch

20 Q All right Tell me a little bit about in your
21 view what some things are that, and I think you
22 discussed this in your deposition, the things
23 that would not be considered, would not be
24 considered substantial changes in your view?

25 A For example, I mean, DHEC will often get

1 proposals They'll get a CON and maybe it's
2 contested and maybe a year, year and a half
3 goes by, and the applicant will come in and
4 say, well, you know, that scanner we originally
5 proposed, well, the manufacturer has a better
6 model available, some new technology, slight
7 changes, or they may get a better deal from
8 another manufacturer, but essentially replacing
9 a top of the line brand new 1.5T from GE with
10 maybe a Phillips or, you know, slight changes
11 in equipment configuration, roughly the same
12 cost, usually within about ten percent DHEC,
13 as a matter of fact, my understanding is that
14 DHEC will accept the project if it goes ten
15 percent over the original cost without any
16 problems For example, let's say, on the
17 project submitted, they showed it next to the
18 emergency room If they maybe move that, you
19 know, maybe ten feet, you know, closer to the
20 emergency room or made a slight change in the
21 configuration, sure, those are things that are
22 commonly, you know, entered as potential
23 substantial changes and DHEC, you know,
24 appropriately concludes those aren't
25 substantial changes, and I don't disagree with

1 that But in this particular case, we have a
2 fivefold difference in cost, completely
3 different configuration, issues that impact
4 patient safety, impact accessibility and the
5 need of being met This is a much different
6 animal than what DHEC typically sees And
7 frankly, I think it was because of the short
8 amount of time that DHEC had to make the
9 decision that played into it

10 Q All right Tell me, what's Belfair's interest
11 in this, in this proceeding? Why does Belfair
12 have a concern or a stake in this?

13 A Well, frankly, the application that was
14 submitted is completely different than what has
15 been implemented and I would like to see an
16 application that is consistent with what's
17 implemented and see that approved
18 appropriately

19 MR PRINGLE Beg the Court's indulgence for just a
20 minute

21 A I apologize for interrupting, Your Honor

22 THE COURT You're fine

23 MR PRINGLE That's all I have, Your Honor

24 THE COURT All right Mr Dayhuff?

25 DR BORELLI - CROSS EXAMINATION BY MR DAYHUFF

1 Q Dr Borelli, the proposed MRI, the 1.5T 2004
2 model and the 1999 refurbished 1.5T model, the
3 MRIs themselves are quite similar, that was
4 your testimony, right?

5 A Yes

6 Q And they're quite similar because they have the
7 same magnetic strength field, correct?

8 A Yes, that's not in dispute

9 Q They are essentially the same model, are they
10 not, Signas?

11 A They're very similar

12 Q They're both -- the gradient speed is listed
13 for both as high speed, is that correct?

14 A Yes

15 Q They're both short bore?

16 A Yes

17 Q They both have the same diameter entrance into
18 the MRI?

19 A Yes, they sure do

20 Q They both have the same slew rate?

21 A Yes, they do

22 Q They both use Diacom 3.0 compatible --

23 A Pretty much all imaging equipment does

24 Q And they have a very similar coil complement,
25 the two, would you agree?

1 A Similar, yes .

2 Q All right You've testified about some things
3 that you believe are different and I want to
4 work through those Oh, channels, I didn't
5 want to forget about channels So your
6 testimony today is that you don't know whether
7 the proposed MRIs are four or eight channel
8 You're just raising the question?

9 A Looking at the documents, I suspected it was --
10 the original was an eight channel system, but
11 it's possible it may have been a four channel
12 system So, no, I would grant you that I
13 don't think it's clear

14 Q All right So you're not offering expert
15 testimony today that the proposed 2004 MRI was
16 eight channel?

17 A I'm not saying it was definitely eight channel,
18 no, I'm not

19 Q All right So that could indeed be another
20 reason they're quite similar They're both
21 four channel systems?

22 A That's correct

23 Q And if they're both four channel systems,
24 they're going to scan your average MRI knee at
25 the same speed, correct?

1 A There's a difference in gradient strength which
2 I talked about earlier

3 Q Okay Gradient strength, and that is measured
4 in millitesla per meter square, right?

5 A Right

6 Q And what is the gradient for the 2004 proposed
7 MRI?

8 A Thirty-three

9 Q And what is the gradient for the actual MRI?

10 A Twenty-three

11 Q All right And it was your testimony that --

12 THE COURT Wait a second Gradient --

13 A Gradient strength

14 THE COURT Gradient strength --

15 A Thirty-three versus twenty-three

16 THE COURT Thirty-three versus twenty-three?

17 A Correct

18 Q Millitesla per meter square, correct?

19 A Millitesla per meter

20 Q Per meter, okay And I believe you testified
21 that that difference in gradient strength would
22 amount to anywhere between a five and forty
23 second difference per sequence?

24 A Potentially, yes, depending on the type of
25 sequence, yes

1 Q Okay And how many sequences would there be in
2 your average knee scan?

3 A Knee, the ACR standard would require five
4 sequences

5 Q Five sequences and --

6 A We do more, but five, I think Six would be a
7 good number

8 Q All right Well, we'll take six So six
9 sequences And you think the difference, it's
10 obviously in the range between five and forty
11 seconds for a knee scan, what would the
12 difference be?

13 A Probably be closer to ten to fifteen seconds

14 Q Ten seconds times six sequences is sixty
15 seconds?

16 A Yeah

17 Q So that's a one minute difference --

18 A Yeah

19 Q -- on the average knee scan?

20 A Exactly

21 Q All right And have you looked at MRI, or I'm
22 sorry, Coastal's utilization numbers?

23 A Yes

24 Q Do you know about how many scans we're doing a
25 day?

1 A I think they did about, the last numbers I saw
2 were about 1,500 per year

3 Q Okay I think it's a little lower than that
4 I think we're doing about four a day Let's
5 assume that for purposes of your testimony If
6 you're doing four scans a day and those were
7 all knee scans, we would be talking about a
8 difference over the course of a day in four
9 minutes of scan time?

10 A If you're just doing knee scans, yeah, uh-huh
11 Not a big difference

12 Q All right Is that a substantial difference to
13 you from a clinical perspective?

14 A If it's a trauma patient, yes, those four
15 minutes count Or an acutely ill patient

16 Q All right Well, we're going to talk about
17 acutely ill patients So it's your testimony
18 that that's a substantial difference That's
19 a basis for DHEC to have found there was a
20 substantial change between the proposed and
21 actual?

22 A Yeah, uh-huh

23 Q All right You mentioned a few other things
24 That the proposed MRI had a non-ferrous IV
25 stand, right?

1 A That's what the quote showed

2 Q That's what the quote showed Do you know
3 whether or not the actual MRI has a non-ferrous
4 MRI stand?

5 A If it was part of the project, it should have
6 been reported to DHEC and it has not been
7 reported to DHEC as far as I know or submitted
8 into evidence, so -- but I don't know

9 Q You don't know?

10 A They could have put a 3T scanner in for all I
11 know

12 Q 3D work station you mentioned, that the
13 proposed has it listed on the quote

14 A Yeah

15 Q Do you know whether we have a 3D work station
16 at Coastal that's associated with the actual
17 MRI?

18 A If it was, it would have had to have been
19 disclosed to DHEC, but I don't know They
20 could have three as far as I know

21 Q But you don't know?

22 A No

23 Q The MRI wheelchair that you mentioned that was
24 in the proposed, do you know whether Coastal
25 has an MRI safe wheelchair?

1 A No, but again, it should have been disclosed to
2 DHEC as part of the MR project

3 Q All right And I believe you testified that a
4 substantial difference between the proposed and
5 the actual would be that you'd have to wiggle
6 the MRI, detachable MRI table, to get it out
7 the door?

8 A Out the door and onto the lift

9 Q Okay You can get it out the door and onto the
10 lift, though, right?

11 A Oh, it can be done but it's just much more
12 onerous

13 Q You just have to wiggle it?

14 A Yes And if you have an acutely ill patient,
15 it's difficult to do while watching the
16 patient

17 Q And that's a substantial change in your
18 clinical opinion, having to wiggle that table
19 to get it out?

20 A Yes, one of many, yes, one of many substantial
21 changes

22 Q Let's talk about the code blue for a moment
23 I'm not sure I understood why you thought the
24 code blue was different in what we -- our
25 proposed facility which would have been a new

1 construction on the left side of the hospital
2 and the code blue system we have in the actual
3 MRI, the mobile that's affixed adjacent to the
4 hospital What was the difference?

5 A If you look at that policy, there is a
6 discussion of what the code team does and what
7 the technologist team does, sort of the
8 interface between the outside environment and
9 the inside environment So, you know, the code
10 team comes in In the meantime, the tech is
11 pulling the patient out and pushing a special
12 button which I suspect doesn't exist everywhere
13 in the hospital It probably exists there
14 simply because that patient is outside the
15 hospital, outside of the intercom system, what
16 have you And that's a difference We also --

17 Q I'm sorry Maybe I'm not understanding The
18 difference is there is a button in the MRI
19 trailer that you would push for code blue and
20 there may not be a button in the interior of
21 the hospital for code blue?

22 A Right, right And it's because on the inside
23 of the hospital, there's an intercom You pick
24 up the phone In the hospitals I've been to,
25 and I've been several, there's a intercom you

1 pick up, you say code blue, room 233B or
2 something And boom, that gets -- everyone in
3 the hospital hears that And with this system,
4 there is a button to press and a number to
5 call The number didn't work The number's
6 not operative I challenge anybody to call
7 that number today

8 Q You called our code blue number?

9 A Yeah, the number 784-5555, yeah

10 Q So the difference there is to get assistance in
11 the hospital, you think we have to make a phone
12 call?

13 A Well, you'd probably use an intercom system,
14 but you probably don't have a button that you
15 push and the button is probably indicating
16 that, hey, we're outside the hospital, you need
17 to bring the code team outside the hospital
18 There's probably special considerations there

19 Q Well, isn't that the key? I mean the code team
20 comes to the area of the hospital where the
21 code is, right? That's how code teams work

22 A Yeah, generally

23 Q So if we had a code in the rehab area, the code
24 team would rush, an emergency room physician I
25 presume, others would rush to that area, right?

1 A Uh-huh (affirmative response)

2 Q Just as they would rush to the MRI out the door
3 under the awning to the MRI unit, right?

4 A Right

5 Q It's substantially the same

6 A One group's going outside, the other one isn't

7 Q And that's a substantial difference in your
8 mind?

9 A Yes, because what you can do in the confines of
10 the MR magnet is very limited So actually the
11 difference is, let me clarify That MR magnet,
12 that MR room, whether it's a magnet room or the
13 consult room, it's a very tight confine And
14 you try to get a code team in there with a sick
15 patient, with a technologist, with this
16 gigantic 88 inch long table, which you've
17 pulled out of the magnet, that's a very tight
18 space to run a code And that's why you need
19 to get the patient off of that table as fast as
20 possible So what the code team's going to be
21 doing differently there, they're going to be
22 trying to treat this patient, but in the
23 meantime, get the patient back into the safety
24 net of the hospital

25 Q Dr Borelli, I want to talk a little about your

1 concerns about your perceived differences
2 between the proposed and the original with
3 respect to acutely ill patients If I
4 understood your testimony, it is that we
5 proposed to treat acutely ill and now we can't,
6 isn't that right, isn't that the summary of it,
7 with our MRI?

8 A You can do it You just can't do it safely
9 without monitoring equipment

10 Q Okay Well, the key for you on that is
11 monitoring equipment, right?

12 A That is a big factor

13 Q All right And so the monitoring equipment
14 that one would use, it needs to be non-ferrous,
15 not metal, right?

16 A It typically has some minor ferrous elements to
17 it, but it has to be so non-ferrous that it's
18 not drawn into the magnet

19 Q I see And is it sometimes a wireless system
20 so you don't have extra wires on the patient
21 while they're being scanned?

22 A Wires on the patient, well, you have to have
23 EKG wires

24 Q Okay So there would be still wires on the
25 patient as they go into the tube as they're

1 being monitored?

2 A Onto the patient, yeah, taped to the patient
3 I've not seen a system without some sort of
4 wire on the patient

5 Q Are you familiar with any manufacturers of MR
6 safe monitoring equipment?

7 A Yes Invivo is one

8 Q Invivo Let's take a look at Invivo Take a
9 look at this screen It's a demonstrative
10 exhibit, DX20 Dr Borelli, is this the Invivo
11 you were referring to?

12 A That is one model by Invivo, yes

13 Q So that is a model that would allow an MR
14 provider, if they purchased this, to monitor
15 folks while they were in the MR environment?

16 A Yes, yes

17 Q Okay Did you see a quote that looked anything
18 like that or had that information on it in the
19 proposed MRI?

20 A I don't recall

21 Q Okay You don't recall whether or not that
22 equipment was listed in the proposed MRI?

23 A Yeah, I don't recall right here as I sit here

24 Q Okay If we didn't propose to buy that
25 equipment and we didn't include an equipment

1 quote that looks something like that, why would
2 you think that's a substantial change between
3 what we had proposed and what we're doing now?

4 A No, my point -- I'm not looking at specifically
5 what physically is there and what physically
6 isn't there and comparing the two I think
7 it's more important to look at, as I stated
8 earlier, what services can be provided and what
9 needs were described in the original
10 application and there's a big disconnect based
11 on everything I've seen

12 Q So you have no evidence that Coastal Carolina
13 intended in 2004 when the CON was approved to
14 buy that kind of equipment, do you?

15 A I don't recall, but I think it's irrelevant

16 Q Well, do you have any evidence that you could
17 offer us today that they intended to buy that
18 equipment, that's my question?

19 A No, I don't have any evidence

20 Q Okay All right And let's talk about acutely
21 ill a little bit Apparently, you reviewed our
22 narrative, our CON narrative, where we said
23 throughout that narrative that we intend to
24 treat acutely ill patients, ER patients,
25 inpatients, is that accurate, and outpatients?

1 A Right I think the acutely ill applies both to
2 the inpatient and ER patients but we can
3 interpret that differently

4 Q Okay Well, Doctor, you're not an expert in
5 determining when someone's acutely ill, are
6 you?

7 A Sure I am

8 Q Are you a hospitalist or an internist?

9 A No, but I'm a physician All physicians are
10 trained in treating acute illnesses

11 Q Well, and let me ask it this way maybe People
12 that are in the hospital as inpatients are
13 acutely ill, aren't they?

14 A Most of the time if you're in a hospital,
15 you're acutely ill If you're not acutely ill,
16 you're on your way in or on your way out

17 Q That's right You shouldn't be in the hospital
18 unless you're acutely ill But when you're
19 acutely ill and in a hospital, not all hospital
20 inpatients are on monitoring, are they?

21 A A large majority are or have some sort of
22 monitoring, otherwise why be in the hospital

23 Q Well, nurses can come check on you
24 periodically You could be in the hospital for
25 a variety of reasons I mean you're not saying

1 today, you're not testifying today that you
2 have to be on monitoring as an inpatient, are
3 you?

4 A No, you don't have to be, of course not You
5 could be in rehab, for example

6 Q And rehab folks aren't on constant monitoring,
7 right?

8 A Apparently not, right But you don't need an
9 MRI 24/7 for rehab patients either

10 Q And neither are inpatients constantly on
11 monitoring, are they?

12 A Most inpatients are

13 Q All right So most are?

14 A Yeah

15 Q How about ER patients? I've been to the ER and
16 I wasn't on constant monitoring Isn't it true
17 that ER patients don't need monitoring?

18 A You can walk to the ER with a sore throat You
19 can walk to the ER having bruised your knee
20 You're not going to need monitoring for that

21 Q Right

22 A But that wasn't the need described in the
23 project You're not going -- you're not going
24 to tell me that you need a \$3 2 million scanner
25 to scan people because of sore throats or they

1 bumped their knee

2 Q Dr Borelli, you would concede, you would admit
3 that not all ER patients, inpatients and -- ER
4 patients and inpatients need monitoring,
5 correct?

6 A I would say the scanner is definitely serving
7 non-acute patients, no question about it
8 There is no question They're serving
9 outpatients We're not disputing that Our
10 point is that the emphasis and the need for
11 24/7 coverage was the need to do acutely ill
12 patients

13 Q And acutely ill patients aren't all on
14 monitoring, are they?

15 A The vast majority If you're acutely ill, in
16 my opinion you need to be monitored

17 Q All right Your opinion as a radiologist, not
18 as a hospitalist or an internist?

19 A As a physician

20 Q Or someone that does rounds through a hospital?

21 A I've done rounds through a hospital many times
22 Too many times to count

23 Q Do you do rounds at Coastal Carolina?

24 A No, but I recall in my medical school which was
25 four years and residency training where we

1 rounded on patients, every one of them had some
2 kind of monitor on them I mean with rare,
3 rare exception,, maybe some patients on the
4 psychiatric ward, but with rare exception, they
5 were monitored

6 Q Do you know whether our med-surg beds all have
7 monitors?

8 A No

9 Q You don't, do you?

10 A No

11 Q All right

12 MR DAYHUFF That's all I have, Your Honor Thank
13 you, Doctor

14 THE COURT Ms Biggers?

15 MS BIGGERS No questions

16 THE COURT Re-direct?

17 MR PRINGLE Very quickly

18 DR BORELLI - RE-DIRECT EXAMINATION BY MR PRINGLE

19 Q Mr Dayhuff asked you some questions about
20 whether the mobile unit contained IV poles and
21 wheelchairs that may have been non-ferrous or
22 MR compatible, is that right?

23 A Yes

24 Q I'll refer you back to the policies and
25 procedures that we were talking about and the

1 one entitled Prevent Missile Effect in MRI
2 Department And I point you to the provisions
3 under that policy and ask whether you have any
4 additional opinion on IV poles or wheelchairs
5 in the mobile unit based upon that document?

6 A Yes Well, we see this policy from Coastal
7 Carolina Medical Center Number seven, "No IV
8 poles or infusion devices shall be brought into
9 the MR environment " Again, the reason that is
10 there is because those devices will fly into
11 the magnet and potentially kill, unfortunately
12 that's actually happened, or injure patients
13 And they have to be MR compatible Above that,
14 number six, "Patients will transported on
15 provided non-ferrous magnetic part
16 Wheelchairs shall not enter the magnet room or
17 any other transport " This seems to indicate
18 that they have a non-ferrous patient litter
19 basically for patients that have to be supine,
20 okay But they don't have an MRI compatible
21 wheelchair And I'll tell you, I would guess
22 that there's a larger number of patients that
23 are in wheelchairs than need to be on a litter
24 in a hospital because there's certainly a
25 substantial number, and we see patients in

1 wheelchairs quite frequently But this policy,
2 unless this policy is inaccurate, it would
3 indicate they do not have an MRI compatible
4 wheelchair I don't know how they get patients
5 into that magnet door who are non-ambulatory
6 especially when they're trying to serve acutely
7 ill patients

8 Q Mr Dayhuff asked you some questions about
9 whether, under the code blue procedures, about
10 who might end up in the trailer or in the MRI
11 Do the code blue procedures talk to who can or
12 can't be in there during a code situation?

13 A Yes Here we see, "Refer to hospital and
14 radiology guidelines for all codes, there are
15 additional duties in the MRI Department It is
16 the responsibility of the MRI technologist to
17 remove the patient from the magnet room in the
18 event of a code or a patient requiring medical
19 attention assistance "

20 Q So who's in the magnet room during a code?

21 A Only the technologist

22 Q Okay, okay Would additional individuals come
23 into the room during a code procedure?

24 A No, not into the magnet room And they are not
25 permitted by policy, and I agree with that

1 appropriate policy Because people that run
2 the code, Your Honor, the physicians, they're
3 generally not going to be working in the MRI
4 environment regularly and a lot of disasters
5 have happened nationwide where patients that
6 are not specifically trained on MR safety have
7 --

8 THE COURT Patients, what do you mean?

9 A Excuse me?

10 THE COURT You said -- I think you said patients
11 who are not --

12 A I meant to say staff, the physicians The
13 physicians and other staff and nurses that may
14 respond to a code are generally not trained and
15 do not have experience with MRI safety And
16 the reason they're excluded from the magnet
17 room by policy, and by this policy here, and
18 it's a good policy, and it comes right from the
19 ACR, our own document, the ACR guidance for MRI
20 safe practice published in 2007, it's because
21 disasters have happened A young boy was
22 killed when one of the -- someone responding to
23 a code brought an oxygen bottle into the room
24 It was a metallic oxygen bottle, went flying
25 into the magnet bore and killed a 12 year old

1 boy It was a horrible accident And so, yes,
2 only people that are MRI certified, in this
3 case, this document says only the technologist
4 is certified to be in that room So what does
5 this mean? So that's really the same between
6 both projects You're going to have an MR room
7 in the fixed project You're going to have an
8 MR room here But the difference here is
9 you've got this whole code team now, they can't
10 go into the magnet room They're stuck to that
11 tiny little place, that consult area If you
12 could pull that up, let's just look at that
13 again And just imagine getting several people
14 in there in a code Now, you know, if you're
15 not scanning acutely ill patients, a chance of
16 someone having a code in the magnet room is
17 diminimus But if you're going to be focusing
18 on acutely ill patients and you're going to put
19 them in that magnet, you better be prepared to
20 run a code because someone's going to try to
21 die on you in there And just look at this
22 space here This is not a large space You're
23 going to have this -- take this table and
24 imagine it right here Now, is there really
25 room to work around that patient in that room,

1 in that area? I would say no It would be
2 very difficult to run a code there and that's
3 why their policy says get that patient out of
4 there, get the patient on the lift, back into
5 the hospital, into the safety net of the
6 hospital

7 Q No further questions, Your Honor

8 MR DAYHUFF Nothing further, Your Honor

9 THE COURT You may step down

10 MR PRINGLE Dr Borelli is MRI at Belfair's sole
11 witness in the case

12 THE COURT All right Do you have a short witness?

13 MR DAYHUFF I do, Your Honor

14 THE COURT Okay

15 MR DAYHUFF Coastal would like to call Dr Dean
16 Moesch

17 THE COURT I think y'all may be answering my
18 question that I had later for y'all today and
19 that is -- you can go ahead and step around
20 And that is I wanted to know if we need to go
21 late tonight to make sure we get through in two
22 days, but it looks like we're going to be able
23 to get through in two days

24 MR DAYHUFF I think we're doing pretty well

25 THE COURT Okay All right

1 DEAN V MOESCH, M D , being duly sworn, testifies as
2 follows

3 COURT REPORTER State your full name, please

4 DR MOESCH Dean Vincent Moesch

5 THE COURT Spell that last name

6 DR MOESCH M-O-E-S-C-H

7 DR MOESCH - DIRECT EXAMINATION BY MR DAYHUFF

8 Q Dr Moesch, where do you live?

9 A Savannah, Georgia

10 Q Have you been asked by counsel for Coastal to
11 be here to offer some opinions in this case?

12 A Yes, sir

13 Q All right Let's start by summarizing the
14 qualifications you possess that would enable
15 you to offer opinions in this matter First,
16 tell me what kind of a physician you are

17 A I'm a radiologist

18 Q And tell me about your professional education
19 starting with medical school

20 A Okay I graduated from the Medical College of
21 Georgia in 1984 I did a one year general
22 surgery residency followed by a four year
23 diagnostic radiology residency

24 Q All right

25 THE COURT Can you hear him?

1 Q You'll have to speak up a little, Doctor We
2 can move that microphone What year did you
3 complete residency?

4 A 1989

5 Q 1989 And after residency, did you begin
6 practicing radiology?

7 A Yes, sir

8 Q Where did you begin practicing?

9 A At an imaging center in Savannah, Georgia

10 Q Okay And just kind of walk us through your
11 experience in radiology after your residency
12 going forward

13 A I worked at an MRI facility in Savannah,
14 Georgia for approximately a year and a half
15 Then joined the group at Candler Hospital in
16 Savannah I was there approximately fifteen
17 years I then took over the Radiology
18 Department at Memorial Health University
19 Medical Center in Savannah I was there for a
20 little under two years and since that time I've
21 been at Coastal Carolina

22 Q All right You said you took over the
23 radiology at Memorial Health What does that
24 mean? Did you direct it?

25 A I was the director of the Radiology Department,

1 yes, sir

2 Q All right And as director, your duties were
3 what?

4 A I was responsible for 17 radiologists, 16
5 radiologists and basically the workings of the
6 department

7 Q What kind of MR do they have at Memorial?

8 A We had a 1.5, I believe we had an open magnet,
9 and we had a magnet in a trailer in the parking
10 lot

11 Q All right And what kind of magnet was it at
12 Candler, if you recall, and you may not?

13 A I believe we had a GE 1.5 in the hospital

14 Q All right, sir And now you're working at
15 Coastal Carolina?

16 A Yes, sir

17 Q All right What do you do for Coastal?

18 A I'm the sole radiologist at the facility

19 Q Do you also direct -- are you also the director
20 of radiology for Coastal?

21 A Medical director, yes

22 Q Medical director, okay And what are your
23 duties as medical director of radiology at
24 Coastal?

25 A I just oversee the examinations and, you know,

1 tailor the examinations to what the patients
2 need

3 Q Are you board certified in radiology?

4 A Yes, sir

5 Q When did you become board certified?

6 A 1989

7 Q And doing work in radiology, obviously MRI is
8 a subset of that Have you had a lot of
9 experience with MRI over the years?

10 A Yes, sir

11 Q All right Working with MRI, reading MRI
12 scans, how many years of experience have you
13 had?

14 A I was really like one of the first groups of
15 residents that were trained in MRI I worked
16 on the second MRI scanner in Georgia at the
17 time, so I kind of started with it in its
18 infancy and been working with it ever since

19 MR DAYHUFF At this time, Your Honor, I'd like to
20 qualify Dr Moesch as an expert in radiology to
21 include clinical expertise in matters regarding
22 MRI

23 MR PRINGLE No objection

24 MS BIGGERS No objection

25 THE COURT He's so qualified

1 Q Dr Moesch, what is your understanding of the
2 MRI project that we proposed, Coastal proposed,
3 in its 2004 CON application?

4 A I believe we proposed a GE 1.5 Tesla magnet to
5 be built on the building to the facility
6 adjacent to the emergency room

7 Q And what do we have currently at Coastal?

8 A We have a GE 1.5 Tesla magnet in a fixed
9 trailer adjacent to the hospital

10 Q All right. Take a look at the screen and let's
11 make sure we're talking about the same MRI. Is
12 this the MRI we have at Coastal that I showed
13 a picture of earlier in the opening?

14 A Yes, sir

15 Q All right. And where is its location in
16 relation to the main hospital?

17 A It is immediately adjacent to the hospital
18 attached by a covered walkway

19 Q All right. Let's go to the next exhibit. This
20 is a document that is in the DHEC record at
21 951. It's 951. Dr. Moesch, can you see that,
22 does that fairly represent the location of the
23 MRI at Coastal?

24 A I'm trying to kind of get oriented here a
25 little bit

1 Q I'm sorry Dan, pull out a little bit so he
2 can see that

3 A Yes, sir, it is

4 Q Okay, good All right You heard Dr Borelli
5 testify earlier today?

6 A Yes, sir

7 Q He offered items that he thought represented a
8 substantial or offered testimony to the effect
9 that the MR we proposed in 2004 is
10 substantially different or is a substantial
11 change from what we ultimately implemented in
12 2007, right?

13 A Yes, sir

14 Q Do you agree or disagree with Dr Borelli's
15 conclusion?

16 A I disagree

17 Q All right What factors or components of the
18 two MRIs are important for you to analyze as a
19 clinician to make the -- come to a conclusion
20 about whether they're substantially the same or
21 different?

22 A The magnets are made by the same vendor They
23 are of the same field strength, 1.5 Tesla
24 They, as I understand it, have the same four
25 chamber scanners The coils are basically the

1 same coils They provide the same images that
2 the proposed would have I really just don't
3 see any type of significant difference

4 Q What were you able to review to make this
5 comparison that I asked you to undertake
6 between the proposed and the actual?

7 A I believe I looked at the proposal that was
8 given, I guess, initially from the hospital to
9 DHEC

10 Q All right Take a look at the screen and tell
11 me if this is what you reviewed And we can
12 get you a little closer to the top

13 A Yes, sir, it is

14 Q All right And what else did you review?

15 A I believe it was like a purchase proposal for
16 the magnet we currently have

17 Q All right Take a look at the screen and tell
18 me if this is what you looked at

19 A Yes, sir, it is

20 Q That look familiar, okay Does what we have on
21 the screen now, which is CCMC Exhibit Five,
22 does that accurately represent the actual MRI
23 that we have at Coastal?

24 A Yes, sir

25 Q All right Well, when you do your inquiry

1 between the quote and this MRI coil inventory
2 is what it's called, what did that inquiry
3 reveal?

4 A That they were, you know, basically the same
5 scanner from a clinical standpoint

6 Q What kind of scans do we do most commonly at
7 Coastal?

8 A Typically we will do MR brains, cervical,
9 thoracic and lumbar spines and joints

10 Q Is there a significant difference in your
11 opinion in the capability of the proposed and
12 actual to perform the scans of the kind we do
13 most commonly at Coastal?

14 A No, sir

15 Q Dr Borelli offered the opinion that it was a
16 substantial difference, the gradient strength
17 was a substantial difference in his mind, 23
18 versus 33 millitesla per meter square or not
19 squared, per meter Do you agree or disagree
20 with that opinion?

21 A It can add a few seconds to your scan time, but
22 I don't think it's a clinically relevant
23 difference

24 Q Dr Borelli also talked a lot about the safety
25 matters with our mobile MRI As the medical

1 director of radiology, do you have knowledge of
2 how we handle safety issues with respect to the
3 MRI?

4 A Yes, sir

5 Q All right Well, tell us about that

6 A Obviously, we take safety very seriously We
7 do mock codes from time to time just to make
8 sure everybody knows, you know, where they need
9 to be going and the fact that, you know,
10 there's a magnetic field and things like that
11 And our technologist obviously understands how
12 we get the patients out and available for
13 whatever measures are necessary

14 Q All right Take a look at the document I'm
15 going to put up on the screen for you to look
16 at and see if you can tell me what this is?
17 This is CCMC Exhibit Six and it's a pretty bad
18 copy, but let's get you to close to the top and
19 see if you can -- can you read that on your
20 screen, Dr Moesch?

21 A Yes, sir

22 Q All right Tell us what that is

23 A That is a list of our basic emergency cart in
24 the MRI scanner

25 Q All right And what's the emergency cart used

1 for?

2 A For any type of codes or whatever in the scan

3 area

4 Q All right And that's -- that list accurately

5 reflects what you have in the emergency cart?

6 A Yes, sir

7 Q All right Let's take a look at the bottom

8 There's something handwritten down there Can

9 you read that?

10 A Yes, sir

11 Q What is a Lifepak 20 defibrillator and monitor?

12 A It is basically like a portable EKG monitor and

13 it provides the shocks to the patient to try to

14 resuscitate

15 Q All right And then it says two O2 tanks non-

16 ferrous What are those?

17 A They're just two oxygen tanks that we have

18 available out in the trailer for emergencies

19 Q All right Let's take a look at the next photo

20 if we could And tell me what we're looking at

21 her, Dr Moesch

22 A You are looking at the steps going up to the

23 trailer

24 Q Okay The trailer that contains the actual

25 MRI, right?

1 A Yes, sir

2 Q And how far is it, I don't know if you measured
3 it, but approximately how far is it from the
4 door to the MRI from the hospital?

5 A From the door of the trailer to the door of the
6 hospital?

7 Q Correct

8 A I would imagine probably 12 yards maybe, 15
9 yards

10 Q Do you believe you could perform CPR on that
11 lift if you had to?

12 A Yes, sir

13 Q Dr Borelli testified, I guess, that there's a
14 substantial difference between the proposed and
15 the actual in that we can't treat patients on
16 monitors or patients being monitored in the
17 actual MRI but we could have in the proposed
18 Do you have any opinions about that?

19 A I'm sorry, could you say that one more time?

20 Q Yeah Dr Borelli testified about our
21 inability now to scan patients who are in need
22 of constant monitoring Do we scan patients
23 who are on constant monitoring?

24 A No, sir, we do not

25 Q All right But do we scan acutely ill patients

1 who come from the ER and inpatient beds, med-
2 surg beds?
3 A Yes, sir
4 Q All right But they're not on monitoring?
5 A Correct
6 Q All right You reviewed the equipment for the
7 proposed MRI in 2004, correct?
8 A Yes, sir
9 Q Did you see any of the wireless non-ferrous
10 specialized MRI monitoring equipment associated
11 with the proposed MRI in 2004?
12 A No, sir
13 Q Please answer any questions Mr Pringle has for
14 you
15 THE COURT Well, Ms Biggers
16 MR DAYHUFF Oh, I'm sorry, Ms Biggers
17 MS BIGGERS I have no questions
18 THE COURT Now Mr Pringle Hold on one moment
19 before you go Hold on one moment
20 MR PRINGLE Your Honor, we may need a break at
21 this point, if possible I don't know whether
22 Your Honor's inclined to grant one
23 THE COURT I'll take a five minute break if you
24 need that
25 MR PRINGLE Okay Okay

1 MR DAYHUFF That's fine I just want to make sure
2 we didn't -- I'd like Dr Moesch to be released
3 if it's okay with you after his testimony I
4 wouldn't want to stretch it over

5 THE COURT We'll take a five minute break I'm
6 going to break for lunch later on Thank
7 y'all

8 (Short break)

9 THE COURT Mr Pringle?

10 DR MOESCH - CROSS EXAMINATION BY MR PRINGLE

11 Q Dr Moesch, you mentioned that CCMC does not,
12 and tell me if this is your testimony, does not
13 scan patients, acutely ill patients, that
14 require constant monitoring, is that correct?

15 A Well, our patients can't go in the scan room
16 with their monitoring equipment on We will
17 consult with their physician whether they are
18 stable or not to be taken off their monitoring
19 equipment to be scanned

20 Q Okay But if they require the monitoring
21 equipment stay on, you're not going to scan
22 them?

23 A That's right

24 Q Okay, okay Can we agree, for example, that a
25 major trauma patient, use an example of someone

1 in a car wreck with a possible spinal cord
2 injury, requires constant monitoring?

3 A Yes, sir, generally they do and they require a
4 neurosurgeon to be --

5 Q Okay So that scan could not be conducted at
6 CCMC?

7 A That's not what I said

8 Q Okay

9 A They can be put in the scanner and scanned but
10 not with monitoring equipment

11 Q Okay

12 A If their only injury was a potential spinal
13 cord injury, they could certainly probably be
14 scanned without their monitoring equipment

15 Q Okay But, again, if the injury required
16 constant monitoring equipment, then CCMC could
17 not do it?

18 A I think I stated that, yes, sir

19 Q Also, how about acute internal injuries caused
20 by a car accident, wouldn't that require
21 constant monitoring?

22 A I think -- can I explain something --

23 Q I think you can answer the question and then
24 explain your answer

25 A Well, then ask the question again

1 Q The answer to the question is yes?

2 A Ask the -- no, ask me the question again

3 Q Okay Would an acutely -- acute injuries,
4 acute illness resulting from internal injuries
5 in a car accident require constant monitoring?

6 A They would but we wouldn't be doing an MRI scan
7 on those patients

8 Q Okay All right Why would you not be doing
9 MRIs on --

10 A Because a CAT scan would be the procedure of
11 choice, not an MRI scan

12 Q Not an MRI scan What about a combination of
13 that internal injuries and a spinal cord
14 injury?

15 A That would be up to the emergency room
16 physician, but I would -- in our facility, they
17 would be stabilized and transferred

18 Q Okay Transferred to another facility?

19 A To a facility where they have a neurosurgeon
20 and a trauma center

21 Q Okay, okay On that point, CCMC is not a
22 trauma center, is it?

23 A No, sir, we're not

24 Q Okay So just as a follow up, does CCMC
25 perform scans on critically ill patients in its

1 MRI?

2 A You have to determine what critically ill is,
3 I suppose

4 Q Okay But going back to the touchstone that if
5 it needs constant monitoring, you won't scan
6 them?

7 A We are not able to scan patients that are
8 monitoring, that require monitoring in the MRI
9 scan

10 Q Okay, okay You were asked some questions
11 about defibrillator, a Lifepak 20 Isn't it
12 true that that Lifepak 20 defibrillator is not
13 MR compatible?

14 A I would think they're probably not compatible,
15 yes, sir

16 Q Okay

17 A So you couldn't use it in a scan room

18 Q Okay, okay So it wouldn't be available for
19 MRI monitoring?

20 A You would not use a Lifepak for MR monitoring

21 Q Okay, okay I talked -- were you in the
22 hearing room when I talked with Dr Borelli
23 about CCMC's MRI procedures and policies?

24 A Yes, sir

25 Q Have you seen these policies before?

1 A To be honest with you, I don't remember seeing
2 those, no, sir

3 Q Okay And you're the director of radiology at
4 CCMC?

5 A Yes, sir

6 Q But your testimony is you haven't seen --

7 A That's not my -- my testimony was I do not
8 remember seeing those, not that I haven't seen
9 them

10 Q Okay You mentioned that you do mock codes of
11 various types and I've pulled up the page on
12 code blue procedures Are you involved in
13 those -- have you been involved in mock code
14 procedures in the code blue instance?

15 A Yes, sir, I have

16 Q Okay And how have you participated, what has
17 been your role in that?

18 A I'm one of the code members that respond

19 Q Okay Take me through what happens in that
20 instance

21 A The whole mock code is not known to anybody,
22 and I believe it's the director of nursing who
23 decides when we're going to have them No one
24 knows that we're having them so they can't
25 prepare for them She goes out to the MRI

1 trailer and begins a code blue procedure

2 Q Okay What is that code blue procedure, how
3 does that work?

4 A There is a button in the trailer that they push
5 that notifies the hospital that there's a code
6 in the trailer It notifies the hospital
7 operator who then calls the code blue over the
8 telephone system, over the intercom system

9 Q Okay Would it surprise you to learn that the
10 number listed in the code procedures is a non-
11 working number?

12 A No, sir, it wouldn't because when the hospital
13 was bought out by Tenet Corporation, all of our
14 telephone numbers changed

15 Q Okay, okay When did Tenet -- has this policy
16 been reviewed?

17 A I'm sorry

18 Q Well, if you could look at the document there,
19 there's a review date contained thereon Could
20 you tell me what that date is? It's in a
21 little box

22 A It was not reviewed by me, no, sir

23 Q Okay Can you tell me what the review date is?

24 A It says February 2008

25 Q Okay So it's due to be reviewed then?

1 A I would assume so, yes, sir

2 Q Do you know whether it was reviewed?

3 A I do not

4 Q Should it have been reviewed?

5 A If it was up for review, I assume so

6 Q Okay Should it have had an updated phone
7 number in it?

8 A I would think so

9 Q Okay

10 A I can assure you that the technologist who
11 works in the trailer knows what numbers to
12 call

13 Q Okay Okay Let me ask you about another one
14 and this is one that Dr Borelli talked about
15 in the -- I believe it was the involving
16 avoiding the missiles And you say you heard
17 Dr Borelli's testimony about wheelchairs
18 that's in item six thereon It says,
19 "Wheelchairs shall not enter the magnet room or
20 any other transport device " Do you see that?

21 A Yes, sir

22 Q How do you get wheelchair bound patients into
23 the MRI?

24 A We would have a non-ferrous wheelchair

25 Q So you do have a non-ferrous wheelchair but

1 this policy says wheelchairs shall not enter
2 the magnet room or any other transport device
3 A It's my understanding, I don't want to
4 misspeak, but it's my understanding that we
5 have a non-ferrous wheelchair
6 Q Okay
7 A And a non-ferrous IV pole
8 Q All right Let me ask you a question I don't
9 know whether you've seen or not, and I don't
10 have this to throw up and I can show you in
11 your -- it's Respondent's Exhibit Number
12 Twenty, and it's a certificate whereby Coastal
13 Carolina was accredited by the Joint
14 Commission Do you know what the Joint
15 Commission is?
16 A Yes, sir
17 Q Tell the Court what the Joint Commission is
18 A The Joint Commission, I suppose, is a reviewing
19 body that makes sure that all hospitals are up
20 to certain standards
21 Q Okay And so -- and does this document
22 indicate that Coastal Carolina has that
23 certification?
24 A What document?
25 Q This is Exhibit Twenty to Respondent's

1 MR DAYHUFF Jack, we can put on the screen if you
2 want Dan, can you put it on the screen?
3 Q It's your understanding that CCMC is so
4 accredited?
5 A Yes, sir
6 Q Okay Along with -- and you're familiar with
7 the Joint Commission generally How about
8 specifically with respect to MRI procedures?
9 A No, sir, I'm not
10 Q Okay Let me ask you if you've seen -- let me
11 show you a document that's from the Joint
12 Commission entitled Preventing Accidents and
13 Injuries in the MRI Suite and ask you to look
14 at, and you can certainly read this if you
15 like, but to look at number eight that's listed
16 thereon in this Joint Commission document
17 regarding preventing accidents and injuries in
18 MRI suites
19 A What's the question?
20 Q Why don't you just read that number eight out
21 loud
22 A "Proactively plan for managing critically ill
23 patients who require physiologic monitoring and
24 continuous infusion of life sustaining drugs
25 while in the MRI suite "

1 Q Okay Did CCMC comply with that particular
2 directive?

3 A If you're asking me if we can monitor patients
4 in the MRI scanner, we are not capable of doing
5 that, no, sir

6 Q Okay Okay To the extent that this document
7 has some recommendations or directives, are
8 CCMC's procedures at odds with that Joint
9 Commission recommendation?

10 A Obviously we can't monitor the patients in
11 there, so I would say the answer is yes

12 Q Okay Why is it that -- why would CCMC not
13 have MR compatible monitoring equipment?

14 A My honest answer would be every time we've
15 requested it we've been told we don't have the
16 money, have the funds available to purchase it

17 Q Okay You're not using the, I think we talked
18 about this a little bit in your deposition,
19 you're not using the scanner in any substantial
20 way after hours, are you?

21 A Substantial meaning?

22 Q Well, you're not doing many scans in the middle
23 of the night, are you?

24 A We do scans, you know, here and there between
25 three and eleven We don't do many after

1 midnight We do some on weekends

2 Q And in fact, there's some documentation that's
3 been provided as an exhibit that shows that
4 over a certain period of time that you did no
5 scans at all between 11 00 p m and 7 00 a m ,
6 is that correct?

7 A Just because they haven't been ordered, yes,
8 sir

9 Q Okay Okay Let's talk a little bit about,
10 you gave an opinion that there was no
11 significant difference, and tell me if this is
12 the case, in quality between the proposed in-
13 house scanner and the mobile that became part
14 of CCMC, is that correct?

15 A I think I testified that they were the same
16 equipment

17 Q Okay But there was some discussion that they
18 do have different gradients, is that correct?

19 A That's correct

20 Q In discussing, for instance, a patient who --
21 well, let me ask it this way In order to
22 perform certain scans, it requires that a
23 patient be still or immobile, is that correct?

24 A That's correct

25 Q Okay And patient motion that takes place in

1 the context of a scan, it may very well cause
2 a scan to take longer, is that correct?

3 A It wouldn't cause it to take longer It would
4 cause it to be of poor quality

5 Q So it will affect quality as well as the
6 efficiency of the scan, being able to get a
7 quality scan in a certain amount of time,
8 correct?

9 A If you have to repeat the scan, it would
10 increase the time

11 Q Okay Wouldn't a higher gradient affect that
12 quality and allow those scans to take place
13 more efficiently?

14 A I think we've established that the gradient
15 difference, you know, adds five, ten seconds to
16 a scan

17 Q Would that difference be augmented or added to
18 a little bit if you're talking about somebody
19 who has to remain in the scanner for a long
20 time and immobile?

21 A In my clinical practice, I don't really see
22 where it's really made any difference to me

23 Q Okay Could it make some difference?

24 A As far as what?

25 Q As far as the ability to --

1 A It makes a difference in it's five seconds
2 longer, that's about the extent of it

3 Q Okay Is CCMC accredited by the American
4 College of Radiology?

5 A No, sir

6 Q Why not?

7 A We haven't applied for accreditation at this
8 point

9 Q Do you have plans to do so?

10 A Yes, sir

11 Q Okay And how long have you been at CCMC?

12 A Several years

13 Q Okay Does Hilton Head Medical Center enjoy
14 accreditation by the ACR to your knowledge?

15 A I don't know

16 MR PRINGLE Okay That's all that I have

17 THE COURT Re-direct

18 MR DAYHUFF Just a couple

19 DR MOESCH - RE-DIRECT EXAMINATION BY MR DAYHUFF

20 Q The defibrillator that was listed on the
21 document that we had up a few minutes ago I
22 think Mr Pringle asked you whether or not that
23 could be brought into the magnet room and you
24 said no?

25 A I'm not sure I don't believe so

1 Q Can it be used in the room that is immediately
2 adjacent to the magnet room?

3 A Correct, yes Yes

4 Q All right He asked you a couple questions
5 about at what times we're treating patients
6 We do the majority of our scans between seven
7 and four or five, kind of normal business
8 hours?

9 A Yes, sir

10 Q Are you aware of scans that we have done
11 between four and eleven?

12 A Yes, sir

13 Q Are you aware of scans that we have done from
14 eleven at night to seven in the morning?

15 A We've done a few

16 Q Not many, but we have done some

17 A We have a technologist on call 24 hours a day
18 and if people order them and want them, if it's
19 an emergency, we'll be happy to do them

20 MR DAYHUFF All right, no further questions, Your
21 Honor

22 MS BIGGERS Nothing

23 THE COURT Any re-cross on those limited questions?

24 MR PRINGLE No, Your Honor

25 THE COURT You may step down How long is the next

1 witness going to be?

2 MR DAYHUFF The next one would be a long witness,

3 I think

4 THE COURT Okay Then we're going to break for
5 lunch

6 (Break from 12 33 p m until 1 30 p m)

7 THE COURT Mr Dayhuff

8 MR DAYHUFF Your Honor, at this time I'd like to
9 call Kathy Platt to the stand

10 KATHRYN M T PLATT, being duly sworn, testifies as
11 follows

12 MS PLATT - DIRECT EXAMINATION BY MR DAYHUFF

13 Q Ms Platt, where do you live?

14 A I live at 691 Amsterdam Avenue, Atlanta,
15 Georgia, 30306

16 Q Have you been retained by counsel for Coastal
17 as an expert in this case?

18 A Yes

19 Q What are your areas of expertise?

20 A Healthcare planning and finance

21 Q Let's summarize your qualifications that relate
22 to your expertise in healthcare planning and
23 finance Let's start with your education

24 A All right I have a Bachelor's of Science in
25 Psychology from Emory University and an MBA

1 concentrating in healthcare and finance from
2 Boston University

3 Q When did you get your MBA?

4 A I graduated in 1989

5 Q And why don't you walk me through your
6 experience in healthcare planning and finance

7 A Okay I worked at Massachusetts General
8 Hospital in Boston for a year in the finance
9 department working with various departments of
10 the hospital on their budgets and financial
11 analysis I moved to Atlanta then and began
12 working with Sullivan Consulting Group in
13 healthcare planning and finance Sullivan
14 Consulting Group is a healthcare only
15 consulting firm And I worked with them from
16 January 1990 until December of 2007 (sic), and
17 then I started Platt HMC consulting firm, in
18 January of 2000

19 Q Give us a sense of what kind of healthcare
20 planning and finance work you're doing as a
21 consultant both with Sullivan and now on your
22 own

23 A Probably about 60 to 70 percent of what we do
24 is either preparation of CON applications or
25 assistance in litigation of CON applications,

1 opposition to applications The remainder is
2 strategic planning, market analysis, business
3 analysis, all within the healthcare context
4 In terms of finance, we do financial analysis
5 for healthcare clients and all CON applications
6 require the preparation of a financial pro
7 forma for presentation to the state

8 Q In what states have you worked?

9 A Let's see Florida, Georgia, South Carolina,
10 North Carolina, Virginia, West Virginia,
11 Kentucky, Alabama I think that's all I can
12 recall at the moment

13 Q In those states give me a sense of how much of
14 your work is related to MRI issues and
15 services

16 A Okay MRI services are routinely regulated by
17 lots of states Some states have more recently
18 begun to deregulate MRI like they have here in
19 South Carolina It may just be a capital
20 expenditure issue But MRI applications are
21 routinely filed all the time in most states
22 I believe last year we may have filed nine MRI
23 applications I think this year to date we've
24 done three so far, so it's the type of thing
25 that we're doing all the time

1 Q Have you had any experience with the
2 substantial change issue that we're litigating
3 today?

4 A Yes

5 Q Tell me about that

6 A It's the type of situation that comes up all
7 the time, clients are inquiring, you know, if
8 we proposed a CON this way and we want to
9 change something about it, is that a problem,
10 you know, how do we find out from the state if
11 that's a problem or not So it's a type of
12 inquiry that I make to state agencies on a
13 routine basis and give my clients advice about
14 all the time

15 Q Have you ever been qualified by a court as an
16 expert?

17 A Yes

18 Q How many times have you been qualified that you
19 recall?

20 A About 30

21 Q And have you been qualified with ALC before?

22 A Yes

23 Q South Carolina ALC Have you ever been denied
24 qualification as an expert?

25 A No

1 MR DAYHUFF Your Honor, we have Ms Platt's CV at
2 Exhibit Seven in our exhibits But at this
3 time, we'd like to move her admission as an
4 expert in healthcare planning and finance

5 MR PRINGLE Without objection

6 MS BIGGERS No objection

7 THE COURT So qualified

8 Q Before we get to your opinions, tell me what
9 work you had to accomplish, if any, before you
10 were able to offer opinions

11 A Okay For this case, I reviewed the DHEC
12 record I looked at a variety of material
13 provided in discovery for both Coastal Carolina
14 and MRI at Belfair, such as utilization data on
15 MRI services I read depositions for Dr
16 Moesch, Dr Borelli, Teresa Urquhart, who is
17 the administrator of Coastal Carolina I went
18 down to Coastal Carolina, looked at their MRI
19 unit and saw the hospital I met with a number
20 of physicians who are on the medical staff of
21 Coastal Carolina Medical Center

22 Q All right Are the documents that you
23 reviewed, the inspections and interviews that
24 you undertook appropriate sources of
25 information upon which a healthcare planner

1 would rely to offer opinion testimony?

2 A Yes, it's the type of documentation that we
3 look at for all of the types of cases we're
4 involved in

5 Q All right Let's move on to your opinions
6 Have you reviewed the DHEC regulations
7 regarding substantial change?

8 A Yes

9 Q Dan, could you put Section 605 for me, please
10 All right Ms Platt, is this the regulation
11 you reviewed?

12 A Yes, it is

13 Q Tell us what your understanding of this
14 regulation is

15 A This is the regulation that provides guidance
16 as to how the Department should look at a
17 project that is either amended or altered after
18 a Certificate of Need is granted and provides
19 that the Department shall determine whether
20 that change would be substantial enough to
21 require an entirely new project review

22 Q All right And what factors do you believe are
23 appropriate to analyze to determine whether a
24 CON project has changed or not, substantially
25 changed?

1 A Well, under the initial review, they look to
2 the CON criteria to determine if the project
3 meets each of those relevant criteria, so under
4 substantial change you would look back to the
5 criteria And not all of them will necessarily
6 apply or the change will not impact all of
7 them, but they would look at the ones that
8 could potentially change as a result of the
9 alternations to the project and decide whether
10 the project would, say, no longer meet on of
11 the project review criterias as revised

12 Q Have you had some exhibits prepared by you or
13 with input by you that will help you explain
14 your opinions to the Court today?

15 A Yes

16 Q All right Let's start through those All
17 right MRI project review criteria, what is
18 this slide?

19 A This is a summary of the criteria that I looked
20 at with respect to the changes to the MRI
21 project at Coastal Carolina Medical Center
22 The first four, I believe, were mentioned
23 previously were the ones that came up in the
24 State Health Plan as being criteria most
25 important to an MRI review And the last two,

1 financial feasibility and adverse impact, are
2 not listed in the State Health Plan, but I have
3 looked at those also

4 Q Let's move through each of these then First,
5 tell us briefly what is need

6 A Need is, there's really kind of two types of
7 need and they're interrelated One is does the
8 service area, the patients who are going to be
9 served by the proposed project, do they have a
10 need for the project, will they utilize the
11 services And typically they would -- you
12 would do utilization projections for the
13 project to show that the project is needed
14 There's also need with respect to the State
15 Health Plan for services that are specifically
16 regulated under the State Health Plan There's
17 sometimes a need methodology or a need
18 consideration under the State Health Plan

19 Q All right Let's move to Ms Platt's need
20 exhibit Tell us what this exhibit or how this
21 exhibit is important to your analysis

22 A All right This is the actual utilization of
23 the MRI unit at Coastal Carolina Medical
24 Center So you can see in the first partial
25 year of operation they provided 240 scans In

1 the second year of operation the volume
2 increased to 993 scans And then in the third
3 year it dropped off just a bit to 845 scans
4 So this is basically a measurement of need now
5 that the project has been implemented It is
6 being utilized by the patients of the hospital,
7 physicians are referring patients to that MRI
8 unit as implemented So it's, you know,
9 meeting the needs of the hospital's patients

10 Q And how does this play into the substantial
11 change issue? How does it factor into that
12 analysis?

13 A Well, if you look at the application, there was
14 a projection of utilization and, you know, a
15 description of the needs of the patients of
16 Coastal Carolina Medical Center for MRI
17 services And you can see that as implemented
18 in the stationary mobile unit, it is needed, it
19 is being utilized So under both the original
20 proposed scenario and the way it was ultimately
21 impacted, the project is meeting the same needs
22 of the patients in the area

23 Q Now, that chart obviously just shows us
24 numbers, numbers of patients Did you also
25 look at the kinds of patients being treated?

1 A I did

2 Q What did that inquiry reveal?

3 A I looked at the types of patients, whether it
4 be inpatients, outpatients, emergency room
5 patients, and as proposed in the application,
6 all of those types of patients are currently
7 being served by the MRI unit as implemented

8 Q All right Let's go to the next slide Tell
9 us about this, what does this show us?

10 A This is a map of the current service area,
11 which is the area from which the MRI draws most
12 of its patients And in the original
13 application, Coastal Carolina proposed to serve
14 Jasper County and to be the only MRI in Jasper
15 County, and to serve parts of Bluffton
16 Bluffton is one of the areas of Beaufort
17 County So I looked at the zip code patient
18 origin, the number of patients coming to the
19 MRI by zip code, and found that, as
20 implemented, the MRI is drawing the majority of
21 its patients from the same area, which I've
22 shaded in green

23 Q The same area that was proposed originally?

24 A Yes

25 Q All right Any other opinions on need that you

1 have for us?

2 A Again, it's the only MRI in Jasper County As
3 proposed, it's serving different types of
4 patients, it serving patients from the same
5 geographic area So with respect to need,
6 there is no change between how the project was
7 originally proposed and how it's been
8 implemented

9 Q Okay Let's go to the next slide, please All
10 right Distribution accessibility Let's
11 start by you briefly telling us what this
12 health planning concept is

13 A Okay Distribution can refer to geographic
14 distribution of services is the service
15 geographically accessible to residents of an
16 area Accessibility can also refer to
17 financial accessibility, do patients from all
18 payor types, Medicare, Medicaid, have access to
19 the service

20 Q All right And you have a couple of exhibits
21 on this project review criteria

22 A Yes

23 Q That's not very easily seen What is that?

24 A It's a drawing of the proposed MRI as it was
25 originally presented in the CON application

1 So this is the drawings that were included in
2 the original CON And you can see there's sort
3 of a dark T-shaped area that sticks out to one
4 of the sides, the left side of the hospital,
5 the little T, was the location originally
6 proposed in the CON application

7 Q All right Let's go to your next slide And
8 what do we have here?

9 A Again, the T, the yellow T, is where the MRI
10 was originally proposed in an expansion to the
11 physical plant of the hospital, and the blue
12 box is where the MRI is currently located on
13 the right side of the hospital immediately
14 adjacent to the hospital

15 Q So what conclusions were you able to draw on
16 the substantial change issue with respect to
17 accessibility and distribution?

18 A Well, in terms of location, typically you
19 really just look at the address of the
20 hospital You know, is the MRI unit still
21 going to located in the hospital? It is, it's
22 right on campus, it's immediately adjacent to
23 the hospital, so it's accessible to patients of
24 the hospital So there's no change whatsoever
25 in terms of location and distribution And I

1 also looked at distribution and accessibility
2 in terms of payor mix. The MRI, as its
3 implemented, is serving all patient types in
4 terms of Medicare, Medicaid patients, so it's
5 financially accessible as implemented, just as
6 it was presented in the application.

7 Q All right. Good. Let's move on then. And we
8 are to acceptability. What's acceptability?

9 A Acceptability is usually measured by letters of
10 support in CON applications. It's whether the
11 project is acceptable to the constituents who
12 would utilize the project, is it acceptable to
13 patients, is it acceptable to the physicians
14 who are referring patients for MRI services.

15 Q And what did you analyze with respect to this
16 acceptability concept?

17 A Well, in the original application there were a
18 good number of letters of support indicating
19 the acceptance of the project. I talked with
20 five different physicians on the medical staff
21 of Coastal Carolina and determined from talking
22 to them that they are very supportive of the
23 MRI unit, they refer their patients to the MRI
24 unit, and the project as implemented is
25 acceptable to them.

1 Q I assume this is the list of folks you talked
2 to?

3 A Yes

4 Q Just run through and tell us what their
5 practice areas are or specialities

6 A Dr Warner is a neurologist and he has a
7 practice in the Bluffton area Trisha
8 Etheridge is an internal medicine physician and
9 she practices up in the Ridgeland area of
10 Jasper County Dr Frank is a primary care
11 physician in Hardeeville which is also in
12 Jasper County Dr Conde is the director of
13 the rehabilitation unit at the hospital and Dr
14 Kennedy is an ER doc, he's the director of the
15 ER at the hospital

16 Q All right So what was your conclusion
17 regarding acceptability?

18 A The project was acceptable as presented to DHEC
19 originally and it's acceptable now to the
20 patients and physicians who are utilizing the
21 service

22 Q Let's move on to cost containment What's cost
23 containment?

24 A Cost containment is a really important CON
25 criteria It's sort of one of the foundations

1 of the CON process and whole reason for CON
2 law So cost containment measures whether a
3 service can be provided in the most cost
4 effective way possible to keep the cost to the
5 healthcare system as low as possible while
6 meeting the needs of the patients

7 Q Do you have an exhibit for cost containment
8 prepared?

9 A Yes

10 Q Let's look at that Tell us about this
11 exhibit

12 A All right This is a summary of the project
13 cost as originally proposed and as implemented
14 The middle column, proposed MRI, is the summary
15 of the cost in the original CON application
16 The equipment, under the equipment line item,
17 1 8 million, about 1 5 million of that is the
18 MRI unit The actual MRI including the trailer
19 and everything that goes along with the trailer
20 was \$535,000 So the total project cost as
21 implemented is a good bit less than the
22 original CON application So in terms of the
23 cost effectiveness CON criteria, the project as
24 implemented actually better meets that CON
25 criteria than the way it was originally

1 presented to DHEC But under both scenarios,
2 that criteria, that CON criteria, is met

3 Q Does the CON statute have any information on
4 cost containment that you wanted to show us?

5 A It does Yes There's a regulation that
6 speaks to --

7 Q I'm sorry The regulation, let's go to the
8 next slide All right Tell us about this
9 regulation

10 A This regulation identifies that the Certificate
11 of Need and the Department in approving the
12 Certificate of Need shall set the maximum
13 capital expenditure that can be spent basically
14 by the applicant to implement a project So
15 the cost is really a ceiling When you have an
16 approved CON, the amount that's identified in
17 the approval is sort of the ceiling You can
18 have about a 10% cost overrun threshold, but
19 it's hitting the ceiling There's no minimum
20 So if you can implement the same project and
21 you can implement it more cost effectively,
22 that's not a problem, it's not a substantial
23 change And in fact, again, it better meets
24 the cost containment criteria

25 Q All right What's the next criteria you

1 analyzed?

2 A Financial --

3 THE COURT One second When you were saying cost
4 containing, said it was the foundation of CON
5 law, and then you said, you were describing
6 what it really means and you said "whether the
7 project is" and I didn't --

8 A Cost effective?

9 THE COURT Yeah, is --

10 A I believe that's what I said

11 THE COURT Okay

12 Q Financial feasibility I think we know what
13 that is, so let's take a look at what you've
14 done on financial feasibility Talk to us
15 about this document

16 A Okay Well, in terms of financial feasibility,
17 all CON applications have to provide
18 information to show that the project would be
19 financially feasible in the form of a pro forma
20 financial projection So I worked with the CFO
21 of the hospital to look at whether the MRI as
22 implemented is actually financially feasible,
23 and he pulled information from their internal
24 financial system and we looked at it two
25 different ways This is an MRI profit

1 analysis, and we're measuring the contribution
2 of the MRI service to the financial performance
3 of the hospital as a whole In this analysis
4 we looked at the feasibility by payor So you
5 can see the FC, the financial class is a
6 numeric code that aligned with the payor,
7 Medicare, Medicare Rehab, Medicaid So that's
8 the financial status of the patient The
9 accounts is the number of patients served And
10 this is an eight month period, it's not a full
11 year And then the total charges would have
12 been the charges associated just with the MRI
13 scan There are no other charges mixed in
14 there like contrast or other associated things,
15 just the MRI And the EBITDA is earnings
16 before interest, taxes, depreciation and
17 amortization So it's the earnings before the
18 capital sort of costs are factored in And on
19 an annualized basis, the EBITDA is \$295,812
20 And then the CFO allocated back in some other
21 fixed costs so that you're looking at the
22 payment by the payors less just variable costs
23 So what is the MRI unit contributing to cover
24 fixed costs of the hospital and of the service
25 So the result of that is a contribution of

1 \$371,562

2 Q And you mentioned that you looked at it in two
3 different ways, you and the CFO did What's
4 the other way?

5 A The other way we looked at it is information
6 was pulled by type of patient, whether they are
7 inpatient, outpatient or emergency room
8 patients That's what the E, I and O stand
9 for So again, it's the same count of
10 patients, 535, same charges, and then under
11 this accounting methodology he calculated the
12 sum of the contribution margin under each of
13 those types of patients and again annualized it
14 because this is the same partial eight month
15 period But the bottom line number is \$369,000
16 in contribution to the hospital as a result of
17 that And so under both methodologies for
18 assessing contribution it's just about the
19 same It's right at \$370,000 a year, which is
20 very similar to the original application I
21 believe the original application showed a net
22 income of about \$400,000 a year coming from the
23 MRI service line So the project was
24 financially feasible as presented in the CON
25 application and it's financially feasible as

1 implemented and contributing positively to the
2 financial performance of the hospital

3 Q Let's move to adverse impact What is adverse
4 impact?

5 A Adverse impact is whether a project can be
6 implemented without adversely impacting or
7 harming existing providers of the same service
8 in the area

9 Q All right And you have an exhibit regarding
10 adverse impact?

11 A Yes

12 Q Let's look at that Tell us what this means
13 for your analysis

14 A The red bar is a summary of the historical
15 utilization of MRI at Belfair And I gathered
16 this information from both DHEC records and
17 also discovery material that was presented as
18 part of this case So you can see from 2004
19 and 2005, which is before Coastal Carolina
20 implemented their CON application, to 2008, MRI
21 at Belfair has had a constant trend in
22 increasing utilization CCMC, Coastal
23 Carolina, came on line for a partial year in
24 2006 and you can see that during the first two
25 and a half years of operation of Coastal

1 Carolina MRI, there's been no impact on MRI at
2 Belfair MRI at Belfair has continued to grow,
3 and so there's no adverse impact as a result of
4 this project on MRI at Belfair

5 Q And how does that compare with what we said
6 about adverse in the 2004 CON application?

7 A In the 2004 CON application, they presented
8 growth and demand for MRI services and that
9 that growth and demand would offset any
10 potential impact on other existing providers,
11 so as a result, MRI at Belfair and other
12 providers in the area would not be impacted by
13 Coastal Carolina's MRI unit And that's in
14 fact what has happened In fact, I looked at
15 all of the MRI units in Beaufort and Jasper
16 County, and all of them as a composite have
17 grown significantly over the last few years
18 during the time period which Coastal Carolina
19 has implemented their MRI unit And the growth
20 has been even greater than what was shown in
21 the original application

22 THE COURT What exhibit is this?

23 MR DAYHUFF This is a demonstrative exhibit, DX11

24 THE COURT All right

25 MR DAYHUFF The data that supports this has been

1 admitted into evidence but the demonstrative
2 has not

3 Q All right Next slide So we're back to your
4 original sheet showing all the project review
5 criteria After analyzing and considering the
6 project review criteria we just went through,
7 what is your ultimate conclusion on the
8 substantial change issue?

9 A Well, when you look at these criteria, the
10 project as originally proposed was consistent
11 with the CON review criteria As its been
12 implemented or modified from the original CON
13 application, it still continues to meet each of
14 those project review criteria There are some
15 other project review criteria that would not
16 even begin to be impacted by the change and how
17 it was implemented, but these are the ones that
18 are most important under the State Health Plan,
19 the ones that might potentially be impacted by
20 the change And I've reviewed all of them and
21 there is no change with how the project meets
22 each of these criteria

23 Q All right You heard the testimony of Dr
24 Borelli, correct?

25 A Yes

1 Q And you've also reviewed his depositions where
2 he's offered various expert opinions regarding
3 substantial change and you've analyzed those
4 opinions as well?

5 A Yes

6 Q All right Did you engage in a review of the,
7 a comparison of the equipment?

8 A I did

9 Q All right I want to go there first And I
10 think we've got a document Tell us about this
11 document

12 A This is a summary that I prepared while I was
13 reviewing Dr Borelli's depositions, Dr
14 Moesch's depositions, reviewing the original
15 quote in the CON application for the MRI and
16 materials on the MRI unit as it was
17 implemented And I just kind of lined up some
18 of the technical aspects of the MRI unit And
19 you can really see that there is no change
20 between the two MRIs as implemented and as
21 proposed You know, it's a GE unit It's a GE
22 Signa The Tesla strength is 1.5 Tesla And
23 that's really the main factor that in my
24 experience DHEC looks at or really any other
25 state agency that I've dealt with looks at in

1 terms of comparing MRI units But when you
2 look at all the other items, you know, the two
3 units are the same Both are four channel MRI
4 The software version is actually newer on the
5 implemented MRI unit, 9 1 And the number of
6 coils, body coils that were acquired is
7 actually there's a few more the way it was
8 implemented, so --

9 Q Let me ask you about channels Why do you
10 believe that the proposed is a four channel?

11 A I reviewed the quote and I also --

12 Q Let's put the quote up

13 A Okay

14 Q And what did you review on the quote that
15 indicated it was four channels?

16 A If you look down at the bottom, the digital RF
17 subsystem section, the little bottom paragraph,
18 it says four channel phase direct

19 Q All right Fair enough And I interrupted
20 you You were going to say you have another
21 reason to believe it was four channel or not?

22 A I also looked at a catalog for the same type of
23 equipment and saw that it, you know, the same
24 equipment with the same sort of model number
25 and everything was also a four channel MRI

1 unit

2 MR DAYHUFF Your Honor, just for the record The
3 data that we relied upon for the adverse impact
4 slide appears at Coastal Exhibit Twelve and
5 Coastal Exhibit Fourteen

6 Q Okay Dr Borelli mentioned a few other things
7 today and I wanted to get your opinions on
8 them, if you have them He mentioned there is
9 a difference in gradient strength I think
10 that's the 23 versus 33 millitesla per meter

11 A Yes

12 Q Do you have any opinions on that or whether
13 that should be part of the consideration?

14 A Well, I do see that that is different between
15 the two, the original quote and the specs on
16 the MRI that was implemented But, you know,
17 as we heard in the testimony today, it might
18 make the difference of a four minutes on a knee
19 scan, it might be a little bit more on a
20 different kind of scan But on a day to day
21 basis that doesn't have any real meaning with
22 respect to health planning It doesn't impact
23 how Coastal Carolina would meet the needs of
24 its patients, especially when they're only
25 serving, you know, just under 1,000 patients a

1 year, four minutes is not going to have an
2 impact on their ability to scan all of the
3 patients Now, it might have an impact on MRI
4 at Belfair that's scanning 7,000 patients a
5 year, but it doesn't really have any impact on
6 Coastal Carolina at all and their ability to
7 meet the needs of the patients

8 Q Do you have any opinion in response to Dr
9 Borelli's opinion regarding our treatment of
10 folks that may need constant monitoring?

11 A I do

12 Q Tell me about that

13 A First of all, in the application they described
14 acutely ill patients Acutely ill patients
15 need to be in a hospital It doesn't mean that
16 they need to be -- have wires affixed to them
17 and have 24 hour constant electronic
18 monitoring Monitoring can take the form of a
19 nurse coming in and checking their blood
20 pressure, of taking their temperature, having
21 eye contact and visual checking on them
22 Really only a few patients in the hospital
23 typically need to be monitored in the ICU beds
24 That's where you typically --

25 MR PRINGLE I'm going to enter an objection here

1 I think Ms Platt is qualified in health
2 planning and finance, certainly not as a
3 physician or in matters medical, and I think
4 these opinions about who is monitored and who
5 is not monitored --

6 THE COURT I'll sustain that at this point You
7 can lay the foundation if you wish

8 Q Ms Platt, in your work as a healthcare
9 planner, have you had occasion to analyze how
10 hospitals work?

11 A Yes

12 Q What kind of patients are in med-surg beds?

13 A Yes

14 Q What kind of patients are in ICU beds?

15 A Yes

16 Q What kind of patients are in the emergency
17 room?

18 A Yes

19 Q Have you had occasion to think about and
20 analyze monitoring for those different types of
21 patients and when it is used and when it is not
22 used generally?

23 A Yes I have written CON applications for all
24 of those types of beds I'm familiar with
25 what's involved in proposing those types of

1 beds, what kind of equipment is usually
2 associated with those CON applications

3 Q All right And what conclusions do you have to
4 offer us in response to Dr Borelli's opinion
5 on this acutely ill monitoring issue?

6 A Again, the term acute means that the patients
7 are in the hospital But typically any
8 patients that are in med-surg beds aren't
9 monitored They're not monitored beds ICU
10 beds are the monitored beds, and that's usually
11 only a small fraction of a hospital's overall
12 bed compliment I believe at Coastal Carolina
13 there may be about seven ICU beds Not even
14 every emergency room patient is monitored
15 continuously They may be checked on
16 frequently by a nurse, they may be, you know,
17 have visual contact in the way the ER is
18 designed, but not all of the emergency bays
19 have monitoring capability, and not all
20 emergency room patients need constant
21 monitoring

22 Q Speaking of monitoring, did you look at the
23 equipment proposed to go along with the 2004
24 application?

25 A I did

1 Q Did you see any monitoring equipment of the
2 kind that we showed Dr Borelli I think?

3 A No, I didn't see any of that proposed in the
4 original application

5 Q All right The wiggle room opinion, I guess
6 the idea that it would be more difficult to get
7 a patient out of the mobile, do you have any
8 opinions on that?

9 A Well, mobile MRI units are approved all the
10 time by DHEC, they're operating at many, many
11 hospitals serving acute patients throughout the
12 state, in other states that I work in It's a
13 very common thing The Ellis and Watts coach
14 that holds the MRI unit is again very common
15 In fact, I think every mobile MRI unit that
16 I've been involved with in terms of a CON or a
17 Determination Letter, typically it is an Ellis
18 and Watts coach So this is a very common
19 piece of equipment serving hospitals all the
20 time, serving acute care patients in hospitals
21 all the time So if it were a problem in terms
22 of quality, in terms of being able to provide
23 sufficient emergency care, then I don't think
24 that these MRIs would be serving hospitals all
25 over the state and all over the country You

1 know, is the wiggle room, you know, maybe it is
2 a little bit tight, but there are policies to
3 address that And again, it's meeting the
4 quality of care standards recognized throughout
5 the industry

6 Q Fair enough Let's look at the JCO certificate
7 that Mr Pringle showed Dr Moesch Tell me,
8 have you had a chance to review this?

9 A Yes

10 Q Where did you get that from?

11 A I got it from the hospital

12 Q All right And tell me why it's meaningful to
13 your opinions, if it is

14 A Joint Commission is sort of the gold seal for
15 hospitals and for health care planners in terms
16 of quality services And Joint Commission
17 reviews all departments within a hospital If
18 you're Joint Commission accredited, it's an
19 indication that your hospital and all the
20 departments within your hospital are meeting
21 the sort of standard of care in terms of
22 quality services This Joint Commission
23 accreditation at Coastal Carolina occurred
24 after the MRI was implemented, so it includes
25 the MRI unit and it certifies that all the

1 departments, including the MRI department, meet
2 the Joint Commission standards on quality of
3 care

4 Q All right Ms Platt, have you had occasion to
5 communicate with DHEC staff regarding the
6 substantial change issue and the philosophy by
7 which they analyze these matters?

8 A I have I've talked to them verbally on
9 several occasions in making inquiries for my
10 clients I've also had some email
11 correspondence with them

12 Q Let's look at your next exhibit Tell us what
13 this is

14 A This is an email from, well, it was in this top
15 part I'm forwarding this on to a client, but it
16 was from Joel Grice to me And I had asked him
17 a theoretical question about a different
18 project with regard to how he would look at
19 substantial change And he wrote back a very
20 well thought out email describing theoretically
21 how the Department looks at substantial change
22 and what they consider

23 Q And what part of the email, I can't see it from
24 here --

25 A If you look at the bottom paragraph I think

1 it might be the second sentence Really, it's
2 the first sentence, but it's a rather long
3 sentence Basically he's pointing to the CON
4 review standards that I just outlined, that
5 when they look at how a project might be
6 amended or altered, they would look to the CON
7 review criteria and he identifies community
8 need documentation, accessability, projected
9 expenses, financial feasibility, cost
10 containment, staff resources So he's
11 outlining for me that, you know, in this
12 theoretical context if they're looking at
13 substantial change they look to the CON review
14 criteria to determine if the project would
15 still meet those criteria

16 Q I want to hit briefly on the void for sale
17 claim Do you have any opinions on the void
18 for sale claim?

19 A I do

20 Q Do you have an exhibit that you've developed on
21 that?

22 A I've got sort of a time line

23 Q Okay Let's look at the time line then All
24 right Tell us about this time line and
25 explain your opinion to the Court

1 MR PRINGLE I'm going to interpose an objection I
2 guess first because I hadn't necessarily seen
3 this opinion before I don't think, and maybe
4 also anticipatorily that it may involve a legal
5 opinion

6 THE COURT Response?

7 MR DAYHUFF It won't involve a legal opinion
8 She's going to walk through the evidence that
9 she's analyzed regarding this issue and there
10 would be no prejudice to Mr Pringle to be able
11 to cross examine her on it

12 THE COURT Are you objecting to the time line, her
13 referring to the time line document?

14 MR PRINGLE Not necessarily to the time line But
15 I was sort of anticipating where this was
16 going

17 THE COURT Well, let's let the testimony go If
18 you object as we go down through it, I'll
19 entertain it at that time

20 MR PRINGLE Okay

21 Q All right Talk to us about the time line,
22 what is this?

23 A This is the time line related to a
24 Determination Letter that was I guess issued by
25 DHEC with regards to sale of the Coastal

1 Carolina Medical Center to Tenet and sort of
2 intertwined with that is the timing for
3 finishing up and implementing the MRI project
4 So the first line, June 22nd, a letter was sent
5 on behalf of Coastal Carolina to DHEC asking
6 for an exemption on the sale of the hospital
7 On June 27th, CCMC finalized the project, they
8 submitted their report for the MRI unit And
9 on June 27th, DHEC also issued their letter
10 indicating that the MRI project was complete as
11 implemented and sort of closing their file on
12 that project So as of June 27th, the MRI
13 project was done On June 28th, DHEC issued a
14 letter approving the exemption on the sale of
15 the hospital, and on July 1st the sale of the
16 hospital commenced

17 Q And those dates, what year?

18 A I'm sorry, 2007

19 Q And how do you know the information that
20 appears here? What did you review?

21 A I looked at the DHEC record and I also reviewed
22 the transcript of Teresa Urquhart, the
23 administrator's deposition

24 Q All right Good Just to finish up, back on
25 the main issue of this case, substantial

1 change From your perspective as a healthcare
2 planner, is this substantial change issue a
3 close call?

4 A No, not at all

5 Q Why not?

6 A For each and every one of the major CON review
7 criteria, you know, the project as proposed met
8 those criteria, the project as implemented
9 continues to meet those criteria You know,
10 they really meet the criteria the same way or
11 in fact, in the case of cost containment, it
12 better meets the criteria So there's not even
13 a close call with respect to whether there's
14 been a substantial change to the project

15 Q Please answer any questions Mr Pringle has for
16 you or Ms Biggers

17 THE COURT Ms Biggers?

18 MS BIGGERS I have no questions

19 MS PLATT - CROSS EXAMINATION BY MR PRINGLE

20 Q Ms Platt, is it your testimony that all 1 5
21 Tesla scanners are roughly equivalent?

22 A From a CON planning perspective, yes, it is
23 When you see completing MRI CON applications
24 for example, you know, DHEC or other agencies
25 that I work with, they don't really distinguish

1 even, you know, between a 1 5, whether it's a
2 Siemens or a GE You know, they say they're
3 all essentially equivalent scanners and they
4 don't really try to distinguish technically
5 between those scanners

6 Q But in that competing providers example, don't
7 the regulators also look at functions and
8 features and services that the MRI provides?

9 A Occasionally, rarely I don't think that's
10 usually their biggest focus If they're trying
11 to decide whether a project should be approved,
12 they really look again to the criteria, is one
13 of them going to be more cost effective, who
14 has the lower project cost, if one of them is
15 going to be more financially accessible,
16 they're going to serve more Medicaid patients
17 So they look at to the bigger picture criteria
18 And if every other criteria was met equally,
19 then they might get down to some of those
20 technical nuances But it's really not a
21 consideration

22 Q Do they look to what the applicant says they're
23 going to use the MRI for?

24 A Yes, they do

25 Q Okay And to the extent that the applicant is

1 not performing the types of procedures or
2 serving the types of patients that they have
3 claimed that they would do, that would be --
4 would you consider that to be significant?

5 A Potentially if that were the case, but in my
6 opinion they are serving the same types of
7 patients They're serving the patients of the
8 hospital They're serving inpatients,
9 outpatients, emergency room patients You
10 know, I spoke to five of the physicians down in
11 the area, we heard Dr Moesch's testimony, and
12 the project as implemented has not changed the
13 way that MRI is being used by physicians and
14 patients of the hospital

15 Q Even if it's not providing scans for all
16 patients of the hospital who might require an
17 MRI?

18 A I haven't heard any evidence that there are
19 patients who are not getting an MRI because of
20 the unit that was implemented There are
21 patients who are transferred because they need
22 a higher level of care, like trauma services,
23 but that doesn't have anything to do with the
24 MRI that was implemented

25 Q So it's your testimony that there's no

1 connection between the fact that MR monitoring
2 services are not available and that CCMC is not
3 providing scans on patients who need constant
4 monitoring in this MRI request?

5 A Well, first of all, I have not heard any
6 physician tell me that they've had a patient
7 who couldn't be scanned that needed to be
8 scanned And second of all, I didn't see any
9 evidence in the original record that there were
10 plans to scan patients who required constant
11 monitoring There were no quotes in the
12 application or anything that indicated that
13 they were going to have those monitoring
14 capabilities in the original application

15 Q What about the language and claims in the
16 original application that have already been
17 spoken to and discussed with Dr Moesch about
18 use for MRIs following auto accidents and spine
19 cord injuries and proximity to I-95 and acutely
20 ill patients who would be too unstable to
21 transfer?

22 A You can have an unstable patient who does not
23 need constant monitoring Or they may need
24 other types of monitoring besides electronic
25 physical monitoring Again, acute means that

1 they need to be in a hospital, it doesn't mean
2 that they have to have constant monitoring
3 And as I've described, the vast majority of
4 patients in a hospital in med-surg beds do not
5 have constant monitoring with that type of
6 equipment They might have a nurse checking on
7 them, they might have visual contact, they
8 might have periodic blood pressure checks, they
9 might have their temperature taken
10 periodically, but they don't all have physical
11 EKG and everything attached to them the whole
12 time they're in the hospital

13 Q You would agree with me that there certainly
14 are certain patients who are both unstable and
15 require constant monitoring, correct?

16 A There probably is some overlap There are some
17 patients who are unstable and need monitoring
18 But again, I didn't hear of any patient who
19 needed an MRI who was in that situation that,
20 you know, it was a problem for any of the
21 physicians I spoke to

22 Q Did you ask that specific question?

23 A We asked them all kinds of questions about the
24 MRI and its availability for the patients that
25 they need to have served, and we didn't have

1 any -- hear any concerns

2 Q Did you ask that specific question?

3 A I don't know that I specifically asked them
4 about whether they had monitored patients But
5 again, they didn't have any concerns with the
6 quality of care as the project's been
7 implemented

8 Q Going back to the 1.5T scanner, so in your mind
9 there's no difference between a scanner that
10 costs \$1.8 million and one that cost \$523,800?

11 A From a health planning perspective, if it's
12 serving the needs of the patients at the
13 hospital and in the area, then there's no
14 difference

15 Q Tell me if this is your testimony That if you
16 can reduce costs and still provide quality
17 services and the same range of services, DHEC
18 will look upon that favorably?

19 A Yes

20 Q Okay What information did CCMC provide to
21 DHEC indicating that the mobile tractor could
22 provide the same services and service quality
23 as the site-built MRI that CCMC would have
24 provided?

25 A They provided information that it was a 1.5

1 Tesla MRI, that it was a Signa, it was
2 manufactured by GE So, you know, it's
3 essentially the same MRI You know, we looked
4 at the technical aspects in detail, and really
5 they're virtually the same in every regard
6 except for the gradient strength, which was a
7 tiny difference in the speed of the technology
8 Even Dr Borelli agreed that it's basically the
9 same piece of equipment

10 Q Would the project have been financially
11 feasible at \$3.2 million?

12 A It was as proposed in the CON application

13 Q And, but under the idea of cost containment,
14 you can have a \$3.2 million project and a five-
15 hundred and thirty odd thousand dollar project
16 and both meet the cost containment objectives?

17 A If you -- if it's presented to the Department,
18 there's a need for the service, it's projected
19 to be financially feasible, then it's totally
20 reasonable to find the \$3.2 million project is
21 financially feasible and cost effective

22 Q How could the -- how could the \$3.2 million
23 project as proposed by CCMC and as claimed by
24 CCMC be the safest and most cost effective
25 solution for MRI services for CCMC?

1 A At the time, I think they believed that that
2 was the most cost effective way to implement
3 the project They obviously found after
4 significant delay that it was more cost
5 effective to implement it with parking a mobile
6 unit permanently on site But it doesn't --
7 you don't have to show the Department that it
8 is the most cost effective way to implement the
9 project You have to show them that it is
10 reasonably cost effective to meet that
11 criteria

12 Q So there's no effect at all to a CCMC claim in
13 its application that a \$3 2 million project is
14 the most cost effective and the safest
15 alternative, safer and more cost effective than
16 the mobile alternatives that were available at
17 the time?

18 A I think what they were contrasting in the
19 application, if I'm recalling it correctly, was
20 a mobile that was transported only a few days
21 a week to the site And they were contrasting
22 those two alternatives And the project is
23 definitely more, it's a higher quality when
24 it's available to patients 24/7, as opposed to
25 a mobile trailer that's coming, you know, only

1 a couple days a week, that magnet is traveling
2 from place to place So the alternatives that
3 they were presenting, it is a better
4 alternative than a part-time mobile unit They
5 weren't comparing the project as implemented
6 and the project as originally proposed

7 Q So is it your testimony that all the
8 description of a mobile MRI in the application
9 had to do with one that was only available
10 several days a week as opposed to one that was
11 available 24/7?

12 A That's my understanding as I read it, yes
13 They were asking for a full-time fixed magnet
14 compared to a mobile service

15 Q Okay You mentioned that DHEC doesn't really
16 look at the technical details of a quote --

17 A Correct

18 Q -- like the quote we discussed How can DHEC
19 determine that the unit can meet the claimed
20 need if it doesn't look at those things and
21 match them up?

22 A They rely on the applicant to present the type
23 of patients that are going to be served and how
24 it's going to be used The quote, the main
25 purpose of having a quote in the application is

1 to establish the price You know, the
2 description that it's a 1.5 Tesla, that it's GE
3 Signa, that's about the level of detail that
4 they look at in terms of the technical aspects
5 of the MRI unit And that would be true for
6 health planners in preparing CON applications,
7 it would be true for the other state agencies
8 that I work with That's generally the level
9 of detail they focus on

10 Q Okay There was some testimony you gave that,
11 and I believe -- and tell me if I characterize
12 this -- that it sort of calls into question all
13 hospital mobile units, that if you're going to
14 do some analysis, that it might -- that you've
15 seen some other hospital mobile MRIs that --
16 and that, you know, DHEC would have to look at
17 every single one of them if these concerns that
18 we're raising are valid Was that your
19 testimony?

20 A My testimony was that in terms of quality of
21 care, a mobile unit that's parked beside a
22 hospital meets the same standards of quality of
23 care if it's Joint Commission approved, if they
24 have all the appropriate policies and
25 procedures in place, meets the same standards

1 of quality of care from a health planning
2 perspective as one that is within the four
3 walls of the hospital

4 Q Okay Now, with respect to the hospital
5 mobiles that you've talked about, are those --
6 knowledge of those particular hospitals
7 stressing the need to scan unstable patients
8 and to scan ones with emergent conditions and
9 immediate conditions from car wrecks and to
10 scan those that have -- in other words, do
11 those hospital MRIs that you referenced, did
12 that need component exist?

13 A In looking at their CON applications?

14 Q Right

15 A I mean, I think that exists to all hospitals to
16 some extent I mean, to a greater degree for
17 a larger more tertiary hospitals, but all
18 hospitals typically have emergency rooms and
19 they typically have acutely ill patients
20 because they are an acute care hospital So
21 that need exists in all hospitals

22 Q You referenced an exhibit that involves some
23 communications that you had with DHEC on the
24 substantial change issue That particular
25 email exchange wasn't specific to an MRI, a

1 substantial change in an MRI context, was it?

2 A No, it wasn't

3 Q Okay But you believe that -- it's your
4 testimony that an MRI substantial change would
5 be analyzed in the same way as a substantial
6 change might be for a hospital adding
7 additional beds?

8 A Yes In a health planning context, again,
9 regardless of the type of project in the
10 original application, you're going to look to
11 whether the project meets the CON review
12 criteria, whether it be a hospital bed project,
13 an MRI project, a radiation therapy project,
14 and under substantial change, you would again
15 look to whether the project continues to meet
16 the same CON review criteria

17 Q Okay You mentioned that there's some
18 community support for the MRI and specifically
19 some doctors and that was for -- now, wasn't
20 that specifically for in connection with the
21 initial proposed project, the fixed in-house
22 MRI?

23 A The letters of support that were in the
24 application, yes, they were for a fixed MRI at
25 the hospital

1 Q And didn't several of those letters, especially
2 those from doctors, actually mention supporting
3 a fixed in-house MRI or in-house MRI?

4 A I don't know if the word in-house was used
5 The word fixed means that it's at the hospital
6 24/7

7 Q Let's take a look here While I'm looking, the
8 doctors that were involved in that, those
9 doctors knew the difference between a fixed and
10 a mobile unit?

11 A I would assume that they know that a mobile is
12 traveling from facility to facility, that's
13 pretty standard industry terminology and
14 knowledge

15 Q Wouldn't they also understand that a mobile
16 could be on site and --

17 A Usually it's not -- I mean, it's in a coach,
18 but when you're referring to mobile, it
19 generally means that it's traveling, again,
20 from location to location

21 Q Let me ask you this I want to go through a
22 little bit of your understanding of DHEC's
23 assessment process, what they do in looking at
24 the MRI, and it's a hypothetical If I had
25 CCMC's original CON and I come to you that I

1 want an approval for the change in the project
2 and that I'm choosing a different scanner

3 A Okay

4 Q Okay And I've got a different scanner chosen,
5 but what I'm telling you is that it's a 1 5T
6 and that it's the same 1 5T that I currently
7 have Do you need any further information to
8 make your assessment of whether this is a
9 different project?

10 A In addition to just knowing that it's the same
11 unit?

12 Q Or, no, the same type of -- same Tesla
13 strength

14 A Tesla?

15 Q Yes

16 A Are you speaking about the magnet itself or
17 other aspects of the project?

18 Q I'm speaking about if I'm telling you, well,
19 I've got -- you mentioned that Tesla strength
20 was the most significant one And if I come to
21 you and tell you I've got a 1 5 Tesla magnet,
22 I'm going to replace it with another one, do
23 you need anymore information to approve that?

24 A Probably not I mean, it would help to know if
25 it was, say, a GE Signa, which in this case

1 they're both GE Signas If it was, say you
2 were going to a Siemens with a different, you
3 know, model name, you might want to know are
4 there some differences But if it's a 1.5 GE
5 Signa and a GE 1.5 Signa, I think that would be
6 sufficient to know that it was the same basic
7 MRI unit

8 Q Okay And that's even if the proposed unit,
9 for example, performed only breast scans as
10 opposed to a range of services that were
11 provided in the original?

12 A Again, if it's a Signa, typically the hospital
13 is not going to propose to reduce their scope
14 to only offering breast scans And breast
15 scans weren't even an issue in the original
16 application

17 Q Well, it wasn't included as one But under
18 your testimony, you don't need to do anything
19 more than to know what the Tesla strength is,
20 correct?

21 A That's generally what is looked at, yes

22 Q And in the hypothetical I just gave it would
23 ignore the fact that the new, the replaced MRI
24 doesn't have the same capabilities that the
25 original one did

1 A I mean, I guess it would be a consideration if
2 it came up, but generally a 1.5T MRI is going
3 to be fairly equivalent in terms of health
4 planning

5 Q Okay I've had a little bit of assistance,
6 thankfully Take a look at that letter and
7 look at the language in there

8 A Okay

9 Q And that language references support for an in-
10 house MRI service?

11 A Right And in -- in that context, in-house to
12 me means offered by the hospital 24/7 I don't
13 think it means physically in the structure
14 In-house means to serve -- the service of the
15 hospital

16 Q Okay

17 A As opposed to a mobile that's traveling from
18 place to place and is not at the hospital 24/7

19 Q So in-house doesn't really mean in-house?

20 A It means it's offered by the hospital at the
21 facility I think if you ask the doctors
22 today, they'd say it's in-house capability

23 Q Okay But none of those doctors are here and
24 they didn't provide letters in connection with
25 the new unit, did they?

1 A No, but again, I spoke to them, I asked them
2 about, you know, how they're using the MRI and
3 they were all very supportive of the MRI as
4 implemented

5 Q Okay Let me just point you towards, and it's
6 one of your trial exhibits, Number Seventeen
7 No, it's one of our trial exhibits, excuse me
8 It would be Number Six

9 A Okay

10 Q Have you reviewed that data? You mentioned
11 that you reviewed a number of statistics Have
12 you reviewed this document?

13 A Yes, I have

14 Q This document shows, does it not, that from
15 September 1st of 2006 to December 31st of 2007
16 that CCMC performed no scans at all between
17 11 00 p m and 7 00 a m ?

18 A During that time period, that's true I've
19 spoken with the MRI tech at the hospital and in
20 more subsequent times, 2008, 2009, they have
21 provided scans to the patients on the 11 00 to
22 7 00 shift It doesn't come up often, but it
23 does happen They have 24/7 call And it
24 happens much more frequently, you can see, on
25 the 3 00 to 11 00 shift in the evening

1 Q Okay But again, this data shows that from
2 11 00 to 7 00, it doesn't happen?

3 A For this time period --

4 Q Right

5 A -- there were not any patients who presented
6 with that need during that shift

7 Q Isn't that period overnight and early morning
8 the most frequent time that trauma and serious
9 injuries are brought, patients are brought to
10 hospitals?

11 A I don't know that that's necessarily true I
12 don't know one way or another I think
13 patients with traumas occur at all times during
14 the day

15 Q Okay All right Let me show you another
16 document Bear with me just a second I beg
17 the Court's indulgence for just one second and
18 then we'll move on

19 THE COURT You're fine

20 Q Have you had occasion to review any literature
21 involving the incidents of traffic accidents
22 during various times of day?

23 A Not recently

24 Q I'll show you a document

25 A Okay

1 Q And I draw your attention to both the graph and
2 the results that are contained If you could
3 read maybe the results there on the first page

4 A You want me to just read it?

5 Q Yes

6 THE COURT Out loud? Because it hasn't been
7 admitted

8 MR PRINGLE Well, I'm going to ask her about it

9 THE COURT All right

10 Q I draw you to the --

11 THE COURT She can read it herself I'm just
12 saying she can't publish it

13 Q Okay What I'm going to ask you is that this
14 information, doesn't this demonstrate that most
15 fatalities and risk for accidents occur in the
16 late evening and early morning hours, not only
17 every day of the week but Friday night and
18 Saturday morning?

19 A It does, but again this is just focused on
20 fatalities and not necessarily other accidents
21 that may not be fatal

22 Q It mentions fatality risk, too, does it not?

23 A Yes

24 Q Okay So that would involve accidents that
25 might cause death or certainly serious injury?

1 A I guess accidents that might result in
2 fatality

3 Q Okay Okay And doesn't this, this document,
4 support the idea that the kinds of serious
5 accidents and fatal accidents do happen during
6 the night and early morning hours?

7 A It would suggest that they happen more
8 frequently during that time but it doesn't
9 indicate that they wouldn't occur other times
10 as well

11 Q Okay Would the fact that these accidents take
12 place during these hours and the fact that CCMC
13 is doing very few scans between 11 00 and 7 00,
14 11 00 p m to 7 00 a m , demonstrate that
15 indeed CCMC is not doing scans involving auto
16 accidents that have a fatal risk involved with
17 them?

18 A Not necessarily, but, you know, I think we
19 heard testimony that if they have, you know,
20 multiple injuries, most likely they're either
21 going to have a CT Scan or they're going to be
22 transported to a trauma facility That doesn't
23 mean that the MRI is not needed to serve
24 emergency room patients in maybe minor auto
25 accidents where the patient might be

1 appropriate to stay at Coastal Carolina, have
2 their services there In a trauma situation
3 they're going to be transported to a trauma
4 center anyway

5 Q Okay All right And in the original
6 application, the claim by CCMC was not that it
7 needed the scanner for minor traffic accidents,
8 was it?

9 A I believe it talked about accidents in general
10 You know, again, they're going to treat the
11 level of trauma that they're capable of
12 treating You know, a significant, major
13 trauma is going to be stabilized and
14 transported

15 Q Okay Is a spinal cord injury a minor injury?

16 A It depends on the level of the spinal cord
17 injury

18 MR PRINGLE Nothing further

19 THE COURT Anything?

20 MR DAYHUFF One follow-up, Your Honor Dan, could
21 you put the letter back up that Mr Pringle
22 showed?

23 MS PLATT - RE-DIRECT EXAMINATION BY MR DAYHUFF

24 Q Ms Platt, Mr Pringle showed you this letter
25 implying that the support for the MRI set forth

1 in this letter by this particular doctor was
2 limited to support for the one we proposed in
3 2004, the MRI that would be within a new
4 addition constructed adjacent to the hospital
5 or as part of the hospital, right?

6 A Right

7 Q Okay And you disputed whether or not in-house
8 meant in the new addition But let me ask you
9 to take a look at the bottom of this letter and
10 tell me if you have any information about this
11 doctor's level of support for the current
12 actual MRI, the mobile that's affixed to the
13 concrete pad adjacent to the hospital

14 A Right This is Dr Frank and he's one of the
15 physicians that I've met with, I met with him
16 in his Hardeeville office, and he's obviously
17 supportive of the MRI as implemented in the
18 modular unit beside the hospital, he's
19 referring his patients there, and he was very
20 willing to talk with me about his support for
21 the project

22 MR DAYHUFF No further questions

23 MR PRINGLE Nothing further

24 MS BIGGERS Nothing

25 THE COURT You may step down

1 MR DAYHUFF With that, Your Honor, let me think

2 I hesitate only because I was considering

3 publishing some of Ms Urquhart's --

4 THE COURT We probably need to take a five minute

5 break anyway, so we'll just take a five minute

6 break and you can cogitate upon that and tell

7 me when you get back

8 MR DAYHUFF Okay But my question for you, it's

9 been admitted into evidence as an exhibit If

10 you'd like, I can read the couple portions that

11 are important to me

12 THE COURT That's fine

13 MR DAYHUFF Okay All right Fair enough

14 (Short break)

15 THE COURT Mr Dayhuff?

16 MR DAYHUFF Yes, Your Honor, I would like to

17 publish just a couple portions of Ms

18 Urquhart's deposition, it's our Exhibit Twenty-

19 Five, Coastal's Exhibit Twenty-Five If you're

20 ready, I'll go ahead and do that

21 THE COURT I guess I'm ready for you to read to me

22 MR DAYHUFF Yeah, I can sense your excitement

23 about this I will make this brief

24 THE COURT Oh, no, I'm just picking I'm fine

25 MR DAYHUFF This is a 30(b)(6) deposition that

1 Belfair noticed and Teresa Urquhart is the
2 30(b)(6) witness for Coastal Carolina On page
3 seven, she testifies, this is Jack's question
4 Question In that corporation, were the shares
5 of that in the corporation were -- all of the
6 outstanding shares in that corporation were
7 purchased by Tenant Health System Medical,
8 Inc ? She answers That's correct Jack
9 asks Okay And that entity that I just
10 mentioned, Tenet Health System Medical is in
11 turn owned either ultimately or in some form or
12 fashion by Tenet Health Care Corporation?
13 Answer That's correct Question Okay
14 Okay And do you know what date the
15 transaction through which, and I'm going to
16 refer now to CCMC's stock, was transferred to
17 Tenet Health System Medical, what date that
18 closed or was completed? Answer The
19 agreement was executed on June 30th of 2007
20 The effective close of the stocks was at 12 01
21 a m , eastern standard time, July 1, 2007 And
22 I'm offering that in relation to the void for
23 sale argument to establish the date of the
24 closing of the transaction And that's all I
25 have We rest our case

1 THE COURT All right Ms Biggers?

2 MS BIGGERS Your Honor, DHEC calls Joel Grice

3 JOEL GRICE, having been duly sworn, testifies as
4 follows

5 MR GRICE - DIRECT EXAMINATION BY MS BIGGERS

6 Q Mr Grice, can you give us background
7 information about your education and degrees
8 that you have?

9 A Yes I graduated from the University of South
10 Carolina in 1968 with a Bachelor's of Science
11 in Biology and a Master's of Science in Biology
12 in 1973 I taught high school four years and
13 joined the Department of Health and
14 Environmental Control in 1975 as an
15 environmentalist And my work in that job,
16 which was a new position at the Department at
17 the time, was to develop educational programs
18 to assist healthcare facilities in training
19 their personnel for environmental sanitation in
20 the hospital and in their food service
21 programs And I joined the Certificate of Need
22 program in 1978 as a reviewer or they called it
23 a Public Health Analyst III at the time, was
24 promoted in 1981 to a Planner IV and was a
25 supervisor for CON review and also responsible

1 for what they called at the time the -- gosh,
2 I've almost forgotten now, it was a federal
3 program where we had to actually go and make
4 sure Certificates of Need were actually
5 implemented and conducted fairly and I'm sorry
6 I can't remember the term But in 1984, I
7 became director of the Certificate of Need
8 program and in the year 2000, became director
9 of the Bureau of Health Facilities and Service
10 Development which is over Certificate of Need,
11 the State Health Plan, the Certificate of
12 Public Advantage Program, as well as -- let's
13 see, there was one other area Oh, I think
14 State Health Plan, Certificate of Need, oh, the
15 Medicaid Permit Act

16 Q So how long overall did you work for DHEC
17 within the Certificate of Need program?

18 A From 1978 and I retired December 2007 so in the
19 Certificate of Need program, I think that was
20 29 years

21 Q And where are you currently employed?

22 A Beginning in January 2008, after my retirement
23 from DHEC in December 2007, one of my
24 colleagues, Albert Whiteside, and I formed a
25 limited liability company called Grice and

1 Whiteside, L L C and we are doing consulting,
2 healthcare consulting, in South Carolina
3 related to the State Health Plan and the
4 Certificate of Need program

5 Q Have you ever been qualified at the
6 Administrative Law Court as an expert in
7 healthcare planning?

8 A Yes, I have

9 Q On more than one occasion?

10 A Yes Probably, almost every trial that I was
11 a witness in the Administrative Law Court,
12 particularly from probably the mid-nineties on,
13 you know, I was qualified as an expert witness

14 MS BIGGERS At this time, I'd like to ask that Mr
15 Grice be qualified as an expert in healthcare
16 planning

17 MR PRINGLE No objection

18 MR DAYHUFF No objection

19 THE COURT So qualified

20 Q Mr Grice, can you tell us what the goals and
21 purposes of the Certificate of Need Act are?

22 A Yes The -- I think basically state law and
23 statute gives basically four goals for our
24 Certificate of Need program in South Carolina
25 and that is to promote cost containment, to

1 prevent unnecessary duplication of services and
2 to guide the establishment of healthcare
3 facilities and services which best meet public
4 needs and to ensure that there are high quality
5 services provided in our facilities in South
6 Carolina

7 Q Can you explain for us more about the goal of
8 cost containment?

9 A Yes That is probably one of the primary goals
10 of the CON program and its purpose We are
11 trying, in the program, to hold our healthcare
12 costs down as low as possible So particularly
13 in times where we might even have competing
14 applications for the same service where we can
15 only approve one, cost containment is one of
16 those factors we look at, who can provide a
17 quality service at the lowest cost We
18 definitely want to ensure in reviewing an
19 application that applicants have tried to
20 contain costs, that they're looking at quality
21 but not necessarily building a too luxurious of
22 a facility, you know, that certainly could
23 become adequate in future years It's a big
24 change in healthcare and certainly evolution of
25 technology so it's good for health providers to

1 look at cost effectiveness in making decisions

2 Q Are you familiar with the regulatory provision
3 in 61-15 regarding substantial change to CON's
4 after the CON has been issued?

5 A Yes, I am

6 Q Can you explain for us how the Department in
7 the past has analyzed proposed changes to a
8 Certificate of Need to determine whether or not
9 it was substantial?

10 A Yes Oftentimes, after a Certificate of Need
11 is issued, there are some changes that an
12 applicant may want to make Oftentimes, when
13 they really have the approval, a lot of times
14 physicians may become involved, particularly
15 the design of the facility, and there's changes
16 they may want to make in architectural plans
17 somewhat But what the Department is really
18 looking is, of course, an applicant would have
19 to come to the Department and present their
20 proposed changes to ask whether or not there is
21 substantial change We want to be sure in our
22 CON program that that substantial change
23 doesn't override the cost threshold that has
24 been approved The Department's policy has
25 been that they will allow total project costs

1 to be as much as ten percent higher without
2 being a substantial change But generally any
3 time a project is reduced in scope, in terms of
4 square footage or other costs, it is not viewed
5 as a substantial change by the Department
6 Because we are focused on cost containment, the
7 main goal is we don't want it to exceed the
8 cost nor do we want the, say the type of
9 equipment or service to exceed what has been
10 specified in the application For example, if
11 a hospital is approved for let's say a 32-slice
12 CT Scanner, you know, and they want to go to a
13 64-slice which would be a, you know, somewhat
14 greater capability, we'd have to look at it
15 very carefully, and that may be seen as a
16 substantial change in that case because it's
17 really going to a higher level than was
18 originally approved

19 Q And when the Department analyzes substantial
20 change issues, does it also look at the types
21 of services that are provided in the CON as
22 originally approved and as implemented?

23 A Yes I mean, you know, every time there may be
24 a request as to substantial change, an
25 applicant will specify what those changes are

1 and we have to look at an array of issues,
2 that's true, and every one is somewhat unique

3 Q Are you familiar with substantial change issues
4 that have come up in the past specific to a
5 provision of MRI services?

6 A Yes

7 Q And what types of factors has the Department
8 reviewed in the past with regard to MRI
9 services?

10 A For MRI services, it has always been rather
11 simplistic I have seen the evolution of MRI
12 development since I was in the CON program and
13 even had a chance to have a site visit to the
14 first one in South Carolina at MUSC in
15 Charleston in the early eighties But what we
16 really looked at is that if a Certificate of
17 Need is issued for a specific Tesla size, that
18 that Tesla size cannot be exceeded, but it can
19 be downsized or the same as long as the cost
20 does is not exceeded by more than 10% If the
21 cost is lowered or even the Tesla size
22 downsized like a 1 5 to 1 0, that is not looked
23 upon as a substantial change and never has
24 been

25 Q Did you make the original decision on behalf of

1 DHEC to approve CCMC's CON application in this
2 matter?

3 A Yes, I did

4 Q And who made the decision on behalf of the
5 Department with regard to the substantial
6 change issue?

7 A Ms Victoria Tibshrany The time that I was
8 director of the Bureau of Health Facilities and
9 Service Development, Ms Tibshrany was the, I
10 guess she was really one of the primary people
11 making decisions regarding non-applicability
12 determinations and follow up, as well as
13 substantial change issues

14 Q And at the time that Ms Tibshrany made the
15 substantial change review, were you Ms
16 Tibshrany's supervisor?

17 A Yes, I was

18 Q So are you familiar with the changes in this
19 particular project from as you approved it
20 originally to as implemented?

21 A Yes, I am

22 Q Can you describe for us any changes between as
23 approved and as implemented for this project
24 with regard to location?

25 A The location, of course, was to be in a modular

1 unit outside the hospital itself but attached
2 by a covered corridor but it was right there at
3 the hospital, the location would be at the
4 hospital, under the license of the hospital
5 So as far as location, that is not substantial
6 In my opinion, this -- in my opinion, this
7 particular modification of the project at
8 Coastal Carolina was one that was very minor in
9 that the MRI was the same size, basically the
10 same type but a refurbished model, but it was
11 much more cost effective for the hospital at
12 that particular time with their financial
13 issues It did -- this was a very important
14 project for the Department and Coastal Carolina
15 because our goal with the State Health Plan is
16 that every hospital must have or should have an
17 MRI on its campus available to treat patients
18 24/7 if necessary And so this is a way that
19 Coastal Carolina was able to implement this
20 project more cost effectively with basically
21 the same project

22 Q Is there any statutory or regulatory
23 requirement for a hospital that its MRI be
24 located within the four walls of the hospital
25 structure itself?

1 A No In fact, that particular standard that I
2 mentioned earlier, that has been in the State
3 Health Plan since the early 2000's where we're
4 encouraging every hospital to have access to an
5 MRI at its facility There were some small
6 rural hospitals where it was only financially
7 feasible for them to have a mobile, for
8 example And according to that, they had to
9 get a Certificate of Need even for the mobile
10 because that was a new service that we had
11 criteria and standards for in the Health Plan,
12 but that helped meet that goal also So in the
13 case of what we really were hoping certainly is
14 every hospital will have a fixed which can be
15 expensive for some smaller rural hospitals
16 But in this case that was our reasoning for
17 approving Coastal Carolina and when they asked
18 for, you know, a modification, we did not see
19 this as a substantial change at all

20 Q When a CON applicant asks to make a change in
21 its MRI equipment from the actual unit that it
22 originally proposed to purchase to a different
23 type of unit, what kind of issues would you
24 look at to see if that change was substantial?

25 A We would look at the Tesla size of the unit is

1 the main issue We had approved a 1 5 Tesla
2 MRI and if they had decided even to downsize
3 that to a 1 0, it would not have been a
4 substantial change using our process at DHEC
5 that we've used for years Now, certainly it
6 would be unrealistic for the hospital to want
7 like a 3 0 which is used mostly in research
8 hospitals But let's say for some reason they
9 had asked for a 3 0, that would have been a
10 substantial change regardless of any cost
11 issues because that, you know, was a different
12 higher level than what was originally approved
13 So the 1 5 replacing the 1 5, that was the main
14 thing we were looking at, and to be sure that
15 our total capital cost ratio was not exceeded

16 Q Did the Department analyze magnet speed when it
17 was looking at a change in MRI units?

18 A No, ma'am That is not an issue that was
19 compelling The technology changes so fast
20 with medical equipment, we have tried to look
21 at the basic issues and that is not something
22 that was under consideration

23 Q And how about total project cost, how would you
24 analyze a change in total project cost to
25 determine whether or not it's substantial?

1 A It would only be considered substantial if the
2 applicant chose a replacement piece of
3 equipment that cost more than 10% -- or made
4 the total project cost of the whole project
5 more than 10% greater than what was approved
6 Now, I think the original application approval
7 may have included some square footage area
8 which, you know, in this case we have the
9 modular housing rather than the square footage
10 of a building, but there was no issue with cost
11 here because the total project cost was less

12 Q So in your opinion, is the change between this
13 particular project from as you originally
14 approved it to as it as ultimately implemented,
15 a substantial change?

16 A No

17 MS BIGGERS Those are all the questions I have
18 THE COURT Mr Dayhuff?

19 MR DAYHUFF Ms Gillespie is going to handle this
20 witness, Your Honor

21 THE COURT Ms Gillespie

22 MR GRICE - CROSS EXAMINATION BY MS GILLESPIE

23 Q Mr Grice, were you here for Ms Platt's
24 testimony?

25 A Yes, I was

1 Q Did you hear her talk about an email that you
2 sent to her regarding --

3 A I did

4 Q -- your opinion? Could you pull that up,
5 please? This is Petitioner's Exhibit Number
6 Eight

7 A Okay

8 Q This is the paragraph that Ms Platt referenced
9 where you sent her your opinion Could you
10 just look that over just for a minute --

11 A Okay

12 Q -- and then I'll ask you some questions

13 A All right Okay

14 Q Okay Do you still agree with -- first,
15 summarize your opinion here in this What were
16 you telling her?

17 A Well, you know, I try -- I'll tell you, working
18 with the Department we always get lots of
19 emails, you want to be sure that in an answer,
20 and I would have never dreamed that we would be
21 looking at this email two years later, but I
22 would -- I always wanted to make it to try to
23 cover everything, cover all bases And she was
24 really focusing kind of on change of site, but
25 I tried to include everything because you

1 really -- it was a hypothetical question So
2 what we're really saying here is that the
3 issues we'd have to look at involving the
4 impact of a site change, you know, it covers a
5 lot, it could be community need documentation,
6 accessibility, projected expenses, financial
7 feasibility, cost containment, all of this
8 And I also went on, you know, like adverse
9 effect on other facilities, zoning, utilities,
10 etcetera A lot of times, a change in a
11 project, particularly with a site, if we talked
12 about say a brand new facility locating say
13 rather than Bluffton say the town of Beaufort
14 or something like that, you know, you have to
15 really look at that because in the original CON
16 review, you had affected people maybe
17 commenting from the community where the
18 facility is located So I tried to cover
19 everything here And I also mentioned that,
20 you know, our policy at the Department was that
21 that total project cost, you know, could not be
22 exceeded by more than 10% So this was kind of
23 tried to cover everything, but I think it -- I
24 agree with this and it does cover, I think, the
25 project we're talking about today where we had

1 a project that was approved with an in-house
2 MRI that was inside the hospital and the change
3 would be that that unit would be located
4 adjacent to the hospital with a covered
5 walkway, but the same equipment, accessibility
6 the same, it's right there at the hospital and
7 the cost was much less where we didn't even
8 have to worry about exceeding 10% of the
9 original approval

10 Q Okay So in this email, you're looking at
11 specific -- you referenced project review
12 criteria

13 A That's right

14 Q And you say that you would look at the proposed
15 project and then the actual project to make
16 sure that the actual project still meets the
17 project review criteria, is that an accurate --

18 A That -- yes, ma'am, that is correct In other
19 words, want to make sure because this is, like
20 I mentioned, the email is trying to answer
21 something that was -- it was brought and not
22 knowing specifically what it would be, but yes,
23 to go back and look and make sure that there
24 would in no way would there be a substantial
25 change in relation to what issues and criteria

1 the Department used in making its original
2 decision

3 Q Mr Pringle brought up, I think when he was
4 questioning Ms Platt, that when she asked you
5 this question she was asking you about a change
6 in location Would this analysis apply equally
7 to an MRI project?

8 A In my opinion, yes, it applies I tried --
9 even though I realized she was kind of focusing
10 on change of site, I tried to make this where
11 it covered just about anything because a lot of
12 times applicants can't be too specific When
13 they're writing, they ask a generic question
14 We want to be sure we cover as much as we can
15 so that there's no misunderstanding in the
16 future So yes, I mean I -- to me, this
17 applies to almost anything that would be --
18 that would relate to a substantial change in a
19 project

20 Q Okay And when you were talking to Ms
21 Biggers, you said that in analyzing, if an
22 applicant proposes to purchase one MRI unit but
23 they submit a request to purchase a different
24 MRI unit, the thing that the Department
25 considers is the Tesla strength, is that

1 accurate?

2 A That is one of the main things I mean, I know
3 that as technology changes and evolves that can
4 be looked upon as very simplistic and at some
5 point in the future the Department may become
6 more defined in that, but today I still agree
7 that is the way we have done it, that is the
8 way that -- that is the main issue we've looked
9 at is the Tesla strength and in this case it
10 was identical

11 Q All right

12 A It was identical

13 Q And does the Department have a radiologist or
14 an expert in MRI units on staff that could help
15 you with more technical issues like gradient
16 strengths, slew rate?

17 A You know, certainly we don't have anybody
18 technically in our CON program and health
19 regulation, but certainly if there were serious
20 issues, there are people, you know, that we
21 would know to call But this was really very
22 simplistic and I saw no reason that we needed
23 to, you know, do any further research

24 Q All right So for purposes of this review,
25 Tesla strength was --

1 A It --

2 Q -- sufficient?

3 A ,-- that is the key in this particular
4 determination

5 Q Okay

6 A And the cost was reduced, so that was great

7 Q And you testified that you, you know, were
8 director of the CON program for a long time

9 I'm sure you've seen a lot of these

10 applications Are you aware of other hospitals
11 in the state of South Carolina that are using
12 mobile MRI services or modular MRI's?

13 A Yes We've had very similar situations occur
14 in other parts of the state that I was involved
15 in A lot of times there can be things that
16 occur where a hospital changes after they get
17 the CON There may be something affecting
18 their budget, unanticipated, and they just make
19 a determination this may be the most feasible,
20 financially feasible thing, for the interim to
21 have that service available, you know, right
22 now

23 Q And from the Department's standpoint, is there
24 any safety issue with using a mobile or modular
25 MRI unit?

1 A No I mean certainly any hospital is going to
2 have to meet certain requirements or licensure
3 standards, fire and life safety So, you know,
4 certainly lots of times there are things a lot
5 more luxurious or pleasant, you know, but this
6 met the requirement and was an important
7 service for that hospital to have the
8 availability of it, and it met all the basic
9 requirements

10 Q So there are other agencies that are looking at
11 the safety of the project, is that --

12 A In the Department of Health and Environmental
13 Control, yes I mean, there are licensure
14 inspectors that go in, certification
15 inspectors, and they're looking at fire and
16 life safety issues and making sure that, you
17 know, worse case scenario that, you know, if
18 there were a fire or problem, the patient could
19 be evacuated in a timely manner

20 Q And did any of those agencies determine that
21 there was a safety issue with CCMC's project as
22 implemented?

23 A No And surveys have certainly been done after
24 all this was put into place and to my knowledge
25 there's no -- there's been no, you know, issue

1 where the hospital had to correct any problem

2 Q Okay And I think I heard you testify when Ms
3 Biggers was questioning you, you were Ms
4 Tibshirany's supervisor at the time that CCMC
5 submitted their substantial change
6 determination request?

7 A That's correct

8 Q So you are familiar with this project?

9 A Yes

10 Q In your opinion, whether CCMC's project as
11 proposed and as implemented, is that a close
12 call at all, whether that was a substantial
13 change?

14 A In my opinion, no, it is not a close call I'm
15 concerned that we had an appeal It's abusive
16 of the program, I feel like, the appeals
17 process No, this is not a close call at all

18 MS GILLESPIE Okay Thank you No further
19 questions

20 THE COURT Mr Pringle?

21 MR PRINGLE Thank you, Your Honor

22 MR GRICE - CROSS EXAMINATION BY MR PRINGLE

23 Q Mr Grice, you mentioned that MRI at Belfair's
24 request for a contested case that this is a
25 substantial change is abusive of the process?

1 A Yes, sir

2 Q Okay The MRI at Belfair was an interested
3 party and an affected party in the CON
4 application of CCMC, was it not?

5 A Yes, it was

6 Q Okay And you were involved in that case?

7 A Yes, sir

8 Q And when the substantial change request was
9 filed on June 12th, you didn't provide a copy
10 of that to MRI at Belfair, did you?

11 A It -- no because, you know, that -- whenever
12 you go through the CON process, the affected
13 persons involved, like MRI at Belfair was, that
14 case was resolved, you know, the CON was
15 issued Now, generally, you know, the
16 Department doesn't have staff, I mean we don't
17 have lawyers on our staff even though we have
18 them for the Department But unless an
19 applicant would write a letter and say -- not
20 an applicant but an affected person -- and say
21 I want to know every move that occurs in the
22 future on this project, you know, normally our
23 staff would be sending out, you know, letters
24 copying the applicant on the final completion
25 report, etcetera Certainly, any affected

1 person could ask under the freedom of
2 information periodically and get information
3 But normally something like this is just part
4 of the development of the Certificate of Need
5 and it is not a situation where you'd be
6 normally, you know, putting notices in the
7 paper or notifying the affected persons

8 Q Okay Well, given that I mean that no notice
9 was provided and it was essentially something
10 between DHEC and the applicant, then wouldn't
11 any challenge to it -- I mean, based on the
12 idea that other people don't know about it
13 unless they happen upon it, wouldn't any
14 substantial change challenge be abusive in
15 DHEC's view?

16 A Not -- not necessarily Now, certainly the
17 Department is working to try to be sure that
18 every decision that it makes is reasonable and
19 correct And there have been requests even
20 when I was at the Department that I had
21 concerns about, not related to MRI, but about
22 the change in a project, whether it was
23 substantial or not and I would -- if there was
24 any question in my mind, I would really look at
25 that in detail and go to our attorney To give

1 you an example, I had a project, it was a
2 facility, an end of life center, can't think of
3 the term right now, but basically they were
4 approved for a site that was not the best site,
5 it was across from a funeral home and a
6 graveyard, and they wanted to relocate and it
7 was only two miles away, it was in the same
8 county, but it concerned me And I did a lot
9 of research, but we did -- we did approve that
10 as not a substantial change and there was no
11 problem But that's one that, you know, it was
12 not controversial, but a lot of times projects
13 are I mean But a project like this where the
14 MRI was approved and it's just a modification
15 within the hospital, where it's located in a
16 modular unit rather than within the walls, same
17 unit, we did not see that as going to be
18 controversial

19 Q Okay And to recall, it is correct, isn't
20 that, that the CON issuance was on appeal
21 during that time period, correct?

22 A The CON issuance was under appeal?

23 Q The CON originally granted to the original
24 project

25 A My understanding would be whenever, whenever

1 there was a -- the Administrative Law Court
2 issued its ruling allowing the issuance of the
3 Certificate of Need to Coastal Carolina, the
4 appeal was concluded CON's are not issued
5 until every appeal is concluded So when MRI
6 had its -- I'm sorry, when Coastal Carolina had
7 its CON, there was no appeal at that time
8 Now, that Certificate of Need was valid for six
9 months, which meant Coastal Carolina Hospital
10 had six months to be able to implement it
11 Probably during that six month period was when
12 the hospital wrote to the Department and asked
13 for a determination as to whether the change of
14 the equipment and placing it outside the
15 hospital would be a substantial change So I
16 don't think there would have been an appeal
17 during that period

18 Q So you disagree with me that there was an
19 appeal pending in the Appellate Courts of South
20 Carolina?

21 A I'm sorry, I don't -- I didn't think about
22 that

23 Q Yeah

24 A There could have been

25 Q Okay

1 A I wouldn't know

2 Q And wasn't DHEC a party to that appeal?

3 A I'm sure they would be, yes

4 Q Okay But what you're saying then, and tell me
5 if I'm characterizing your testimony right, but
6 that it's up to DHEC to decide whether a
7 substantial change takes place without input
8 from other parties who might be interested or
9 affected in a CON context?

10 A Yes Generally, I mean, DHEC is the entity
11 issuing the CON DHEC would not issue the CON
12 until the Administrative Law Court gave its
13 permission And certainly there can be other
14 appeals, you know, that may be in the court
15 system in South Carolina but the -- once a CON
16 is issued like that, you know, the applicant
17 corresponds directly with DHEC in how they
18 initiate the project There are -- there's
19 nothing that I'm aware of in any CON
20 regulations that requires the Department to get
21 other affected persons involved in the
22 administration of the development of that
23 Certificate of Need
24 Q Okay But again my question was about
25 substantial change requests

1 A Uh-huh (affirmative response)

2 Q You believe that that is a determination DHEC
3 should make without the benefit of other
4 interested parties?

5 A Well, there is no requirement that DHEC help
6 other interested parties Now, certainly there
7 could be cases that would be very complex,
8 particularly, let's say one where a brand new
9 hospital or nursing home is going to be
10 relocated in a county from one town to another
11 Let's say a nursing home or a hospital, the
12 need is projected by county as far as beds
13 But if we approve that facility, let's say in
14 Bluffton, and the applicant says we now want to
15 relocate it to Beaufort or Hilton Head, that is
16 a Department decision, but in my opinion that
17 relocation may be a substantial change But in
18 certain issues, certain situations, depending
19 on the need of that county and, you know, where
20 there is a tremendous need, let's say, for
21 nursing home beds, we -- in a case like that,
22 we might would, say, even ask the applicant to
23 run a notice in the paper and see would anyone
24 be concerned about a substantial relocation
25 The costs, if the costs were the same and the

1 need being met in the same county and no one
2 really objected, certainly in my opinion, the
3 Department would say that would not be a
4 substantial change But in this particular
5 situation where we have a hospital that's
6 trying to get an MRI and all they're doing is
7 just changing very minor, getting refurbished
8 equipment rather than brand new, the same size,
9 cost's lower, that is one that in my opinion is
10 not as complex and is pretty straightforward

11 Q Okay You mentioned that, and I want to touch
12 on this right now, that there were some
13 financial issues involved with CCMC that led
14 them to this substantial change request?

15 A I don't know the specifics of that
16 Unfortunately, I'm afraid because of money that
17 had been spent probably, and I can't document
18 this, but on the previous appeal, I'm sure when
19 you look at a new hospital starting up and
20 they're spending hundreds of thousands of
21 dollars on an appeal initially and then they
22 get their Certificate of Need for the unit,
23 certainly some of that money allocated for the
24 new MRI has already been spent And this is
25 unfortunately one of the problems we're having

1 with our CON program in South Carolina, how, in
2 my opinion, the appeals process is being
3 abused We are spending tremendous amounts of
4 money on legal fees that are unnecessary And
5 I don't want to get off the topic, but
6 unfortunately I guess now that I am no longer
7 employed by the Department and a consultant, I
8 get to see things from the other side, a
9 different perspective, but it is something that
10 concerns me very much

11 Q And this MRI, CCMC MRI, is in operation, isn't
12 it, right now?

13 A It is

14 Q Okay Okay You mentioned, and I wanted to
15 just clarify this, you talk about that the
16 Tesla strength is the main and overriding
17 consideration in an MRI replacement and a
18 substantial change, correct?

19 A Yes, that has been the Department's focus --

20 Q Okay

21 A -- for years, yes

22 Q Okay But you've also referenced the email
23 that came up here that talked about that in a
24 substantial change context that there were a
25 number of the project review criteria that you

1 considered

2 A That is true, but we've got to remember that
3 that email was one that I was trying to cover
4 everything, not knowing specifically

5 Q Okay

6 A If that email had been specifically MRI or
7 specifically CT --

8 Q Yeah

9 A -- we could have gone into more detail, but I
10 wanted to be sure we covered all the facts in
11 that email that was more of a general email to
12 cover everything

13 Q Okay Your substantial change analysis that
14 took place, given that it involved the Tesla
15 strength, didn't involve any analysis of
16 whether there had been any changed need for the
17 MRI services or the way those services were
18 going to be provided, did it?

19 A No, because the need, you know, had certainly
20 been demonstrated in the original CON approval
21 which was still valid That CON was less than
22 six months old

23 Q Okay Okay And you've seen the testimony and
24 the documents about MRI policies and procedures
25 of CCMC?

1 A Yes

2 Q You did not review those in connection with the
3 substantial change request?

4 A No

5 Q Okay

6 A No, not specifically Of course now I'm not
7 the one that did the --

8 Q Sure

9 A -- you know, the review on substantial change
10 But that's not -- you know, those policies and
11 procedures would not be, in my opinion, a main
12 focus either on the substantial change because,
13 as I mentioned earlier, the hospital must meet
14 minimal licensure requirements for the
15 operation of all of its services

16 Q Well, to the extent that the safety procedures
17 as have been testified to here today and argued
18 here today, the safety procedures and the way
19 CCMC does business goes to the need that they
20 sought to demonstrate in the original
21 application, could DHEC consider that in the
22 context of a substantial change request and in
23 fact wouldn't they not be obligated to?

24 A I'm sorry, could you repeat the question again?

25 Q To the extent that, as it's been presented and

1 argued here today, there is a change in the
2 need that is being -- the types of scans that
3 are being provided by CCMC pursuant to the MRI,
4 to the extent that that has changed, would that
5 not be something that DHEC could consider and
6 indeed would consider if it were going through
7 an analysis of whether a substantial change
8 took place?

9 A No In my opinion, no We had already made a
10 determination there was a need for an MRI In
11 fact, our State Health Plan states every
12 hospital should have its own MRI So what this
13 focus was on this substantial change was
14 capital expenditure and the equipment and
15 neither -- when we really get to focus on that,
16 the equipment was basically the same category,
17 the capital expenditure was not exceeded, in
18 fact it was substantially less

19 Q Okay

20 A It was not a substantial change

21 Q At that time -- that's a good point that you
22 mentioned At that time, DHEC took the
23 position that every hospital should have an MRI
24 regardless of the other project review
25 criteria, isn't that correct?

1 A Not regardless of the other project review
2 criteria Criteria number one, Regulation 61-
3 15, Section 802 1, says an applicant should be
4 -- applications should be consistent with the
5 State Health Plan So when you look at an MRI,
6 you have to look at the South Carolina Health
7 Plan under magnetic resonance imaging and the
8 main standard at that time, and I think this
9 project was reviewed under the 2004-2005 South
10 Carolina Health Plan, is that each hospital --
11 we should give priority, each hospital have its
12 own MRI Which meant if there had been
13 competing applications, let's say if it had
14 been an application for a freestanding MRI
15 somewhere in Bluffton and then the hospital, we
16 would have to give priority to the hospital
17 They would have to get the approval first

18 Q Okay Let me ask you this about if you were
19 having a comparison between two freestanding
20 MRIs, wouldn't you look at things like
21 capabilities in order to determine which one to
22 --

23 A If there were competing applications, as I
24 mentioned earlier, the particular Health Plan,
25 what would be given precedence -- preference

1 under the Health Plan would be the hospital had
2 to have it first

3 Q Okay

4 A So that would override Even if a freestanding
5 center wanted to have some state of the art,
6 that hospital must have it first And that was
7 the compelling issue for approving Coastal
8 Carolina for an MRI as well as any hospital in
9 the state who didn't currently have MRI
10 services

11 Q Okay My question is about two competing
12 freestanding MRI applications and whether DHEC
13 would look at capabilities and services to be
14 offered and what, put it this way, what the MRI
15 can do?

16 A If there had been two competing applications,
17 freestanding, non-hospital related, certainly
18 those could be issues Now, there would be a
19 lot of other issues Community support It
20 could also be the financial feasibility and the
21 cost Still, even though you could have one
22 super MRI, if its costs were excessive, you
23 know, or we felt like really a little bit out
24 of line, certainly we would be looking at the
25 more cost-effective project But yeah, I mean

1 those are things we certainly would consider if
2 we -- if we have competing applications and one
3 unit could have superior technology with
4 everything else being fairly equal, that would
5 be a strong issue for approval of the applicant
6 who had the latest technology

7 Q Okay Let me give you a hypothetical Say a
8 1 5 Tesla scanner is to be upgraded with some
9 new electronics Okay Correct me if I'm
10 wrong, but DHEC asks three questions Is there
11 a field strength change, is the cost over
12 \$600,000 00, or does it have any new
13 capabilities Is that correct?

14 A I'm sorry, when you say DHEC asks three
15 questions, is that related to what now? Is
16 that related to substantial change or --

17 Q No, that's --

18 A -- whether it requires another CON?

19 Q Whether it requires another CON

20 A It would be -- now, here again, I haven't
21 worked at the Department in a year and a half,
22 but generally if an existing MRI wanted to
23 upgrade, I think the main thing we look at,
24 would there be a capital expenditure in excess
25 of \$600,000 to upgrade That's the key right

1 there

2 Q Would you also look at whether there are any
3 new capabilities of that MRI?

4 A Certainly, if it costs more than \$600,000,
5 they'd have to go through the CON process And
6 if they had to go through the CON process, that
7 would be to the applicant's benefit to be able
8 to demonstrate by spending more than \$600,000
9 there was some benefit to the community and the
10 patients by having additional capability

11 Q Such as the capability to provide scans to
12 trauma patients?

13 A Well, you're only going to get a trauma patient
14 at the trauma center Unfortunately, in South
15 Carolina, we've only got three trauma centers

16 Q What about acute care patients that require
17 constant monitoring?

18 A Here again, that's going to be in a hospital,
19 so a freestanding is not going to be asking for
20 that

21 Q Okay Okay You agreed in your deposition
22 that took place earlier in this that access for
23 emergency patients was an important issue

24 A I've never had a deposition in this case

25 Q Let me show you a document Did you give a

1 deposition in this case or didn't you give a
2 deposition in this case on Monday, December 17,
3 2007?

4 A Could have been, if -- if the document says I
5 did, I did I just didn't remember

6 Q Okay, okay And I'll refer you -- and then you
7 can put this up -- to the question and answer
8 that was given to you "Is it a fact that one
9 of the main reasons that you approved the fixed
10 in-house MRI was so that emergency patients
11 could have access to the MRI?" And your answer
12 is yes "And is it a provision of services
13 that you considered important as part of the
14 CON approval process, wasn't it?"

15 A Okay I agree -- excuse me -- I agree with
16 that

17 Q Okay So that was your testimony in this --

18 A Right, but -- but nothing about a trauma
19 center

20 Q Okay, understood And further on down the --
21 further on down, that whether you can provide
22 -- whether the applicant can provide emergency
23 services to emergency patients is an important
24 part of the CON process

25 A Yes

1 Q Okay

2 A And, of course, that's related -- that's why
3 the State Health Plan would like every hospital
4 to have its own MRI 24/7

5 Q You've also said -- is it your testimony that
6 a 1.5 Tesla unit is basically the same type of
7 MRI services?

8 A As a 1.5?

9 Q That's right

10 A Yes I mean, I know that's very simplistic,
11 but that is what -- in our CON program we try
12 to make things basic in that regard and we look
13 at the Tesla size, so we look at 1.5's as being
14 very similar

15 Q Okay Moving along, you had a quote, didn't
16 you in the original MRI application, that had
17 a list of capabilities and equipment and
18 ancillary equipment associated with the
19 original project?

20 A Yes, that would have been the application

21 Q That would have been in the application

22 A Yes

23 Q There was no such document contained in the
24 substantial change application, was there?

25 A It probably was not Now, I'm sure in the

1 substantial change document they would have

2 given a estimated total project cost

3 Q Okay

4 A To show that it was less than the original

5 approval

6 Q But that's all that you considered?

7 A Well, taking the applicant's word certainly

8 that it is -- was 1 5 unit and that, you know,

9 I think it was very similar It was

10 refurbished rather than brand new

11 Q Okay You could have asked -- DHEC could have

12 asked for a similar quote for the refurbished

13 unit, couldn't it have, in connection with the

14 substantial change request?

15 A Asked from?

16 Q The applicant

17 A Certainly it could have been asked You know,

18 it could have been I don't know that it would

19 have been important You know, generally it --

20 I've work with some applicants and MRI

21 companies recently and the quotes, you know,

22 you can get them easily if you want Most of

23 them are only valid so many days, etcetera

24 But, yes, I mean we could have asked for it

25 Q Okay Let me give you a hypothetical that I

1 pose That I come to you I've got a 1 5
2 Tesla scanner and I come to you and I tell you
3 that I want to replace the 1 5 Tesla scanner
4 with another 1 5 Tesla scanner Do you need
5 anymore information in order to determine
6 whether that's a substantial change, other than
7 cost?

8 A It would -- certainly we'd need to know a
9 little bit about the location I mean, where
10 it's going to be in the hospital, etcetera I
11 mean, certainly, you know, we would have to
12 look at the particular request you submitted
13 and see if it appeared to be complete But,
14 generally, you know, we do -- hospitals,
15 generally we trust I mean, you know, they
16 have -- they have gotten the Certificate of
17 Need and in that Certificate of Need they
18 signed a statement that everything in that
19 application is true to the best of their
20 knowledge and belief And in terms of
21 fulfilling that Certificate of Need, you know,
22 if they come to us and say they want to
23 downsize or whatever and we took their word, if
24 there wasn't a quote in there, but certainly it
25 had to be less money in terms of it being

1 refurbished rather than brand new and a modular
2 unit rather than inside the hospital

3 Q Well, let me ask you this question If the
4 project is reduced in scope, as you've just
5 described, isn't it indeed possible that it
6 could be reduced in the amount of services
7 provided by the MRI and the need that it is
8 purported to meet in the original application?

9 A I wouldn't think so If it was a very similar
10 unit, the same unit, refurbished rather than
11 brand new, I mean, you know, I wouldn't foresee
12 the scope of services being reduced

13 Q Could it?

14 A Anything is possible

15 Q All right And going back to the hypothetical
16 I just gave you, you would not consider it a
17 substantial change if a 1.5 Tesla scanner was
18 substituted for another 1.5 Tesla scanner, the
19 cost may have gone down or stayed the same, but
20 yet the new unit could only do breast scans
21 whereas the original unit could do an array of
22 scans?

23 A I would think -- I know there is some new MRIs,
24 1.5, that specialize in breast scans and that's
25 an important issue We certainly want the

1 hospital scanner to be able to do a varying
2 array of type scans But, you know, that was
3 an issue that didn't come up and that's -- I
4 would think that, and I'm not an MRI expert,
5 but I would think it would only be very
6 sophisticated new MRIs that focus on breast
7 scanning

8 Q Well, indeed the issue didn't come up, but
9 DHEC, isn't it correct to say that DHEC didn't
10 raise the issue?

11 A May not have

12 Q Okay

13 A I mean, we're not the police You know, we
14 take people at their word and there was no
15 reason for us to have any suspicion

16 Q Okay Does DHEC see any differences between
17 1.5 Tesla MRI projects costing less than
18 \$600,000 and those costing more than \$600,000?

19 A I'm sorry, what was that?

20 Q Does DHEC see any difference between 1.5 Tesla
21 MRI projects costing more than \$600,000 and
22 those that cost less than \$600,000?

23 A Well, you know, as we all know in the evolution
24 of MRIs, because we've had that technology
25 around for much more than 20 years now, there's

1 a lot of refurbished equipment and it's like
2 used automobiles, I mean, you can buy it now
3 beneath the threshold Years ago that wasn't
4 the case, every MRI was going to require a CON
5 review But I think in this particular case
6 when you have a General Electric unit that is
7 refurbished or one of their gold seal units,
8 that's high quality And I would have no
9 problem if someone elects to get that
10 particular unit rather than brand new and it's
11 more cost effective, it would not generally
12 raise a question with the Department

13 Q But are you making a determination that that is
14 indeed high quality?

15 A That is -- I have talked to General Electric
16 representatives that I've had a great deal of
17 respect for and I would certainly think, you
18 know, if it has the same type unit, and I think
19 this was a Signa, etcetera, I would think there
20 would be, you know, it would give very similar
21 type services

22 Q Okay What is the CON threshold? It's
23 \$600,000?

24 A It is currently \$600,000, that's correct

25 Q Okay So there's a difference in the review

1 process between those MRIs that cost less than
2 \$600,000 and more than \$600,000?

3 A That's correct If an applicant can prove
4 that, and that would be a hospital ap -- any
5 healthcare facility would have to obtain a CON
6 regardless of cost, even if they got a \$100,000
7 unit, because we have criteria and standards of
8 the State Health Plan for MRI, any cost
9 initiate that MRI service as far as review
10 But any freestanding unit, if they can
11 demonstrate to the Department that their total
12 project cost is below \$600,000, they can
13 receive an non-applicability determination, but
14 that's appealable also So it's -- sometimes
15 you're doomed whichever way you go as far as
16 being appealed But I have always recommended
17 the applicants to get the equipment they want,
18 the best equipment they want regardless of
19 cost, and go through the appropriate process
20 for approval

21 Q Why does the non-applicability determination
22 threshold exist in the regs?

23 A If --

24 MS GILLESPIE Your Honor, I'm sorry, I'm going to
25 object He continues to ask questions We're

1 here on a substantial change determination

2 We're not here to determine whether or not

3 we've exceeded --

4 THE COURT I understand

5 MS GILLESPIE -- the \$600,000 threshold

6 THE COURT Why would that be --

7 MR PRINGLE Well, I'm talking -- exploring the

8 differences, DHEC's evaluation of differences

9 in cost, and whether it looks at either the

10 quality of units above a certain --

11 THE COURT Well, I think you can stay within the

12 range of this case

13 MR PRINGLE Okay

14 THE COURT When you start get into the non-

15 applicability --

16 MR PRINGLE Okay

17 THE COURT -- determination, I think we're getting

18 too far afield

19 MR PRINGLE Okay, okay

20 Q Well, just suffice it as to say, there are

21 certain -- there is a certain threshold below

22 which the review doesn't take place, correct?

23 A That's correct

24 Q Okay If you've got -- aren't there

25 differences between a 1 5T scanner that costs

1 less than \$600,000 and a 1.5T scanner that
2 costs more than \$600,000?

3 A Certainly I mean, you know, probably the 1.5
4 that costs less is probably an older unit and
5 one that costs more is newer or refurbished
6 and, of course, then you can get 1.5's that
7 cost two million dollars. So it's just, you
8 know, it's like buying a computer or anything
9 else, it's just the newness and quality and the
10 technology that you want. But a basic, a
11 hospital like Coastal Carolina, they're wanting
12 an MRI to be able to take care of their
13 patients, particularly in the emergency room,
14 24/7. If there were a very serious problem
15 with a patient, as has been testified earlier,
16 they would be sent, you know, to a trauma
17 center or major hospital for treatment, but
18 diagnosis is very important initially.

19 Q How would they send those patients who --
20 doesn't a patient have to be stable to
21 transport?

22 A Probably that would be preferable, that's
23 correct. But who knows -- you know, a hospital
24 near I-95 if there was a serious accident, you
25 assume the medical services would have direct

1 -- correct transportation But I guess there's
2 always the case someone could be brought in
3 with a much more serious problem than what
4 might have been detected by EMS So certainly,
5 you know, an emergency room physician would
6 have to make those decisions

7 MR PRINGLE That's all I have, Your Honor

8 THE COURT Ms Gillespie?

9 MS GILLESPIE Just one follow-up question

10 MR GRICE - RE-CROSS EXAMINATION BY MS GILLESPIE

11 Q Going back to your comment that you thought
12 this appeal was an abuse of the CON process,
13 when you made that comment were you talking
14 about the fact that appealing a substantial
15 change is an abuse of the process or the fact
16 that this was such a close call that it was an
17 abuse of the process?

18 A In my opinion, this was a close call -- it's
19 just this is a determination the Department
20 would have made that I would have never dreamed
21 would have been appealed because it was, you
22 know, very simplistic in terms of the
23 Department's decision and, you know, that it
24 was very, very clearly, in my opinion, not a
25 substantial change

1 Q Okay And, just so the record is clear, I
2 think you said this is a close call, is that
3 what you want your testimony to reflect?

4 A No, I'm sorry It's not a close call It's so
5 clear that this is not a substantial change, in
6 my opinion, that it's almost no question in my
7 mind a 1 5 for 1 5, basically same brand and,
8 you know, the cost is lower and it's there at
9 the hospital under the hospital's license
10 adjacent to the hospital with a covered
11 corridor, so in my opinion it is absolutely not
12 a substantial change

13 Q Okay And last question Mr Pringle asked
14 you questions about DHEC's review You were
15 the supervisor on this project, right?

16 A Yes, I was director of the Bureau and I had a
17 staff that was very capable Ms Tibshirany was
18 an excellent staff person, very educated, and
19 I let her work independently If she had any
20 questions, she would come to me

21 Q And so as the supervisor, would you have
22 reviewed every single thing that Coastal
23 Carolina would have submitted?

24 A Not everything, no I mean, I did make the
25 decision on the original application On the

1 substantial change, that was -- those type
2 requests were handled by Ms Tibshrany and, you
3 know, she was very, very good at her job And
4 basically only if there had been something that
5 was really troublesome to her would she have
6 come to me, you know, if we had really had to
7 analyze it in detail, but this was not one of
8 those situations because this was very clear
9 cut

10 Q Okay Thank you, Mr Grice No further
11 questions

12 MS BIGGERS No further questions

13 THE COURT Any follow-up on the questions Ms
14 Gillespie had?

15 MR PRINGLE Nothing further

16 THE COURT All right You may step down

17 MS BIGGERS And, Your Honor, DHEC has one more
18 witness that would be Ms Tibshrany, but when
19 we were planning for today I was actually
20 thinking we wouldn't get to her until tomorrow

21 THE COURT Okay

22 MS BIGGERS So she had to make childcare
23 arrangements and she's not available this
24 afternoon, but is available first thing
25 tomorrow morning, so if --

1 THE COURT All right

2 MS BIGGERS And I actually brought this to the
3 other attorneys' attention and I don't believe
4 any of them would have objections, if you
5 wouldn't mind, if we broke early today and took
6 Ms Tibshrary first thing in the morning

7 THE COURT That's fine I wasn't necessarily
8 looking forward to seeing y'all tomorrow, but
9 that's fine

10 MS BIGGERS I appreciate it, thank you

11 THE COURT Are there any other witnesses after her?

12 MS BIGGERS Not from DHEC, Your Honor

13 MR PRINGLE We might put up Dr Borelli for a
14 brief reply

15 THE COURT Reply Well, they've got to finish
16 before you can do that

17 MR PRINGLE Oh, I understand I just was -- you
18 asked --

19 THE COURT It would be more convenient for you to
20 go ahead and do that now, wouldn't it?

21 MR PRINGLE I imagine so

22 THE COURT Okay Well, let's just break Thank
23 y'all for your time

24 (There being nothing further at this time, the
25 hearing was adjourned at 3 48 p m)

1 DAY TWO - WEDNESDAY, AUGUST 5, 2009

2 THE COURT Ms Biggers?

3 MS BIGGERS Your Honor, I call Tori Tibshrary

4 TORI TIBSHRARY, being duly sworn, testifies as
5 follows

6 MS TIBSHRARY - DIRECT EXAMINATION BY MS BIGGERS

7 Q Ms Tibshrary, are you currently employed?

8 A No

9 Q Did you used to work at the Department of
10 Health and Environmental Control?

11 A Yes

12 Q And how long did you work for DHEC?

13 A I worked for DHEC for approximately seven and
14 a half years

15 Q What were your job positions and
16 responsibilities during that time?

17 A I had a number of job positions over the course
18 of the seven and a half years I started as a
19 CON reviewer, and did that for approximately
20 a year and a half, where I was solely reviewing
21 Certificate of Need applications After that
22 time, I reviewed exemption and non-
23 applicability requests, I performed CON follow-
24 up for applications that had been approved, and
25 did the follow-up on those And later I served

1 as program director overseeing the CON
2 reviewers and the exemption and non-
3 applicability reviews

4 Q And when did you leave DHEC?

5 A I left DHEC in January 2009

6 Q Can you give us some of your educational
7 background?

8 A I attended the University of South Carolina
9 from 1995 to 1999 and received a finance
10 degree I received a Master's in Health
11 Administration in 2001 and went to work for
12 DHEC shortly thereafter

13 Q You said part of your job responsibilities at
14 DHEC included follow-up once a CON was
15 approved Can you explain for us what all that
16 entailed?

17 A Recipients of Certificates of Need were
18 required, are required to submit monthly
19 follow-up reports in which they detail the
20 progress of the projects, and are also required
21 to demonstrate that projects are underway I
22 reviewed that documentation as it came in and
23 ensured that all projects were following the
24 time lines that were -- that were demonstrated
25 in the application

1 Q Did any of those applicants, during that
2 follow-up process, ever submit requests to the
3 Department to change any part of the CON as it
4 had already been approved?

5 A Yes

6 Q And did you review those requests for change?

7 A I did

8 Q Are you familiar with the section in Regulation
9 61 15 that talks about substantial change to a
10 CON once it's been issued?

11 A Yes

12 Q I'd like for you to read that aloud

13 MS BIGGERS And if I may provide the witness with
14 this copy of the reg?

15 THE COURT Okay

16 Q Could you read Section 605 aloud for us

17 A "If an applicant amends or alters his project
18 after receipt of a Certificate of Need, the
19 Department will decide whether or not the
20 amendment is substantial and thereby
21 constitutes a new project "

22 Q And is that the provision in the reg that you
23 applied when reviewing requests for change?

24 A Yes

25 Q How did you go about reviewing such requests

1 while you were employed by the Department?

2 A Requests would come in from an applicant I
3 would read the request I would generally pull
4 the application and go back and review the
5 original scope of the project, comparing what
6 -- comparing the proposed change or the
7 proposed amendment to what we originally
8 reviewed and approved, and often I may ask for
9 additional information, depending on the
10 information that was provided by the applicant,
11 and go from there From project to project,
12 the different aspects or the change that I may
13 be looking at, you know, would be different, or
14 may be different, but in general that's how I
15 would go about it

16 Q Can you give us a couple of examples of changes
17 you've reviewed to CON applications in the past
18 that were, in your determination, substantial?

19 A I know I have I can't think of any --

20 Q Just in general It doesn't have to be a
21 specific actual project

22 A Sure I do remember a project actually
23 involving an MRI It was in Greenville It
24 was St Francis Hospital in Greenville We had
25 approved them for a 1.5T MRI, and they came

1 back later and asked to purchase a 3 0 Tesla
2 MRI instead, and we told them that that would
3 be a substantial change I'm not positive that
4 they actually -- that they submitted a formal
5 request for this, they may have, but I know
6 that they ended up asking us to void their
7 original CON so that they could go back through
8 the CON process for a 3 0

9 Q And what was it about that change that you
10 determined was substantial?

11 A That the equipment was not like equipment
12 having similar capabilities The capabilities
13 for the 3 0 Tesla MRI exceeded that of the 1 5
14 that we had approved in the application

15 Q Did you review the substantial change request
16 for CCMC in this case?

17 A Yes

18 Q And that was also an MRI project, right?

19 A That's correct

20 Q What are some of the factors that you look at
21 when the change request involves a CON for an
22 MRI unit?

23 A We look at the capabilities of the unit itself,
24 specifically we have traditionally looked at
25 magnet strength We also look at cost of the

1 unit, of the original unit versus the new unit
2 that is proposed, and the location

3 Q Will you turn in DHEC Exhibit One to Bates page
4 896 And can you tell us what this document
5 is, starting on page 896, when you get to it?

6 A This was the letter from Coastal Carolina
7 Medical Center requesting a determination of
8 whether their proposed amendment constituted a
9 substantial change to the project

10 Q Can you summarize for us what the proposed
11 changes are that CCMC set forth in its request?

12 A They requested to purchase a modular unit, a
13 modular MRI unit that would be housed in a
14 modular building just outside of the hospital
15 instead of constructing an addition to the
16 hospital building which would house a fixed MRI
17 unit In addition, the proposed unit would be
18 a refurbished unit, where the initial unit that
19 was proposed in the application was a new unit

20 Q And was there a change to the project cost as
21 well?

22 A Yes, there was, there was a significant
23 decrease in the project cost

24 Q And what documents did CCMC provide along with
25 this request to give you more information to

1 review?

2 A They provided the sales, a draft version of the
3 sales agreement for the proposed MRI unit

4 They also provided quotes for I believe
5 skirting the unit -- let's see, yes, skirting
6 the unit, removing the wheels from the modular
7 building, and an itemization of capital costs,
8 a diagram of where the unit would be located

9 I believe that's it in this particular letter

10 Q And are those all in the DHEC file attached to
11 the Bates page 896 and going on through 910?

12 A Yes Through 908

13 Q 908, okay What did you do once you received
14 this information?

15 A I read it, I reviewed it, and I'm sure that I
16 pulled the initial file and went back through
17 and compared what was being proposed here to
18 what was in the initial CON application, what
19 we had approved there I also, after doing
20 that, requested additional information from
21 them

22 Q Will you turn to Bates page 911 And can you
23 tell us what that document is?

24 A That is my letter to Coastal Carolina Medical
25 Center requesting additional information

1 Q What kind of additional information did you
2 request?

3 A I asked for more detail regarding the project
4 setting and the proposed change I asked if
5 they proposed to permanently house the mobile
6 unit in this coach, what else needed to be
7 completed in order to accomplish that service
8 I asked them to specifically state the proposed
9 location of the equipment I asked if this was
10 the mobile unit that they had been operating on
11 an interim basis I asked if it would be the
12 same mobile pad and the same electrical hookups
13 they were currently using at the time with the
14 mobile unit and the cost of those items I
15 asked for a revised time table I also asked
16 if the -- I asked them to confirm that this
17 mobile unit was the one that they had been
18 leasing on an interim basis, and then
19 additional questions if it was not And asked
20 them to provide detail regarding the age of the
21 proposed equipment

22 Q And did CCMC respond to your request?

23 A They did

24 Q Can you tell us where in the DHEC file marked
25 Exhibit One that response is located?

1 A Page 913 through 915

2 Q Did you feel that CCMC answered your questions
3 satisfactorily to give you that additional
4 information to review?

5 A Yes

6 Q And what was your determination once you
7 reviewed all of that information?

8 A My determination was that the proposed
9 amendment was not a substantial change to the
10 original project

11 Q What were the reasons for that decision? And
12 if you could just focus on the changes that
13 they actually proposed to make and why you
14 thought those changes were not substantial

15 A The location of the project was not changing,
16 the unit would still be located at the
17 hospital The cost substantially decreased,
18 there was no increase in cost And the unit
19 was substantially the same, it was -- they were
20 -- they had initially proposed a 1.5T MRI and
21 what they proposed to -- what they proposed to
22 purchase here was a 1.5 Tesla MRI, and they did
23 not indicate that there were any significant
24 changes in the equipment in their letter

25 Q If you turn to DHEC Exhibit One, Bates page

1 916 And can you tell us what that document
2 is?

3 A That is the letter that I sent back to Coastal
4 Carolina Medical Center approving the proposed
5 amendment

6 Q After you approved the proposed amendment, what
7 else did you do with regard to this particular
8 file as far as follow-up?

9 A I also reviewed their final completion report
10 that they submitted on June 26, 2007

11 Q And did you find that satisfactory?

12 A Yes

13 Q Once they submitted and you approved the final
14 completion report, what happened?

15 A The file was closed at that time

16 Q Did CCMC submit any other request to DHEC
17 around or just right after the time of this
18 change in the project?

19 A Yes There was an exemption request submitted
20 to DHEC for a change in ownership

21 Q Of the hospital?

22 A Yes

23 Q And do you recall, was that before or after you
24 had determined that this project was closed?

25 A It was after the project was closed

1 Q And what happened with that exemption request?

2 A It was approved

3 Q Okay Was there any reason, in your opinion,
4 as you were reviewing that exemption request,
5 for that change of ownership to affect this CON
6 file that you had reviewed?

7 A No The CON file at that point was closed
8 The CON no longer existed, the project was
9 complete The CON was over at that point

10 Q Did anyone from MRI at Belfair, or claiming to
11 represent MRI at Belfair, bring to your
12 attention any objections or concerns or
13 comments regarding that transfer of ownership?

14 A Not that I can remember, no

15 Q Okay Those are all my questions

16 THE COURT Ms Gillespie

17 MS GILLESPIE Thank you, Your Honor

18 MS TIBSHRANY - CROSS EXAMINATION BY MS GILLESPIE

19 Q Ms Tibshrany, how long did you say you had
20 worked at the Department?

21 A Seven and a half years

22 Q Okay And in your time that you were there in
23 those seven and a half years, how many
24 substantial change requests would you say you
25 reviewed?

1 A Numerous I don't know that I could put a
2 number on it, but

3 Q Okay So it's fair to say you have experience
4 in reviewing and making these substantial
5 change determinations?

6 A Yes

7 Q Okay

8 MS GILLESPIE Could you pull up 61 15, please?

9 Q I think Ms Biggers already went through this
10 with you, but Okay Is this the portion of
11 the regulation that you -- that is at issue
12 when you're making substantial change
13 determinations?

14 A Yes

15 Q Okay And how much guidance does this
16 regulation give you in determining what
17 constitutes a substantial change?

18 A This is about as far as it, as the regulation
19 goes with it

20 Q Okay So would you agree that DHEC has a great
21 deal of discretion in determining what
22 constitutes a substantial change?

23 A Yes

24 Q And do you see anything in this regulation that
25 outlines what an applicant should provide to

1 DHEC in requesting whether a change is
2 substantial or not?

3 A No

4 Q So it's left up to the Department and the
5 applicant to decide what is enough information
6 to determine whether a change --

7 A What is relevant to that particular project,
8 yes

9 Q Okay And would you say that in reviewing a
10 project to determine whether changes are
11 substantial or not, you view that from a health
12 planning perspective or a clinical perspective?

13 A A health planning perspective

14 Q Okay And do you make any clinical
15 determinations when you're reviewing changes,
16 as to whether they're substantial?

17 A No

18 Q And why is that?

19 A Because my background and what I've been tasked
20 to do throughout my seven and a half years at
21 DHEC, both as a CON reviewer and in making
22 these types of determinations, has been based
23 on health planning issues, not clinical issues
24 There would certainly be a clinical factor to
25 that, but as a whole it's from a health

1 planning standpoint

2 Q Okay How does the project review criteria
3 that is identified as being important in the
4 original CON application factor into your
5 substantial change determination?

6 A They would still be relevant We're looking to
7 see that the changes that are being made to the
8 project don't affect the initial criteria that
9 were deemed to be important at the time of
10 review

11 Q So with the changes, does the applicant still
12 have to meet the same project review criteria
13 they did in the original application?

14 A Yes

15 Q Okay And listening to you go over the letter
16 -- could you pull up the letter, 896 and 897?
17 This is Respondent Coastal's Exhibit One, Bates
18 number 896 and 897 If you'll pull up the
19 second page, Dan You went through the changes
20 with Ms Biggers that Coastal requested to make
21 to their project, and I think the three changes
22 I heard you say were location, cost, and
23 machine?

24 A Yes

25 Q Is that accurate?

1 A Uh-huh (affirmative response)

2 Q What project review criteria would location

3 relate to?

4 A I'm going to need to go back and -- is it okay

5 if I look through this file?

6 Q Sure Yes

7 A And are you asking me in relation to the

8 initial review of the CON or in general what

9 project --

10 Q Their original CON

11 A Okay Accessibility

12 Q Okay And was accessibility identified as one

13 of the project review criteria in the original

14 CON?

15 A Yes

16 Q Okay

17 A It was one of the first

18 Q So after analyzing the change in location that

19 Coastal planned to make, would Coastal's

20 project still meet the accessibility project

21 review criteria that they did in the original

22 application?

23 A Yes

24 Q Okay I heard you say cost was one of the

25 changes that they proposed to make What

1 project review criteria does cost relate to?

2 A Cost containment

3 Q Okay And after the changes that Coastal
4 planned to make, would Coastal's project still
5 meet the cost containment project review
6 criteria?

7 A Even more so, yes

8 Q Okay And why even more so?

9 A Because the amended project was substantially
10 lower in cost than the initial project

11 Q Okay And the third change I heard you say was
12 a different MRI unit What project review
13 criteria would that relate to?

14 A It would -- well, acceptability, but it
15 wouldn't necessarily relate to a specific
16 criteria The point of it being that it is
17 substantially the same unit that we approved in
18 the initial application

19 Q Okay And after looking at the new unit that
20 Coastal planned to implement, did you determine
21 that it was substantially the same unit that
22 they proposed in their original application?

23 A Yes

24 Q Okay There are other project review criteria
25 that were identified as important, need,

1 acceptability, things that weren't identified
2 as important, but financial feasibility,
3 adverse impact Did you consider any of those
4 project review criteria in your analysis?
5 A Yes
6 Q You did And can you tell me about your
7 analysis of those project review criteria?
8 A Specifically, financial feasibility?
9 Q Well, you can start with need, did you consider
10 need in determining --
11 A Yes Need had been demonstrated in the
12 Certificate of Need application It was
13 determined to be a relevant factor in approving
14 that application And the project didn't
15 change as a result of these changes -- of the
16 proposed amendment, the need was still there
17 and it was still being accomplished with the
18 1 5T MRI unit located at the hospital
19 Q Okay So, would you -- in your opinion, was
20 need still met in the proposed changes, as it
21 was in the original project?
22 A Yes
23 Q Okay And acceptability I didn't see any
24 letters of support with our request for
25 changes Did you consider acceptability in

1 your analysis?

2 A The letters that were sent with the initial
3 Certificate of Need application certainly
4 covered what was being proposed because, as I
5 said, the project was not substantially
6 changing The support for the original project
7 served as support for the amended project

8 Q And do you typically see letters of support
9 submitted with substantial change requests?

10 A I've never seen a letter of support submitted
11 with a substantial change request

12 Q Okay How about financial feasibility? Did
13 you consider financial feasibility in
14 determining whether the changes were
15 substantial and whether we still met that
16 criteria?

17 A Yes Clearly, if -- clearly, if the initial
18 project was financially feasible, this project
19 was -- the amended project was going to be
20 financially feasible because the cost was
21 greatly reduced

22 Q Okay And how about the final one, adverse
23 impact Did you consider adverse impact in
24 your analysis?

25 A Yes and no, for the same reasons that the

1 project was not substantially changing If
2 adverse impact was not an issue to start with
3 in the original CON application, it wouldn't be
4 an issue here simply because the project is
5 substantially the same

6 Q Okay So, in your opinion, did the changes
7 that Coastal proposed to make in the new
8 project, did they still meet all of the same
9 project review criteria that we just went
10 through as they did in the original CON
11 application?

12 A Yes

13 Q And do you still agree with that opinion --

14 A Yes

15 Q -- today? Okay Let's look again at this
16 letter Actually, we went through the three
17 changes, we just went through them, location,
18 cost, and the unit Do you see any other
19 changes that Coastal proposed to make in this
20 letter?

21 A If you don't mind, I am going to flip back to
22 this letter in the book because I have a hard
23 time reading on the screen

24 Q Sure It's Bates 896 and 897

25 A Okay I believe that the three factors you

1 just mentioned are the three main factors that
2 are addressed in this letter

3 Q Okay So if Coastal was planning on making a
4 change like providing full-service MRI versus
5 just breast scans, would you have expected
6 Coastal to outline that change in their letter?

7 A Absolutely

8 Q And if they didn't, did you make any
9 assumptions about any other changes?

10 A No I assumed unless they disclosed something
11 like we are only going to be offering breast
12 scanning services, that the services that they
13 would be offering were the same as those
14 initially proposed in the CON application

15 Q Okay You would have to agree with me that the
16 total project cost in the original CON
17 application of \$3 2 million and the total
18 project cost as implemented of approximately
19 \$571,000 is a big difference in cost, wouldn't
20 you?

21 A Yes

22 Q Why is that not a substantial change?

23 A It's been past practice of the Department to
24 look at substantial change in terms of
25 increases in cost Cost alone -- a cost

1 decrease alone would not constitute a
2 substantial change Other factors along with
3 it could But in this case there were not
4 other factors along with the -- along with the
5 cost decrease that would result in a
6 substantial change determination

7 Q Okay So the original CON application is more
8 of a maximum or a ceiling?

9 A Yes There has generally been a 10% overrun
10 kind of cap that cost alone, if it exceeded 10%
11 of what -- 10% higher than what we approved
12 would result in a determination of it being a
13 substantial change due to cost However, a
14 decrease would not be the same thing

15 Q Okay And I heard you say, when you were
16 talking to Ms Biggers, that in analyzing the
17 difference in the two machines what you looked
18 at was Tesla strength, is that correct?

19 A Yes

20 Q Is that the only thing that the Department
21 considers in determining if there's a
22 substantial change in the unit itself?

23 A It is the major factor in determining whether
24 it is like equipment having similar
25 capabilities That determination is made for

1 both exemptions and for changes to CON
2 applications And to be consistent in our
3 types of reviews, it is the main factor that we
4 look at However, it is not the only factor
5 For example, if someone had a mobile MRI unit
6 and requested an exemption for a fixed -- let's
7 say a mobile 1.5 Tesla MRI unit and requested
8 an exemption to replace it with a fixed 1.5
9 Tesla MRI unit, we do not necessarily -- we
10 don't consider those to be like equipment

11 Q Why not?

12 A Because a mobile unit would only be operating
13 at a facility less than five days per week A
14 fixed unit would be there on a full-time basis

15 Q Okay So --

16 A In this case, this is not a mobile unit that
17 they are proposing, it is a modular unit that
18 -- it has fixed -- capabilities isn't the right
19 word, but it is in a fixed setting

20 Q So in the scenario that you just described to
21 me, the focus is more on the hours of operation
22 rather than the capabilities of the machine, is
23 that correct? Or the time that it's available
24 to the provider?

25 A That's right

1 Q Okay Do you -- when you were reviewing this
2 file, was this a close call --

3 A Can I --

4 Q -- for you? I'm sorry

5 A Can I go back to something?

6 Q Sure

7 A I just want to -- what I'm trying to say is
8 that the Tesla strength is an indicator of the
9 capabilities, and that is what we use to
10 determine that the capabilities are remaining
11 somewhat similar

12 Q Okay Was this a close call for you?

13 A No

14 Q Okay I've prepared a demonstrative of the
15 time line of your review based on the documents
16 that you just went through with Ashley Can
17 you pull up the time line? Okay Does this
18 accurately represent the time line of the
19 documents that you just went through with Ms
20 Biggers?

21 A Yes

22 Q Okay Tell me about how long it took you in
23 making your determination

24 A The initial letter came in on the 12th and my
25 letter requesting the additional information

1 went out on the 21st, so there was nine days of
2 review time there Their letter giving
3 additional information came back the same day
4 as my request went out, and the next day I
5 approved the project

6 Q Okay So how much time elapsed between the
7 original request and the time that you made the
8 final decision?

9 A Ten days

10 Q And in your opinion, is that an adequate amount
11 of time to review a project as to whether the
12 changes are substantial?

13 A Yes

14 Q Is that similar to review time that you've done
15 in the past?

16 A Yes

17 Q Okay Last question I heard you talk to Ms
18 Biggers about the exemption request that
19 Coastal submitted for the sale?

20 A Uh-huh (affirmative response)

21 Q And I heard you say that no one from MRI at
22 Belfair raised the issue as to whether the
23 exemption was approved or not Did anyone from
24 MRI at Belfair raise the issue that that
25 exemption voided this CON?

1 A No

2 Q Okay Thank you, no further questions

3 THE COURT Mr Pringle

4 MR PRINGLE I believe Mr Beach is going to do the
5 cross-examination

6 THE COURT You believe that?

7 MR PRINGLE It is my understanding

8 MS TIBSHRANY - CROSS EXAMINATION BY MR BEACH

9 Q Good morning

10 A Good morning

11 Q How are you?

12 A I'm fine, how are you doing?

13 Q I'm doing fine, thank you You know who I am

14 A Yes

15 Q I'm John Beach and I'm representing MRI at
16 Belfair here Ms Tibshrany, would it be safe
17 to say that the time line of this particular
18 situation, when you consider -- and the
19 occurrences in this particular situation, when
20 you consider that the mobile or modular unit
21 was put into place temporarily back in 2006 and
22 then they ask for the mobile or modular unit to
23 become the replaced project in '07, and then
24 immediately on the heels of that there was the
25 sale of the hospital that had to be approved,

1 was a pretty unique set of different
2 occurrences?

3 A That certainly didn't happen every day Yes,
4 that --

5 Q Okay And so, is some of the things that we're
6 wrestling here, could it be because of the fact
7 that this unit was wheeled onto the property in
8 2006 and begun to be used as a temporary unit
9 then, but then later it was that temporary that
10 was asked to be the replaced project?

11 A I'm sorry, would you -- I'm not --

12 Q Well, let me ask this Have you ever had
13 another situation where there was a temporary
14 MRI unit put into place and then there was a
15 downsizing, if you will, of the project just
16 before the end of the period to implement it,
17 like this?

18 A I can't think of -- I can't think of a
19 situation offhand, although it wouldn't
20 surprise me if there had been

21 Q Okay Now, you've called this a modular unit
22 It was actually rolled onto the property
23 initially, was it not?

24 A That's correct

25 Q And is it your understanding that at least

1 until the time when the substantial change
2 request was approved, that it still had wheels
3 under it and could have been rolled off of the
4 project?

5 A That is -- and that -- that's the same for any
6 modular unit Modular units by definition are
7 units that can be rolled on at one point and
8 have the wheels taken off and I suppose put
9 back on at some point down the road and rolled
10 back off

11 Q Aren't modular units though typically -- when
12 you use the term modular, aren't they really
13 more like these temporary buildings that are
14 used at schools and whatnot to house people
15 while they're being renovations done? I mean,
16 they're wheeled onto the property but they're
17 not really tractor-trailer rigs like this one
18 was, isn't that right?

19 A I -- would you say that again? I'm not trying
20 to --

21 Q Well, isn't another word for modular -- another
22 sense in which we understand modular units to
23 be modular units that are wheeled onto the
24 property but aren't really designed to go up
25 and down the interstate like this one was?

1 A And I think that goes back to what I just said
2 All modular units by definition have mobile
3 capabilities But if you want to affix them to
4 a pad by taking the wheels off and skirting the
5 unit, that capability is there as well

6 Q Okay But some modular units, as you call
7 them, are designed to be used in a mobile
8 setting so they move from one place to another,
9 they hook up to a tractor rig and it's a
10 tractor-trailer And I think this one was
11 designed that way, was it not?

12 A Sure And I guess my point is, at some point
13 in the game they all have that capability, that
14 you can disable that capability, which is what
15 the hospital did here eventually But --

16 Q Well, aren't there some modular units that
17 aren't designed for everyday mobile use? You
18 can put the wheels under them long enough to
19 get them from one place to another --

20 A Sure

21 Q -- but they're really designed to be fixed once
22 they're --

23 A Yes

24 Q Okay And this wasn't that kind of unit? Or
25 do you know?

1 A My understanding is that, and I think I keep
2 repeating myself, but my understanding is that
3 they all have the capability at one point to be
4 mobile, but by affixing them to a pad they are
5 modular

6 Q All right Well, let me just give you an
7 example that I think we can all --

8 A Modular is, I'm using it as removing the mobile
9 capability It's keeping it from being able to
10 be hooked up to a truck and hauled off the next
11 day

12 Q Okay And what I'm trying to do is distinguish
13 between modular units that could be used on an
14 everyday basis as a mobile unit week in and
15 week out and modular units that are like a
16 double wide, that might temporarily have wheels
17 under it so you can get it from one place to
18 another but it's not designed to go regularly
19 from here to here to here on a set schedule
20 Those are the two kind of modular units that
21 I'd like you to tell me whether you can
22 distinguish between those

23 A Yeah --

24 MS BIGGERS Objection I think this has been
25 asked and answered a couple of times now

1 THE COURT I'm going to let him go forward one more
2 time on this

3 A I understand your distinction

4 Q Okay

5 A I just I think that we -- I think you and I see
6 this differently I think that -- I don't
7 know I feel like I -- I apologize for
8 repeating myself, but the two types of units
9 that you're referring to can both be mobile
10 units --

11 Q Right

12 A -- and they can both be affixed

13 Q Okay In your parlance, both of those are
14 modular units, if the wheels are taken out from
15 under them?

16 A Yes

17 Q Okay But this one is the kind of modular unit
18 that could be used on a weekly basis to go from
19 this hospital to this facility to this
20 facility?

21 A Sure

22 Q Okay Now, the thing that I didn't notice, the
23 two things that I did not notice on the time
24 line that was up there was, number one, the
25 request in 2006 to have this unit, which still

1 had wheels on it for that time so it was a
2 mobile unit I believe, in your parlance, to be
3 used for -- during the interim period while
4 they were -- while CCMC was implementing the
5 CON, is that correct?

6 A I will be honest, in preparation for this I did
7 not go back and study that, but that sounds
8 correct to me

9 Q Okay You understand that this unit was
10 initially placed on the lot, or rolled onto the
11 lot, by CCMC in 2006 and it was used on an
12 interim basis --

13 A Yes

14 Q -- while they were implementing the CON?

15 A I'm aware of that Yes

16 Q Okay And then the other thing that I think
17 you did mention you were aware of is very
18 shortly after your June 26, 2007 approval of
19 this request for substantial change exemption
20 or whatever, there was a change in ownership of
21 the hospital to Tenet, is that correct?

22 A That's correct

23 Q Now, if that change in ownership had been
24 requested before the CON project was finalized,
25 which -- and the CON was final -- report was

1 submitted and was approved by DHEC, based on
2 your experience, what would have been the
3 implications of that change in ownership?

4 A The change in ownership --

5 Q Had --

6 A -- without any further detail, would have
7 voided the CON

8 Q Okay

9 A And I guess the time frame here is kind of what
10 makes this a little bit gray But assuming
11 that none of this was underway and the CON was
12 just open and it, you know, implementation and
13 completion of the project was nowhere on the
14 horizon, then yes, the change in ownership of
15 the hospital would have voided the CON

16 Q Okay But could a change in ownership occur
17 before the project was implemented and approved
18 and some -- and it wouldn't have been voided by
19 the statute?

20 A No

21 Q Okay

22 A I guess what I'm saying is if an exemption
23 request had come in somewhere in the midst of
24 their implementation and I had not issued an
25 exemption yet, and the change of ownership had

1 not occurred --

2 Q Right

3 A -- and the project closed somewhere midway --

4 Q Right

5 A -- then that may not have But I'm saying, you

6 know, if you take that out of the equation,

7 yes, it would have voided the CON

8 Q Well, and just so we're clear, as far as I

9 know, there's a thick black line that the

10 statue draws, and it is when the CON project is

11 implemented and approved?

12 A Right

13 Q And any change in ownership prior to that time

14 voids the CON, is that correct?

15 A Right I think your initial question asked

16 about the ap -- the exemption to the change in

17 ownership The change in ownership itself

18 would have most definitely voided the CON had

19 the CON not been completed and closed out

20 Q Okay But you're thinking that if the

21 exemption had been requested but the change

22 hadn't occurred, maybe there could have been

23 some adjustment?

24 A Yeah Or the exemption hadn't been reviewed

25 yet

1 Q Right

2 A I mean, obviously not all requests are reviewed
3 the same day they come in

4 Q Okay

5 A As you saw, this one took ten days before my --
6 or nine days before my request for additional
7 information

8 Q Okay So let me -- I think I understand you

9 A And I'm not trying to make this more difficult
10 than it is

11 Q I don't think so And let me see if I can
12 encapsulate this the way I understand it If
13 the change in ownership had occurred before the
14 CON was implemented and approved, that would
15 have automatically voided the CON, correct?

16 A And closed out Yes

17 Q Okay Thank you When an applicant amends a
18 project after the receipt of the CON but before
19 it's -- before the CON is finally implemented
20 or approved, like happened here, and submits a
21 change request pursuant to Rule 605, or Section
22 605, what happens if your department determines
23 that the amendment is substantial?

24 A Then they can either go forward with the
25 approved project, or they can opt to have the

1 CON voided and go back through CON review for
2 the project that they would like to do in its
3 amended form

4 Q Okay And I think the words, the exact words
5 in 605 are that it would constitute a new
6 project if you determine that it was a
7 substantial change, isn't that right?

8 A Yes I would -- yes Now, what happened here,
9 they requested our determination before they
10 went through with these changes so that they
11 could get the Department's interpretation of
12 whether or not this is a substantial change

13 Q Okay

14 A Had it been a substantial change, that
15 determination would not have automatically
16 voided their CON simply because they asked for
17 the determination They still could have gone
18 forward with the project as we approved it in
19 the CON application

20 Q Right

21 A It wouldn't -- that determination would not
22 have resulted in the immediate voidance of the
23 original CON

24 Q All right But if they wanted to proceed with
25 the project as amended, as they've reflected it

1 in Mr Summer's --

2 A They would have to go through CON review

3 Q Okay Mr Summer's June 12, 2007 letter, then
4 they would have to go -- it would be treated as
5 a new project and they'd have to go through a
6 new CON?

7 A Correct

8 Q So if you determined that it was a substantial
9 change, the amended project could still receive
10 the CON if it goes through that process, am I
11 correct?

12 A Yes

13 Q Okay Dependant upon whether it meets --

14 A Certain review criteria

15 Q Okay Thank you Let's look at a statute that
16 we haven't spent much time on over the last day
17 and a half It's 44-7-230(A), and I have it up
18 on the screen right now And you can
19 familiarize yourself with it

20 A Okay

21 Q Okay Thank you Are you familiar with this
22 statute?

23 A Yes

24 Q Okay If you would please, just read the first
25 sentence into the record

1 A "The Certificate of Need, if issued, is valid
2 only for the project described in the
3 application, including location, beds and
4 services to be offered, physical plant, capital
5 or operating costs or other factors as set
6 forth in the application, except as may be
7 modified in accordance with the regulations "

8 Q Okay Great Now, from the Department's
9 perspective, what is the purpose of that part
10 of section A?

11 A To clarify or specify that the CON is only
12 valid for the project that was reviewed, and
13 that substantial changes to the project would
14 invalidate the Certificate of Need

15 Q Okay So based on that, does the Department
16 rely on that language in order to carry out
17 Regulation 61 15, Section 605?

18 A Yes

19 Q Okay And would you agree that many of the
20 factors that you look at in determining whether
21 a project amendment is a substantial change, or
22 in executing 605, are actually set forth in
23 section A?

24 A Yes

25 Q Okay And those factors are location, beds and

1 services to be offered, physical plant, capital
2 or operating costs, and other factors as set
3 forth in the application?

4 A Yes

5 Q If you would, let's take a look at the work
6 location there Now, in reviewing CCMC's, and
7 I'm going to call it a substantial change
8 request, if that's all right with you, just
9 because it's easy for me to refer to it as
10 that, did you review the location within or
11 outside of the hospital of the originally
12 proposed in-house MRI suite?

13 A Yes

14 Q Okay And where was it to be located?

15 A The initial unit was to be in an addition that
16 was to be constructed on one side of the
17 hospital I believe it's the opposite side of
18 the hospital from which the mobile unit ended
19 up being located

20 Q Okay And just to be clear, I think it was
21 adjacent to the emergency room?

22 A Yeah

23 Q All right Now, in reviewing CCMC's
24 substantial change request, did you also review
25 the location for the proposed modular or mobile

1 MRI unit?

2 A Yes

3 Q Okay And that was actually one of the

4 questions that you asked Mr Summer in your

5 June 21, 2007 letter to him, correct, to --

6 A Yes

7 Q -- clarify the location issue? All right

8 Now, would you agree with me that the

9 Department considers that term location, as it

10 is used here, to include patient access?

11 A Yes, it can include location -- I mean, patient

12 access

13 Q Patient access to the unit?

14 A Yes

15 Q Okay So in reviewing this CCMC substantial

16 change request, did your department consider

17 how the proposed -- I have a hard time not

18 saying mobile unit, but I'm not trying to make

19 it sound like anything other than just what I

20 know it as

21 A Sure

22 Q But the unit, the proposed unit, changed the

23 patient access that CCMC's original in-house

24 MRI suite would have provided? In other words,

25 did you look at the question or consider how --

1 A Yes We were aware of that

2 Q Okay And just so we're clear, patient access
3 is one of the things that you actually have to
4 review in a situation like this to determine
5 whether there's a substantial change, isn't it?

6 A Yes

7 Q Okay In reviewing CCMC's substantial change
8 request, could you tell whether or not an
9 emergency patient on a Gurney could be fit into
10 the trailer in order to have an MRI performed?

11 A I don't -- it did not specifically address
12 that

13 Q Okay And based on the material that you were
14 provided, you couldn't have -- you could not
15 have determined that, is that correct?

16 A That's correct

17 Q Okay Now, let's get back to those factors,
18 and I think -- services to be offered, is that
19 the same thing as scope of services, do you
20 think?

21 A Yes

22 Q Okay And do you take scope of services into
23 account when you were reviewing an application,
24 substantial change application like this?

25 A Yes

1 Q Okay Would you agree that the scope of the
2 MRI services would take into account what type
3 of MRIs were proposed, the speed of the MRI,
4 and the capabilities of the equipment?

5 A Yes

6 Q Now, back to 44-7-230, would the term physical
7 plant include where the equipment would be
8 housed?

9 A Yes

10 Q Okay

11 A It could, yes

12 Q All right In this instance would it be an
13 appropriate thing for you to have looked at, or
14 the Department to have looked at, in reviewing
15 these substantial change requests?

16 A Yes I think that kind of falls under the
17 broad category that we've been calling
18 locations

19 Q Okay What are operating costs in the context
20 of the Department's substantial change
21 application review?

22 A Operating costs were not outlined in the
23 substantial change request

24 Q All right Would operating costs, as it is
25 used here, be costs associated with operating

1 the project that would not fall under the
2 definition of capital costs?

3 A Yes

4 Q Okay What investigation did the Department
5 undertake after receiving Mr Summer's June 12,
6 2007 letter requesting this change to the 1999
7 refurbished unit, to determine whether or not
8 this would increase or otherwise affect
9 operating costs when compared to the original
10 in-suite CON?

11 A I do not believe that we asked any questions
12 regarding operating costs

13 Q Okay I think you mentioned, you and Mr Grice
14 have both mentioned something about the age of
15 equipment Is age of equipment a factor that
16 could come into play in reviewing one of these
17 substantial change applications?

18 A It's a factor that could come into play We
19 were not made aware of any reasons why the age
20 of the equipment would affect its capabilities
21 in comparison to what was initially reviewed
22 and approved And I think, as you may have
23 read in my letter, I specifically asked a
24 question about age to verify that the cost was
25 -- the cost of the unit was an appropriate one

1 Q The cost to purchase the unit?

2 A Right

3 Q Okay So you were aware of the fact that the
4 amended proposal was a 1999 unit, which was
5 older than the one that was proposed in the
6 original CON application?

7 A Yes

8 Q The Department was aware of that?

9 A Yes

10 Q Okay Is it possible that an older unit might
11 actually have high ongoing operating costs from
12 week to week than a new unit because of needed
13 maintenance and that --

14 A It's possible, yes

15 Q Okay Ms Tibshrary, if operating costs
16 increase, do healthcare facilities typically
17 pass on those increases in operating costs to
18 patients in the form of higher charges?

19 A Yes, they certainly can

20 Q Okay Now, I think we're at other factors,
21 next Can you give me an example of other
22 factors that may have affected your
23 department's decisions on substantial change
24 applications?

25 A I'm sorry, will you repeat that again?

1 Q Can you give me an example of other factors
2 that might have affected the Department's
3 decisions on substantial change applications in
4 the past?

5 A Outside of the ones that we've talked about
6 I mean, for instance, if you want to look at
7 location, I know that's something we've already
8 talked a good bit about, but if the location of
9 a project was proposed to be moved to another
10 county or down the street or to, you know, to
11 another site which that was significantly
12 higher in cost, a lot of the same issues we've
13 talked about here can be looked at differently
14 But I'm not exactly sure what you're asking

15 Q This gets back a little bit to the equipment
16 capabilities, but let me ask this If a CON
17 application itself delineated the types of
18 patients and the types of illnesses or
19 conditions that the MRI was designed or
20 proposed to diagnose, would the Department
21 look, in determining a substantial change
22 application, whether the substitute MRI could
23 treat those same types of patients and the same
24 types of illnesses or conditions?

25 A Yes

1 Q Okay Did your department make that analysis
2 in deciding upon CCMC's substantial change
3 request?

4 A It was a factor that was looked at It was not
5 the sole factor but it was looked at, yes

6 Q Okay Sitting here today, based on your review
7 of this record and information that you were
8 provided by Mr Summer in the context of the
9 substantial change application, do you know and
10 did you know then whether or not the MRI
11 outlined in the original CON application had
12 additional patient diagnostic capabilities than
13 the 1999 refurbished unit that was ultimately
14 put into question?

15 A I am not aware that the original unit has
16 additional capabilities than what was proposed

17 Q Do you know one way or the other?

18 A No I can say that they did not specify that
19 there were any capabilities that it would not
20 have in their request for addition information,
21 therefore, it was assumed that the capabilities
22 were substantially similar

23 THE COURT You said their request for information,
24 do you mean your -- in their response to your
25 request for information?

1 A Yes, or their -- I'm sorry, their request for
2 a determination

3 THE COURT Okay

4 A I apologize

5 Q So they didn't specify any differences in their
6 request for a determination, so the assumption
7 was that there was no difference, is that what
8 you just said?

9 A Yes

10 Q Okay Would you agree that the price of the
11 MRI unit itself, in the original application,
12 was \$1 8 million and that that price decreased
13 to around \$535,000 or less for the 1999 unit?

14 A Yes

15 Q Okay Could a decrease of this magnitude
16 suggest that the 1999 unit could have provided
17 substantially less patient diagnostic
18 capabilities than the MRI proposed in the
19 Certificate of Need application?

20 A It could, but not necessarily It could
21 indicate that it's four years older than the
22 unit that was initially proposed in the CON
23 application and it was a refurbished unit

24 Q Okay Would that discrepancy in price at least
25 cause the Department to -- should have caused

1 the Department to take a close look at the
2 different capabilities between the two units?

3 A I think that it's clear that the Department
4 carefully reviewed the request and requested
5 additional information and that had there been
6 substantially different capabilities between
7 the two units the applicant would have had
8 plenty of opportunity to disclose that
9 information

10 Q Okay And that disclosure would have been a
11 voluntary disclosure that they were expected to
12 make to the Department?

13 A Yes

14 Q Okay One moment, and I think I may be
15 through Thank you very much

16 THE COURT Anything on --

17 MS BIGGERS No re-direct

18 MS GILLESPIE Just two questions, Your Honor

19 MS TIBSHRANY - RE-CROSS EXAMINATION BY MS

20 GILLESPIE

21 Q When you were reviewing the substantial change
22 request, did you have any reason to believe
23 that the operating costs would change?

24 A No

25 Q Did you --

1 A Not significantly

2 Q Did you see any evidence that the operating
3 costs were going to change?

4 A While I certainly understand the point of an
5 older refurbished unit potentially increasing
6 operating costs, I also see operating costs
7 that may be increasing from that being offset
8 by the fact that there's not an addition to the
9 building being constructed and that a modular
10 unit may be more efficient from a cost
11 standpoint than an addition to the building

12 Q Right Can you --

13 MS GILLESPIE Jack, can you pull up that statute?
14 Can you emphasize (A), pull out (A)?

15 Q And what word do you see that appears between
16 capital and operating?

17 A Or

18 Q Or And so the fact that one may be offset by
19 the other -- if you considered one but the
20 other may go up, do you think that explains the
21 reason "or" is in the statute?

22 A Possibly, yes

23 Q Okay One other question Does DHEC routinely
24 approve mobile or modular MRIs?

25 A Yes

1 Q And does DHEC find them to be accessible to
2 patients?
3 A Yes
4 Q Okay Thank you
5 MS GILLESPIE No further questions, Your Honor
6 THE COURT Any follow-up on those specific
7 questions?
8 MR BEACH None, Your Honor, thank you
9 THE COURT You may step down Ms Biggers?
10 MS BIGGERS Your Honor, DHEC rests
11 THE COURT All right Mr Pringle, you indicate a
12 potential reply?
13 MR PRINGLE I believe we do We want to call Dr
14 Borelli for some brief reply
15 THE COURT Okay Go ahead
16 MR PRINGLE Okay
17 COURT REPORTER You are still under oath, sir
18 DR BORELLI - DIRECT REPLY EXAMINATION BY MR
19 PRINGLE
20 Q Dr Borelli, were you present yesterday in the
21 courtroom for the testimony of Ms Platt on
22 behalf of CCMC?
23 A Yes, I was
24 Q Okay And you recall some testimony that
25 discussed acutely all patients and the type of

1 patients to which CCMC would be providing, and
2 indeed is providing, MRI scans?

3 A Yes, I do

4 Q Okay Let me just ask a couple of
5 clarification questions What's an unstable
6 patient?

7 MR DAYHUFF Your Honor, I want to offer an
8 objection Dr Borelli's been qualified as an
9 expert in clinical and operational MRI issues
10 He's not an expert in acute care patients, he's
11 not a hospitalist, I don't think there's any
12 basis for him to be allowed to offer opinion
13 testimony in this area

14 THE COURT Well, at this point in time he hasn't
15 been qualified He is a doctor, but I will --
16 I'll sustain the objection

17 MR PRINGLE Okay Much as Ms Platt --

18 THE COURT At this point in time

19 MR PRINGLE I understand I will ask a few
20 questions to Dr Borelli

21 Q Dr Borelli, do you have experience working in
22 hospitals?

23 A Yes, extensive experience working in hospitals

24 Q Tell me a little bit about that experience

25 A During my medical school training My second

1 through fourth years of medical school I spent
2 in hospitals, acute care hospitals in
3 Philadelphia, they were all level one trauma
4 teacher -- teaching hospitals, tertiary care
5 centers, most frequently dealing with patients
6 that were acutely ill, unstable, knife and gun
7 club, you name it And in residency, we
8 actually admitted patients in my radiology
9 residency So I have extensive experience both
10 admitting, diagnosing, and working in emergency
11 rooms treating acutely ill patients of all
12 types

13 Q Would that involve unstable patients as well?

14 A Of course

15 Q Okay

16 A Patients don't choose to be stable or unstable
17 That happens 24/7, and they come in and they
18 present the way that they do

19 Q Okay

20 MR PRINGLE I'd assert at this time that Dr
21 Borelli's certainly qualified to answer
22 questions on this topic and give opinions

23 THE COURT In what manner do you request that he be
24 qualified?

25 MR PRINGLE I request that he be qualified as an

1 expert to give opinions on the issue of the
2 types of care provided to acutely ill patients,
3 unstable patients, as well as the monitoring
4 and other considerations associated with those
5 types of patients

6 THE COURT The type of care and the monitoring?

7 MR PRINGLE Well, in particular --

8 THE COURT He's testified that he's certainly
9 cognizant of what is an acutely ill patient

10 MR PRINGLE Right

11 THE COURT And he's admitted patients in that
12 regard I don't know -- did he testify as to
13 his familiarity with their care?

14 Q Do you have familiarity, Dr Borelli, with the
15 care, treatment, and monitoring of acutely ill
16 patients and unstable patients?

17 A Yes As the admitting physician, I was
18 responsible for the orders for monitoring
19 patients of all kinds

20 THE COURT All right

21 MR DAYHUFF Voir dire, Your Honor?

22 THE COURT What?

23 MR DAYHUFF Can I have some voir dire on this
24 issue?

25 THE COURT Yes, you may

1 DR BORELLI - VOIR DIRE BY MR DAYHUFF

2 Q Dr Borelli, when did you graduate from medical
3 school?

4 A Medical school would have been '87

5 Q 1987

6 A Uh-huh (affirmative response)

7 Q And you had a couple years of work with acutely
8 ill patients during your time in medical
9 school, is that right?

10 A Three years

11 Q Three years?

12 A Yeah Hundreds of patients

13 Q Hundreds of patients

14 A Yeah

15 Q And you were working at, I think you said a
16 tertiary care center?

17 A That's correct

18 Q All right That's a very high level of care
19 provided by that center for very ill people, is
20 it not?

21 A Yeah It's not the only place I've worked at
22 though I've worked at community hospitals as
23 well on rotation

24 Q How much time did you spend at community
25 hospitals?

1 A I'd say actually about a third to half my time
2 in medical school, yes
3 Q So a third to --
4 A For example, I went to Easton, Pennsylvania, as
5 an example
6 Q A third --
7 A Worked at the community hospital there
8 Q A third or half of your two years of med school
9 were spent --
10 A Three years
11 Q Three years of med school at community
12 hospitals?
13 A Clinical rotations, yes
14 Q Were any of those clinical hospitals, hospitals
15 with under 50 beds in a rural county?
16 A Actually, yes I believe the hospital in
17 Easton was that size Easton, Pennsylvania
18 Q How many beds did it have?
19 A I don't know exactly, but small Well under,
20 I would say 50 to 75 beds I didn't count them
21 to be honest with you It was a very small
22 hospital
23 Q All right Since 1987 you have not been
24 admitting patients, caring for patients that
25 are acutely ill or unstable, have you?

1 A No, that's incorrect You heard me incorrect

2 I said in residency we did admit patients

3 Q And --

4 A Frequently I did a full year of

5 interventional radiology Those were patients

6 that needed to be monitored, and we performed

7 procedures on them They came in with acute

8 conditions, and they had damages to their

9 arteries, they may be bleeding, and we would

10 have to admit them to our service

11 Q You would have to admit them to your service to

12 provide radiology services to them, correct?

13 A All services They were under our service, we

14 were the docs, we were the docs in charge

15 Q Were you assisted by hospitalists at these --

16 A No, no --

17 Q -- residencies?

18 A No

19 Q All right So how long ago was your residency?

20 A That was '87 to '91

21 Q All right Since 1991 have you admitted

22 patients to the hospital or participated in

23 providing acutely ill, unstable patients care

24 at a hospital?

25 A Not at a hospital, no

1 Q All right

2 A Actually -- no, I have not -- in -- I'm sorry,
3 in 1998 and 1999 I was on staff at a tertiary
4 acute care hospital, 250 bed trauma center, and
5 I was on staff at that hospital, worked very
6 closely with physicians that admitted those
7 types of patients and worked closely in the
8 work up of those patients but was not the
9 admitting physician

10 Q Right Which hospital was that?

11 A That was Conemaugh Memorial Medical Center,
12 Johnstown, Pennsylvania

13 Q All right And your consults on those patients
14 were with respect to radiology issues, weren't
15 they?

16 A Yes

17 Q Not monitoring issues?

18 A Well, actually yes We would have to
19 frequently interpret x-rays, and patients that
20 were monitored we'd have to describe where the
21 monitors are located For example, they may
22 have tubing in them or leads on them, we had to
23 look to assess to see if they were in the
24 proper position

25 Q So you were identifying where the monitoring

1 equipment was on a scan that you read?

2 A Or an x-ray

3 Q Were you determining how the patients were to
4 be monitored?

5 A In consultation with the physicians, yes

6 Q Really?

7 A Uh-huh (affirmative response) Yeah

8 Q All right You've kept yourself up to date on
9 monitoring equipment over the years?

10 A I mean, that's not my specialty but frankly,
11 the indications for monitoring, if anything,
12 have gone up over the years --

13 Q All right, sir

14 A -- because of advances in the equipment, and
15 the fact that we're treating more acutely ill
16 patients now in hospitals

17 Q It's not part of your practice now to be up to
18 date on how patients are monitored at hospitals
19 when they are in ICU or in --

20 A No, no

21 Q Not part of your practice at all?

22 A No Not now, no

23 Q Do you have any idea -- have you observed the
24 ICU beds at Coastal Carolina?

25 A No, I've not I'm not on staff there

1 Q You don't know how they monitor there, do you?

2 A No, I do not

3 Q All right Have you monitored -- have the
4 observed the med-surg beds at Coastal Carolina
5 Medical Center?

6 A No, I've not

7 Q And do you know how they monitor patients in
8 the med-surg beds?

9 A No

10 MR DAYHUFF Your Honor, I object to him being
11 qualified as an expert in monitoring He's
12 done it years and years ago I don't think
13 that is enough to qualify him as an expert in
14 this area

15 THE COURT Ms Biggers?

16 MS BIGGERS I have nothing to add, Your Honor

17 THE COURT All right I qualify him as an expert
18 in regard to the proper qualifications I do
19 recognize, Mr Dayhuff, that his lack of recent
20 experience is something to be considered, but
21 that goes to the weight of the testimony as
22 opposed to whether or not he's qualified He
23 has sufficient education as a doctor and
24 experience historically in this area to offer
25 an expert opinion

1 MR DAYHUFF Thank you

2 MR PRINGLE Thank you, Your Honor

3 DR BORELLI - CONTINUED DIRECT REPLY EXAMINATION BY

4 MR PRINGLE

5 Q I'm not sure where I was in the questioning
6 before I was so politely interrupted by Mr
7 Dayhuff But does an unstable patient require
8 monitoring?

9 A By definition, a patient that is unstable
10 requires monitoring, yes By definition If
11 a patient is unstable, that means they are at
12 risk of death And the current standards in
13 place back when I was in training haven't
14 changed You have to monitor them, it would be
15 unconscionable not to monitor someone who's at
16 a risk of imminent death

17 Q Okay Going back to the CCMC application, did
18 the original CCMC application filed back in
19 2004 claim, and in fact demonstrate, a need to
20 perform MRIs on unstable patients?

21 A Yes I believe the exact language was, Your
22 Honor, that they had a need to provide MRI
23 services for patients who were too unstable to
24 transport to another facility

25 Q Okay

1 A And --

2 MR DAYHUFF Your Honor, let me object I think
3 this is outside the scope of our presentation,
4 our opposition, our case I don't think Dean
5 Moesch testified that we provide monitoring and
6 scanning to those who are so unstable that they
7 have monitoring

8 THE COURT I understand your objection Matter of
9 fact, I think it's a valid objection, Mr
10 Pringle, unless you're going to direct me
11 otherwise

12 MR PRINGLE Well, the --

13 THE COURT Because it -- you're offering reply
14 testimony --

15 MR PRINGLE Right

16 THE COURT -- to the evidence that he offered

17 MR DAYHUFF Sure

18 MR PRINGLE Well, and I believe that Ms Platt
19 offered testimony that a great many of the
20 acutely ill patients of CCMC did not require
21 monitoring

22 THE COURT Yeah

23 MR PRINGLE And it was a small subset And where
24 I'm going with this is to demonstrate, I was
25 going to put up a page from the record that's

1 in evidence to demonstrate that this -- that
2 medically unstable patients was a specific part
3 of the application and therefore something that
4 was part of the need

5 MR DAYHUFF She testified that there are acutely
6 ill patients who do not need monitoring I
7 don't think Ms Platt testified that unstable
8 patients on monitoring, or about that topic at
9 all That would be outside of her expertise
10 anyway

11 MR PRINGLE Her point was is that they
12 demonstrated a need for the patients they
13 sought to serve with MRIs And my point in
14 reply is that that need was specifically
15 articulated for unstable patients

16 THE COURT Well, I'll -- I'm going to sustain his
17 objection I will allow you -- you said it's
18 in evidence?

19 MR PRINGLE Right

20 THE COURT You can certainly address it --

21 MR PRINGLE Okay

22 THE COURT -- as far as the consideration of this
23 case

24 MR PRINGLE Right

25 THE COURT I just don't think, since that wasn't

1 brought up in their case in chief, and you had
2 even an opportunity to potentially make it an
3 issue in cross-examination I 'didn't hear that
4 phraseology I don't think it's a proper
5 reply

6 MR PRINGLE Okay Just for clarification, and I
7 don't want to belabor this

8 THE COURT Yeah I don't mind you doing that

9 MR PRINGLE That you didn't hear -- that we didn't
10 hear a description of --

11 THE COURT The issue

12 MR PRINGLE Yeah

13 THE COURT Acutely ill patients is one issue

14 MR PRINGLE Right

15 THE COURT Unstable patients is evolving into
16 another issue, and I think it's a separate
17 issue That's why you're bringing it up, to
18 address this point And again, reply testimony
19 is that -- at least what I'm going to allow in,
20 my discretion, is that you can present that in
21 your case in chief, you know, you're now at the
22 point in time of replying to a new matter that
23 was raised by the respondents I don't see
24 that they raised a new matter for which you're
25 presenting reply testimony

1 MR PRINGLE And this is the last thing, and I

2 certainly don't want to argue with you

3 THE COURT I'll let you know when I start to --

4 MR PRINGLE All right I appreciate that, Your

5 Honor Is that Ms Platt's testimony and her

6 presentation was is that the scans that CCMC is

7 doing now are consistent with and not

8 substantially different from those that it

9 proposed in its application And there was a

10 great deal of testimony about the types of

11 scans that were performed, the various types,

12 and that those were -- that you didn't need to

13 consider -- or that those were roughly equal or

14 the same, and not substantially different And

15 I'm replying to that testimony with --

16 following up on what Dr Borelli already said,

17 with the proposition that her characterization

18 of the scans that are being performed then

19 versus now is not in fact correct, that there

20 were more -- there was a different type of scan

21 that was specified, claimed, needed,

22 demonstrated in the original application that

23 is not being provided now

24 THE COURT All right Here's the -- his

25 phraseology is evolving and he's actually

1 moving to a little bit different request So
2 what is your response to that, that we -- he's
3 responding to the fact --

4 MR DAYHUFF He's doing better?

5 THE COURT Yeah, he's getting a little better

6 MR DAYHUFF Maybe a little I'd still -- it was
7 good, but I still think we're trying to get
8 into an issue that we didn't raise in our case
9 in chief We focused on the service of
10 inpatients, outpatients, and emergency
11 patients We did talk about acutely ill
12 patients And now we're going back into
13 something that I think they talked about in
14 their case in chief We didn't make an issue
15 of unstable patients And they're trying to do
16 it now, and I think it's outside the scope of
17 what they should be allowed to do in reply

18 THE COURT Did you bring, in your case in chief,
19 the issue of the scans being substantially the
20 same as the original application?

21 MR DAYHUFF The scans, the types of patients we
22 would scan?

23 THE COURT Yeah

24 MR DAYHUFF Yes

25 THE COURT I'll allow you to go into it

1 MR PRINGLE Okay Can you put this up real quick?

2 THE COURT In limited fashion

3 MR PRINGLE Oh, I understand, believe me

4 Q I'm just going to show you a page from the DHEC
5 record Number Fifty-six and if you could look
6 at the first paragraph of that

7 A Paragraph two there, where it says two?

8 Q Actually, I believe it's in the first paragraph
9 up above that

10 A Okay Carolina, starting at Carolina?

11 Q Sure And that's obviously carried over from
12 the previous page

13 A That's Coastal Carolina But, Carolina will
14 endure significant inconvenience and potential
15 adverse medical impact as delays in diagnosis,
16 decision making, and medical treatment are
17 incurred in having to travel, be transported to
18 MRI providers located beyond the local area
19 In addition, comma, Coastal Carolina's
20 medically unstable patients, the acutely ill
21 patients, and the emergency room patients will
22 all incur additional costs associated with
23 transportation to outside providers Coastal
24 Carolina strongly agrees with the State Health
25 Plan standards and submits that the proposed

1 MRI project is consistent with this standard

2 Q So the application -- in the application CCMC
3 proposed to provide MRI scans to medically
4 unstable patients?

5 A Yes As a matter of fact, that was emphasized,
6 and I believe even in this Court's ruling that
7 was emphasized

8 Q Okay Can CCMC do so, scan medically unstable
9 patients?

10 A I think we heard from Dean Moesch, Dr Moesch's
11 testimony that they don't have monitoring
12 equipment and they're not scanning patients
13 that require monitoring Unstable patients
14 require monitoring, so they're not serving
15 unstable patients

16 Q Okay

17 A And I would also say that acutely ill patients
18 frequently require monitoring They --

19 Q All right Let me ask you this question Do
20 you have any response to Ms Platt regarding
21 her assertion that many of the acutely ill
22 patients that's seen by -- serviced by CCMC do
23 not require monitoring?

24 A I think that's a mischaracterization And in
25 fact, most patients admitted through an ER

1 require telemetry monitoring As they would
2 find a reference, and actually 70 percent of
3 the top ten admitting diagnoses to emergency
4 rooms today, this is a very recent article, and
5 I think we can even provide it if we like, but
6 70 percent require monitoring, just telemetry
7 monitoring, that's cardiac monitoring And why
8 is that? Common admitting diagnosis Why do
9 people get admitted to hospitals and how do
10 people die from severe illnesses? The two
11 biggies are going to be heart attack and
12 stroke It should be obvious to everyone in
13 this courtroom, if someone comes in with a
14 heart attack, they're going to have their heart
15 monitored continuously, okay Patient with a
16 stroke, why are patients monitored -- why is
17 the patient's heart monitored when they've had
18 a stroke? It's because frequently patients
19 that have had a stroke, about 20 to 30 percent
20 of them, the stroke is caused by an arrhythmia
21 of the heart that was previously undiagnosed
22 So they go to the hospital because of a stroke
23 when actually they have a cardiac problem So
24 those patients are routinely monitored for at
25 least 24 hours to see if they've had a stroke

1 THE COURT Dr Borelli?

2 A Yes?

3 THE COURT Patients with heart attack and stroke
4 normally don't have MRI scans, they normally
5 have a CAT scan, do they not?

6 A No Patients -- this -- CCMC has made the
7 argument that there are stroke patients, that
8 they need the MRI for stroke patients And as
9 we know, cardiac patients have -- when they
10 come into the hospital, lots of new things are
11 found, not just -- it's not just they're coming
12 in for a heart problem There's -- my point
13 is, patients get admitted to acute care
14 hospitals because they're acutely ill for a
15 number of reasons The two biggies, or two
16 very large categories, are stroke and heart
17 attack And that's going to be your patient
18 population And some of those patients do need
19 MRIs at some point during their care, or may
20 need MRIs at some point during their care

21 THE COURT Anything else?

22 Q Do you have anything else to add?

23 A I think also I think we see that, you know, 18
24 months of time, during 18 months of time that
25 hospital has not served a single patient

1 between the hours of 11 00 p m and 7 00 a m
2 And the point they make is that they need this
3 in-house MRI for patients that are too unstable
4 to transport, and the reason they can't
5 transport them is because there's going to be
6 a delay in diagnosis So it's -- you can't --
7 you don't have that 30 to 45 minutes to
8 transport a patient away, yet you can wait
9 until the next shift starts? So they're not
10 scanning between the hours of 11 00 and 7 00
11 a m , we know that They're not -- that
12 service is not available to those patients
13 during those hours, and that's completely --
14 that's a substantial change from the original
15 application, and the findings of this Court in
16 fact

17 Q Okay

18 MR PRINGLE I tender the witness

19 THE COURT Mr Dayhuff or Gillespie

20 MR DAYHUFF It's my turn I guess

21 THE COURT Okay

22 DR BORELLI - CROSS REPLY EXAMINATION BY MR DAYHUFF

23 Q Dr Borelli, did you hear Dr Moesch's
24 testimony?

25 A Barely He was a little quiet

1 Q All right Well, were you able to hear it
2 enough to understand the testimony, understand
3 his opinions?

4 A I think for the most part If you ask me a
5 specific issue, I'll let you know whether I
6 heard him clearly

7 Q Okay He testified, didn't he, that we don't
8 scan patients in our MRI at Coastal who are so
9 unstable as to need constant monitoring, is
10 that right?

11 A Yes I was surprised to hear that

12 Q Okay And he also testified that in our prior
13 -- or in our proposed CON application that we
14 had no equipment that could be used to scan --
15 used to monitor patients that was MRI safe, do
16 you recall that?

17 A It's about as \$20,000 purchase I'm surprised
18 they didn't do it

19 Q All right So --

20 A Why would they not want to -- why would they
21 not want the system to be accessible to those
22 patients? All they have to do is spend a
23 little bit of money

24 Q There was no --

25 A It's not \$3 2 million, it's only about \$20,000

1 Q So there was no quote in the proposed CON for
2 that type of monitoring equipment, and we don't
3 have it now, isn't that correct?

4 A I think DHEC trusted that they would put that
5 equipment in place

6 Q Just, if you could stick to answering the
7 question Was there a quote for the MR-safe
8 monitoring equipment, that you saw in the
9 original CON application?

10 A No, there was not a quote

11 Q And it's your understand, is it not, that we
12 don't have that MR safe monitoring equipment
13 now?

14 A Is it my understanding? I haven't been there
15 to see it, but I believe that was testified to
16 yesterday

17 Q So you don't know from personal observation?

18 A Well, I saw -- you threw up a picture of an MR
19 compatible monitor, what was that all about?

20 Q Now, Dr Moesch testified that he will consult
21 with the patient's doctor, a patient who may be
22 unstable, and sometimes, with the consultation
23 of that doctor, they come to a conclusion that
24 they're stable enough to scan and they remove
25 the monitoring equipment and scan that patient,

1 isn't that true?

2 A That's a compromise

3 Q Isn't that true?

4 A It's possible, but it's a compromise

5 Q Okay All right You heard that testimony?

6 A Doesn't need to be There doesn't need to be
7 that compromise

8 Q And you don't disagree that there are acutely
9 ill patients who aren't on constant monitoring?

10 A Acutely ill patients that aren't on constant
11 monitoring?

12 Q Correct

13 A Typically when they're admitted they're on
14 monitoring for the most -- the vast majority of
15 them But as they stay in the hospital longer,
16 that monitoring may come off But we know the
17 lengths of stay have dropped dramatically since
18 I was in medical school Patients are in the
19 hospital a much shorter period of time, they're
20 intensively monitored and diagnosed and
21 treated, and then they get them out of the
22 hospital once they're stable

23 MR DAYHUFF I beg the Court's indulgence for a
24 moment Dan, can you pull up page 58 of the
25 DHEC record?

1 Q All right, Dr Borelli, your counsel pointed
2 out for you, or perhaps you found it, that
3 there is one line in our CON application that
4 referred to unstable patients, isn't that
5 right?

6 A I don't recall that characterization

7 Q Doctor, didn't you -- you saw one -- on the
8 screen a moment ago, you saw one reference, one
9 sentence referring to unstable patients?

10 A I believe there are more in the application
11 I haven't read the application in a couple of
12 years, but I believe there were more

13 Q Do you know if there are any others?

14 A I believe there are I don't know

15 Q Okay All right So, in fact, it may be the
16 only mention in the entire CON application of
17 unstable patients?

18 A I think it was mentioned in the stay -- stay
19 lift motion that you made

20 Q Yeah I'm focusing on the CON application
21 right now, because we're of course comparing
22 the proposed MRI to what we actually
23 implemented

24 A The stay lift is more recent -- more recent
25 information you would have

1 Q Yes But you need to answer the questions that
2 I'm asking

3 A What is the question again, sir?

4 Q The question is, are you aware of any other
5 mention of the word unstable, scanning unstable
6 patients, in our CON application in 2004, other
7 than the one that was put up on the screen?

8 A That's a large document I can't say that I
9 have perfect memory of that

10 Q All right Are you aware of any, as you sit
11 here right now, that you could point me to?

12 A I'd be happy to, you know, take a break and
13 look through the document and try to find one
14 for you, but I'm not aware if I can point to
15 one -- point you to one right now, of course
16 not

17 Q I'll take that as a no Take a look at page
18 59 It refers to patients that we're going to
19 treat It's in answer to number 13 Says --
20 read the first bullet point for me, it starts
21 absent

22 A Absent an on-site MRI at Coastal Carolina's --
23 I'm sorry, what is --

24 Q Sic

25 A Sic, will require its acutely ill and emergent

1 patients to be transported by ambulance to
2 outside providers for their MRI scans which
3 will result in additional expenses for these
4 patients, as well as third-party providers

5 Q No mention of unstable patients there, right?
6 That's an easy question

7 A Well, the -- the term acutely ill includes --
8 is a broader term, where you have stable
9 acutely ill and unstable acutely ill

10 Q Does the word unstable appear in that sentence
11 you read?

12 A No --

13 Q Okay

14 A -- but it's implied

15 MR DAYHUFF Let's look at page 59, Dan That was
16 58 I guess? That was 58? Oh, 58, Dan, please

17 Q All right Look at disposition number one, do
18 you see that? After reject, read that
19 sentence

20 A I think we looked at that yesterday Reject,
21 without an in-house MRI, Coastal Carolina's
22 acutely ill and emergent patients would need to
23 be transported to an outside MRI provider which
24 is costly, risky, and stressful All patients
25 would incur delays in diagnosis and treatment

1 as well

2 Q No mention of scanning unstable patients there,
3 is there?

4 A Again, acutely ill includes stable and unstable
5 acutely ill patients When a patient comes
6 into a hospital and they're acutely ill,
7 sometimes they're stable and sometimes they're
8 unstable And the majority of them require
9 monitoring

10 MR DAYHUFF Let's go to 65, Dan, please, in the
11 DHEC record

12 Q Take a look, if you can read it, at the second
13 asterisk and read that for me please

14 A It will reduce the risk associated with
15 transporting Coastal Carolina's acutely ill and
16 emergent patients by ambulance to a free-
17 standing MRI site

18 Q Any mention of scanning unstable patients
19 there?

20 A Again, implied by the term acutely ill

21 Q Okay Do you know who wrote the CON
22 application for Coastal?

23 A I think you may have

24 Q Do you know?

25 A No, I don't know

1 Q All right Do you know who Eric Deaton is?

2 A Yes, I know him personally

3 Q All right Chief executive officer -- former

4 chief executive officer of Coastal, right?

5 THE COURT Are you going to answer that question?

6 A I'm sorry, that was a question?

7 Q Former chief executive officer of Coastal?

8 A Is he, or was he?

9 Q Yes

10 A I believe he was, yes

11 Q All right Would it surprise you that he
12 wrote, or signed at least, the CON application
13 on behalf of Coastal?

14 A No, it would not

15 Q Okay All right

16 MR DAYHUFF No further questions, Your Honor

17 THE COURT Ms Biggers?

18 MS BIGGERS No questions

19 THE COURT Follow-up on those specific questions?

20 MR PRINGLE Sure

21 DR BORELLI - RE-DIRECT REPLY EXAMINATION BY MR
22 PRINGLE

23 Q Let me get you to put this up while I ask you
24 some questions about the number of times
25 something appears This is page 41 of the

1 record I believe Can you read the paragraph
2 that has the highlighted term in it?

3 A With the increased use of MRI services and
4 increased population growth of the area,
5 Coastal Carolina finds it necessary to expand
6 its service to include on-site MRI services
7 MRI services are routine diagnostic services
8 that provide the needed insight for physicians
9 treating the critically ill acute care
10 patients In-house MRI services in hospitals
11 have become the standard of patient care

12 Q Okay What does critically ill mean?

13 A Critically ill means most likely unstable,
14 requiring monitoring

15 Q Okay Let me point you towards -- and I'll
16 identify the document first Can you identify
17 this document in the record?

18 A Yeah It's a memorandum dated September 20,
19 2004 It's to members of the project review
20 committee, it's from Albert Whiteside, Director
21 of the Division of Planning and Certificate of
22 Need It's regarding the project review
23 committee meeting

24 Q Okay To your knowledge, does this document
25 contain information about the project?

1 A Yes, it does

2 Q Okay Let me point you towards a term in
3 there

4 MR PRINGLE I beg the Court's indulgence for just
5 a moment

6 Q If I could point you down the second paragraph
7 under paragraph one And let me ask you a
8 question This is a document created by DHEC?

9 A Yes, it is

10 Q Okay Could you read the third sentence in the
11 big paragraph under subsection one?

12 A Okay Third sentence, let me see

13 Q Might be fourth

14 THE COURT Starting with in addition?

15 Q Starting with, In addition, Coastal Carolina's

16 A In addition, Coastal Carolina's medically
17 unstable patients, the acutely ill patients,
18 and the emergency room patients will incur
19 additional costs associated with transportation
20 to outside providers Coastal Carolina
21 strongly agrees with the State Health Plan
22 standards and submits that the proposed MRI
23 project is consistent with this standard

24 Q Okay So that, the language that was in the
25 CCMC application was adopted by DHEC in its

1 memo on the project?

2 A Yes

3 Q Okay That's all I have

4 DR BORELLI - RE-CROSS REPLY EXAMINATION BY MR
5 DAYHUFF

6 Q One question That's a DHEC document, not a
7 document created by Coastal, is that correct?

8 A I believe so

9 Q Okay No questions

10 THE COURT You may step down, sir

11 A Thank you

12 THE COURT Ms Biggers?

13 MS BIGGERS No questions

14 THE COURT Any further reply?

15 MR PRINGLE No further reply

16 THE COURT All right Do y'all wish to make
17 closing arguments?

18 MR DAYHUFF We would like to make a brief one

19 THE COURT All right Do you want to take a five
20 minute break?

21 MR DAYHUFF That would be --

22 MR PRINGLE That's fine

23 (Short Break)

24 THE COURT Mr Pringle, you can go first, last or
25 both, but if you go both, you've got to open in

1 full and close

2 MR PRINGLE I would like to go last

3 THE COURT Okay

4 CLOSING ARGUMENT BY MR DAYHUFF

5 MR DAYHUFF All right Your Honor, in closing,

6 obviously it's the Court's task to apply

7 Regulation 605 to the evidence that we've heard

8 in this case You have heard from Kathy Platt,

9 Joel Grice, Tori Tibshirany analyses of the

10 healthcare planning concepts that Coastal

11 believes apply in this matter And I want to

12 go through the evidence you've heard on these

13 You heard from several witnesses that the

14 actual MRI that's in place now is serving

15 patients from the same service area, same zip

16 codes as we proposed to do in our original

17 You heard evidence that our proposed MRI

18 identified a need and our actual MRI is serving

19 that need, and we have utilization data to back

20 that up You've also heard that we originally

21 proposed in our application to serve

22 inpatients, outpatients, and emergency

23 patients, and the acutely ill We are serving

24 those same folks Kathy Platt analyzed that

25 And I would like to -- we've had a little fun

1 with the unstable issue here most recently
2 THE COURT You can go into that briefly if you
3 want I really don't think that's relevant
4 I will address that with Mr Pringle, but I'll
5 tell you that, you know, the unstable issue,
6 we've chosen not to go into the need of the --
7 or the very basis of whether you get the CON to
8 begin with, and the project review criteria
9 The issue is substantial change So you've got
10 one machine and a new machine The issue is
11 whether there's a change as a result of the
12 proposed machine The unstable issue, there
13 was not the capability of making those scans
14 before and there is not one now, I don't need
15 to hear about all of that

16 MR DAYHUFF All right I know when to move on
17 All right Let's go to the next healthcare
18 planning concept So need, there's no
19 substantial change in the need Distribution
20 accessibility, moved from the left of the
21 hospital to the right of the hospital We also
22 heard from Ms Platt about financial
23 accessibility We are serving all types of
24 payors, Medicaid, Medicare, self-pay,
25 insurance There has been no change in

1 distribution or accessibility Acceptability,
2 we have in our proposed application physician
3 support in the form of letters For our actual
4 MRI, we have physician support in the form of
5 interviews and maybe more importantly, we have
6 physicians actually utilizing this facility,
7 showing their support by sending referrals
8 And we saw the other day that we have
9 physicians who both supported the 2004 and
10 support the actual now Acceptability, there's
11 no substantial change Cost containment,
12 proposed was \$3 2 million, the actual was a
13 little under \$600,000 A savings of \$2 6
14 million We actually did better on cost
15 containment Financial feasibility, in our
16 2004 application we were projecting to be
17 profitable Ms Platt looked at our actual
18 contribution margins by both payor and patient
19 type, with the help of the CFO We're showing
20 a positive contribution margin in the range of
21 371 to 369 So it has --

22 THE COURT That's per year?

23 MR DAYHUFF That was based on a truncated year

24 And I could get you the -- the source for that
25 is Exhibit Sixteen

1 THE COURT Okay

2 MR DAYHUFF I think it was a nine month period
3 perhaps I'd have to look it up, but it was
4 not a full year Annualized I'm sorry, that
5 is annualized, Your Honor

6 THE COURT So according to that chart, you all will
7 more than have paid for the project after two
8 years? Doing simple math, \$600,000 --

9 MR DAYHUFF Well, that's a contribution margin,
10 which is outside of my understanding to explain
11 fully I'd have to ask Ms Platt about that

12 THE COURT Okay

13 MR DAYHUFF My understanding of contribution margin
14 is though that there would be an overhead
15 amount that would be assessed to that modality
16 as well, but that's a little beyond my -- I
17 don't think I can answer your question as to
18 whether that would pay off the project in two
19 years So financial feasibility, they're both
20 feasible I think a healthcare planner would
21 say with a contribution margin of that size,
22 it's financially feasible Adverse impact, we
23 proposed in our original application that we
24 would not adversely affect other providers in
25 the area because the growth in the market for

1 MRI would more than compensate everyone We've
2 analyzed Dr Borelli's facility in particular,
3 and as this graph shows very clearly, he's not
4 doing badly at all So that pretty much runs
5 through all our concepts that I think are
6 relevant And we make a showing of no
7 substantial change on all of them Now, Dr
8 Borelli's analysis Dr Borelli raised some
9 issues about the MRI equipment Dr Borelli
10 conceded that the equipment was quite similar
11 Now, I think that's a bit of an understatement
12 We have MRI equipment that is the same Tesla
13 strength, it's the same Signa model, both are
14 high speed gradients, both are short bore, both
15 are four channel, both have the same slew rate,
16 same software, substantially similar coil
17 complements The only difference that Dr
18 Borelli highlighted for us was a ten millitesla
19 per meter difference in gradient strength, that
20 as we understood through a hypothetical with
21 him would result on an average day in a four
22 minute increase in scan time over the course of
23 the entire day Not a substantial change when
24 it comes to equipment Other differences that
25 Dr Borelli raised There were several

1 Wiggly room, that we couldn't easily get our
2 MRI table out of the coach I think you heard
3 testimony from Ms Platt that these MRIs in
4 this configuration are everywhere, and that's
5 not an issue I think it was speculation on
6 his part Code blue button I think the core
7 of this was that we have a code blue button
8 instead of a phone I don't think that's a
9 difference that merits consideration

10 THE COURT I think his testimony was code blue
11 button as opposed to intercom

12 MR DAYHUFF As opposed to intercom I don't think
13 that's a substantial issue worthy of
14 consideration for purposes of health planning
15 The MRI compatible monitoring we've touched on
16 We didn't propose -- nowhere in our application
17 of 2004 does it say we're going to scan
18 patients so unstable they have to be on
19 constant monitoring And by the way, here's a
20 quote for this specialized equipment -- it's
21 not there in 2004, we don't do it now I think
22 the key to all of these is they're not relevant
23 to a proper 605 analysis Now, void for sale
24 is our other issue We have heard evidence
25 from Ms Platt, from Ms Tibshirany, that the

1 final completion report was June 27th DHEC
2 closes their file on June 27th The exemption
3 is approved June 28th and the sale of the
4 hospital is July 1 Importantly, we also heard
5 there was no protest by Belfair, there was no
6 raising of a claim that the sale of the
7 hospital had some effect upon our MRI CON
8 They didn't raise it, they didn't exhaust their
9 remedies To raise it now I think would be
10 barred by laches, and I would also submit to
11 you that substantial change moots that issue
12 So finally, Your Honor, I would ask, I
13 respectfully ask the Court to find that in this
14 matter there has not been a substantial
15 amendment to Coastal's CON project that would
16 justify the voiding of that CON, nor has the
17 sale of Coastal's hospital in 2007 voided our
18 CON Thank you

19 CLOSING ARGUMENT BY MS BIGGERS

20 MS BIGGERS Your Honor, I'll be very brief The
21 evidence presented by Respondents establishes
22 that this is similar equipment providing
23 similar services at the same hospital as
24 approved in the original application When you
25 weigh the evidence presented by Petitioners and

1 by Respondents, I believe you'll see that the
2 Petitioners have failed to meet their ultimate
3 burden of persuasion to show that any of the
4 project changes rise to the level of
5 substantial changes that would warrant voiding
6 the CON

7 THE COURT Mr Pringle?

8 CLOSING ARGUMENT BY MR PRINGLE

9 MR PRINGLE May it please the Court, very briefly,
10 Your Honor I'd like to have the Court's
11 attention focused on the language of 44-7-230
12 and 605, and what it says specifically with
13 respect to -- that the project must be the same
14 as originally approved Not the unit, but the
15 project And the project of course involves,
16 as you've heard a lot of testimony about today,
17 the location, the services, the things
18 associated --

19 THE COURT Well, but when I got -- what I
20 originally said to Mr Dayhuff a while ago is,
21 when it comes to the project the only thing
22 that we're dealing with today is the change in
23 the MRI unit There's nothing offered about
24 any other aspects of the -- that they requested
25 to amend the project So when you say that the

1 project is changed, the -- I'm dealing with the
2 evidence that was offered, because Mr -- when
3 you were asking questions of one of these
4 witnesses, of Ms Tibshirany, you were asking
5 what DHEC considered on this and what DHEC
6 considered on that, y'all have got to offer
7 evidence because this is the hearing --

8 MR PRINGLE Right

9 THE COURT -- as to whether or not there's a
10 change The only evidence that's before me is
11 evidence concerning the change of the MRI unit,
12 and that's all that they requested as far as be
13 changed So I don't know how you can -- they
14 make a request to change the MRI unit, you
15 don't -- we're not considering the whole
16 project in this case, we're considering the
17 substantial change Where you get -- how do
18 you move to the project?

19 MR PRINGLE Because the reg, as well as the
20 statute, says that what you're considering is
21 whether it's a change to the project

22 THE COURT I agree with that Within the
23 parameters of the evidence that's presented

24 MR PRINGLE Okay And we presented a great deal
25 of evidence that changes in the project, with

1 the installation of the mobile MRI, with the
2 policies and procedures that go along with
3 this, with the fact that MR monitoring is not
4 provided in connection with that, that indeed
5 because of the way that project was
6 implemented, or this part of it was
7 implemented, it is at odds with and
8 substantially different from the original
9 application and what was claimed with respect
10 to the types of scans and types of patients,
11 and in fact it was demonstrated and formed the
12 basis for that original application and
13 approval of that CON

14 THE COURT Well, they said -- you say claimed, they
15 claimed to scan unstable patients

16 MR PRINGLE Uh-huh (affirmative response)

17 THE COURT But there's testimony that unstable
18 patients could potentially be requested -- or
19 after consult with the doctor, they could be
20 scanned But what the greater question for me
21 is what evidence have you offered that the
22 original project was going to scan people who
23 were monitored and that the new project is
24 substantially different in that regard?

25 MR PRINGLE Well, I think the testimony of Dr

1 Borelli established that unstable patients have
2 to be monitored and that if you can't do that,
3 they --

4 THE COURT I understand that I said what evidence
5 have you offered that the original proposed
6 MRI, in that proposal they had equipment to
7 scan patients who were being monitored whereas
8 now they don't?

9 MR PRINGLE Well, it's certainly, as we referenced
10 in the project documents that was part of their
11 claim to demonstrate the need, the need was
12 that they needed to do this for unstable
13 patients I think even Your Honor's order in
14 the original case referenced the need to do
15 those things, and that that was part and parcel
16 of, and in fact, you know, a lynchpin to show
17 the necessity for a 24/7 scanner on site was to
18 do those types of patients And that if --
19 that that was shown in the original application
20 was the basis for it and that when in fact this
21 project shows that that can't be done, that is
22 a difference and a substantial one I mean, it
23 takes -- it pulls one of the, you know, pieces
24 of the foundation out from under the original
25 application and says, you know, that this is

1 something different, something that ought to be
2 -- ought to be reviewed, especially if it is
3 emphasized so strongly as part of, you know,
4 what was, you know, what was to be done I
5 mean, what CCMC is doing is saying, well, you
6 can look at, you know -- this equipment is
7 roughly the same, and of course if you focus on
8 equipment rather than the larger project to,
9 you know, lead you toward a different view
10 But it says, well, we're doing scans, you know,
11 time has borne -- shown that we're doing some
12 of that, but the point is they're not doing the
13 scans and serving the type of patients that
14 they -- that was the basis for the original
15 application and the original grant And
16 that's, you know, they -- Dr Borelli testified
17 to the policies and procedures of the MRI, of
18 the new MRI, talked about the difference in
19 location, talked about some of the safety
20 characteristics I mean, those are differences
21 in the project that go to whether it's, you
22 know, whether it's the same, whether it's
23 substantially different than what was
24 originally filed And I think that, you know,
25 all of those things go -- I mean,

1 notwithstanding the fact that DHEC believes
2 that its only equipment and that the analysis
3 never goes any farther You know, DHEC also
4 believes that that's their -- it's at their
5 sole discretion to make that determination and
6 doesn't take input from other people But our
7 point is that they took way too narrow of a
8 view of it in a very short period of time in
9 order to, you know, try to beat a deadline that
10 would avoid the CON and that, you know, we've
11 shown here today that there are those
12 substantial differences in the project, if not
13 -- you know, and beyond the equipment that show
14 that it's just not the same thing I mean, you
15 put the two up next to each other for what they
16 said they would do and what justified their
17 receiving the CON, and they just -- they cannot
18 do it And they've testified, Dr Moesch
19 testified that they can't do that monitoring
20 within their MRI, and do those patients, those
21 very same critically ill patients, unstable
22 patients, the ones that they've, you know, that
23 they've dwelled on for so long, talking about
24 in the original application with respect to
25 automobile accidents and the type of injuries

1 that they wanted to be able to treat So it's,
2 you know, it's -- it is something that's very
3 different in a substantial way related to --

4 THE COURT I'll ask you one more time --

5 MR PRINGLE Sure

6 THE COURT What did they request to be changed?

7 When they made their request to change, they
8 being CCMC, what did they request to be
9 changed? It was the MRI machine, right?

10 MR PRINGLE It was And then it was requested
11 that it be put in a different place and subject
12 to a bunch of different -- a new set of
13 policies and procedures that didn't exist under
14 the old application, that have a date on them
15 that are subsequent to that application, and
16 that set forth a way of doing things that's
17 inconsistent --

18 THE COURT What you're doing is you're trying to
19 take the machine and project that onto a
20 different issue and say that the project as
21 proposed was not the project -- we don't
22 believe that it's the same project that was
23 truly implemented But that theory goes to
24 whether or not the project itself should be
25 approved or not, whereas the issue before us

1 again is whether there was a change or not, a
2 substantial change Well, just change -- Mr
3 Borelli -- or y'all have thrown a lot of darts
4 as far as maybe change, but as far as
5 substantial change, that's the issue I've got
6 to decide

7 MR PRINGLE Right And again, going to that, you
8 know, it's -- certainly the machine was
9 replaced, but it was certainly not replaced in
10 the same place and under the same policies and
11 procedures and under the same circumstances,
12 and that's what --

13 THE COURT That's a point at least to argue

14 MR PRINGLE Well, and that's -- I think that's
15 clearly, you know, the point we're trying to
16 make, is that this focus solely on 1 5T to 1 5T
17 doesn't encompass all the things that might
18 change substantially within a project and that
19 is it very, very substantial, the admission
20 that they cannot and do not, cannot and do not
21 do the scans that formed in part the basis for
22 their original application and their original
23 CON That is no longer on the table, and
24 that's a big difference And Dr Borelli
25 pointed out, you know, as I mentioned, several

1 -- a number of other things that are different,
2 and substantially different, from what was
3 proposed originally Very briefly on the void
4 I don't want to rehash necessarily the
5 arguments we had on summary judgment If the
6 substantial change request wasn't proper, then
7 the project was still in play and then when the
8 -- when CCMC was transferred, whatever existed
9 at that point was voided That's -- and I
10 think that's the question there I mean, if
11 something --

12 THE COURT Whatever was at issue at that point?

13 MR PRINGLE Whatever was -- well, not necessarily
14 what was at issue but what existed in terms of
15 --

16 THE COURT All their CONs were not voided, so --
17 that were already implemented

18 MR PRINGLE Well, no But under our theory --

19 THE COURT Because you don't just get rid of the
20 entire hospital every time you sell it

21 MR PRINGLE No Not the entire hospital, this
22 MRI

23 THE COURT So if you -- if a hospital had sought an
24 MRI for every -- I mean, I CON for all their
25 different machines in the radiology department

1 and whatever other, a new wing, since the
2 hospital came into existence, and they sell the
3 hospital, under your theory that they've got to
4 go back and get a new CON for every one of
5 those units and the new wing again?

6 MR PRINGLE No

7 THE COURT Okay

8 MR PRINGLE And I'll explain why This -- and
9 remember, in this instance we had -- the CON is
10 issued and then there was a certain amount of
11 time before it has to be implemented

12 THE COURT Yeah

13 MR PRINGLE And in fact, when it's implemented and
14 the final completion report is issued, the CON
15 no longer exists and you are authorized for
16 that service So, and what we're saying here,
17 but that during the pendency of the actual CON,
18 which is supposed to be, you know, book-ended
19 in time, if you will -- an inartful way to say
20 that -- if a transfer occurs during that time
21 period --

22 THE COURT Oh, during that time?

23 MR PRINGLE Right

24 THE COURT Okay

25 MR PRINGLE So that's what I'm saying, is that if

1 the substantial change request --

2 THE COURT So you're arguing if there is a

3 substantial change, then we're -- which I agree

4 with you

5 MR PRINGLE Okay

6 THE COURT I see that point

7 MR PRINGLE Okay And that's the point that we're

8 making

9 THE COURT No substantial change, no issue

10 MR PRINGLE That is correct

11 THE COURT Okay All right

12 MR PRINGLE That is correct And I think I'll

13 leave it at that But just to sum up is,

14 looking at the project as a whole, certainly

15 the way it was done originally versus the way

16 it's done now, there were substantial changes

17 that should, or mandate that a new application

18 be filed with DHEC

19 THE COURT Okay All right Thank y'all for your

20 time I'll wait to hear from y'all with

21 proposed orders

22 (There being nothing further, the hearing was

23 concluded at 12 10 p m)

A Joseph Borelli, Jr, M D

DATE OF BIRTH March 5 1962

BIRTHPLACE Pittsburgh Pennsylvania

MARITAL STATUS Married

BUSINESS ADDRESS MRI at Belfair LLC
18 Clarks Summit Drive
Bluffton SC 29910
(843) 815-9700
joeborelli1@mac.com

HOME ADDRESS 15 Bear Island Road
Hilton Head Island SC 29926
(843) 681-5005

ACADEMIC APPOINTMENTS Assistant Clinical Professor of Radiology
Division of Neuroradiology
Medical University of South Carolina
August 2001 to June 2004

PROFESSIONAL EMPLOYMENT Chairman
Committee on MRI Accreditation
American College of Radiology (www.acr.org)
September 2006 to present

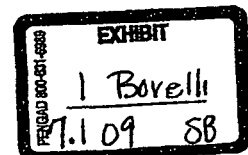
Medical Director
Health Inventures (www.healthinventures.com)
February 2006 to January 2008

Committee on Breast MRI Accreditation
American College of Radiology
January 2006 to present

President and Medical Director
MRI at Belfair (www.mriatbelfair.net)
Bluffton SC
April 2002 to present

Medical Director
HealthSouth MRI
Hilton Head Island SC
October 2000 to October 2004

Committee on MRI Accreditation
American College of Radiology
September 2001 to present



Radiology Advisory Board
HealthSouth Corporation
December 2000 to October 2004

Accreditation Reviewer
Committee on MRI Accreditation
American College of Radiology
February 1999 to present

Director/Founder
Laurel Highland Advanced Imaging (www.lhai.org)
Johnstown PA
March 1999 to October 2000

Medical Director
University of Pittsburgh Medical Center
Lee Regional MRI
Johnstown PA
March 1992 to March 1999

CORPORATE AFFILIATIONS

Consultant/Speakers Bureau
Apple Inc (www.apple.com)
2006 to present

National MRI Show Site
GE Healthcare
April 2002 to present

Speakers Bureau (MRI Products and Solutions)
GE Healthcare
2002 to present

Speakers Bureau
CADStream Prostate/Breast
Confirma Inc (www.confirma.com)

Clinical Evaluation Site
GE Healthcare MRI Products and Solutions
2003 to present

Clinical Evaluation Site
CADStream Prostate/Breast Products
2005 to present

MEDICAL LICENSURE

Pennsylvania South Carolina

BOARD CERTIFICATION

Diagnostic Radiology
American Board of Radiology June 1991

MEMBERSHIPS/ORGANIZATIONS

American College of Radiology
Radiological Society of North America
American Roentgen Ray Society

EDUCATION

FELLOWSHIP

MRI neurological abdominal musculoskeletal
University of Pittsburgh Medical Center
Pittsburgh PA
July 1991 to March 1992

RESIDENCY

Diagnostic Radiology
Department of Radiological Sciences
University of Oklahoma Health Sciences Center
Oklahoma City OK
July 1987 to June 1991

MEDICAL SCHOOL

Hahnemann University School of Medicine
Philadelphia Pennsylvania
September 1983 to May 1987
Doctor of Medicine

UNDERGRADUATE

University of Pennsylvania
Philadelphia Pennsylvania
September 1979 to May 1983
Bachelor of Arts (Honors Chemistry)

SECONDARY

Shady Side Academy
Pittsburgh, Pennsylvania
September 1975 to June 1979

AWARDS AND HONORS

Special Award for Outstanding Medical Contributions
HealthSouth Corporation (www.healthsouth.com)
2001

Community Service Award
Volunteers in Medicine Clinic (Hilton Head Island)
2001 - 2007

Cum Laude Society
Phi Lambda Upsilon Honorary Chemical Society
Letter of Commendation
Dean's List
President of the United States' Award for
Environmental Protection Services

CPR CERTIFICATION

Advanced Cardiac Life Support (ACLS)
Pediatric Advanced Life Support (PALS)
Basic Lifesaving (BLS) - current

PUBLICATIONS/PRESENTATIONS

VIDEO

Apple Seminars Online
Getting Started with OsiriX
<http://www.seminars.apple.com/seminaronline/osirixintro/apple>

PUBLICATIONS

Non-Contrast MR Arthrograms Generate Exquisite Images
Signa Pulse - Spring 2008
GE Healthcare
http://www.gehealthcare.com/euen/mri/signapulse_magazine.html

A Conversation with A. Joseph Borelli, Jr, M.D.
RT Image, vol 21, no 2 – January 14, 2008
<http://www.rt-image.com>

Borelli A, Sneddon L. Structural Characterization of 6,4',5' [1-(η -C₅H₅)Co-2,3(CH₃)₂C₂B₄H₃][2',3'-(CH₃)₂C₂B₄H₅] A Coupled-Cage Cobaltacarborane Complex Containing a Three-Center Boron Linkage
Inorganic Chemistry 1982 21 1328

INVITED LECTURES/PRESENTATIONS

OsiriX in Clinical Practice Advanced Applications
Apple Inc
VA Palo Alto Health Care System
Palo Alto CA
April 7 2008

Hands On Workshop Introduction to OsiriX
Apple Inc
Radiological Society of North America (RSNA)
Chicago IL
November 25 – 28 2007

Hands On Workshop CADStream Prostate
Confirma Inc
Radiological Society of North America (RSNA)
Chicago IL
November 27 2007

Press Briefing CADStream Prostate
Confirma Inc
Radiological Society of North America (RSNA)
Chicago IL
November 27 2007

A Day in the Life of Excite HD MRI
GE Healthcare
Waukesha WI
April 27 2006

A Day in the Life of Excite HD MRI
GE Healthcare
Atlanta GA
April 13 2006

Imaging of Hepatic Tumors New Methods and Rationale
Memorial Health University Medical Center
Savannah GA
May 19 2005

Implementing Breast MRI
GE Healthcare
Miami FL
May 16 2005

MRI Clinical Applications Recent Advances
GE Healthcare
Florence SC
August 8 2004

Cardiac MRI in Clinical Practice
Evansville IN
April 4 2004

Developing a Cardiac MRI Program Lessons from a Freestanding Facility
North Carolina Radiology Society
Pinehurst, NC
November 15 2003

Developing a Cardiac MRI Program
MRI Head to Toe (Ryals and Associates)
Westin Resort
Hilton Head Island SC
March 15 2003

Silent Strokes A Devastating New Epidemic
Sun City Hilton Head
Bluffton, SC June 14, 2002

MRI from Head to Toe What the Referring Physician Needs to Know
Hilton Oceanfront Resort
Hilton Head Island SC
June 13 2001

Advanced MRI and MRA Applications Update for Clinicians
Volunteers in Medicine Clinic
Hilton Head Island SC
January 19, 2001

MRI Breakthroughs Changing the Practice of Medicine in the 21st Century
Hilton Oceanfront Resort
Hilton Head Island SC
July 26 2000

CT vs MRI Cost Effective Complementary Utilization
Cambria Somerset Council on Continuing Education
Johnstown PA
March 21 1995

Diagnosis of Torsion of the Wandering Spleen Role of Ultrasound and 99m Tc-Sulfur Colloid Scintigraphy
8th Annual Intern and Resident Conference
University of Oklahoma Health Science Center
Oklahoma City OK
May 20 1989

Department: Coastal Carolina Medical Center Imaging Department		Policy Number	
Section: MRI		Effective Date: February 2007	Page: 1
Title Code Blue Procedures in MRI Trailer		☒ Non-Clinical ☐ Clinical	
Approved by: Medical Staff		Review Date: February 2008 Revision Date:	

Code Blue Procedures in the MRI Trailer

- 1 Push Code Blue button**
- 2 MRI tech will call 784-5555**
- 3 MRI tech remove patient from the MRI**
- 4 MRI tech un-locks the table, moves table and patient into the control area**
- 5 Start CPR on patient**

Emergency Department will

- 1 Start bagging patient with oxygen bottle**
- 2 Attach defibrillator**
- 3 Push drugs from locked Crash Cart cabinet in MRI**
- 4 Move patient to ED by MRI table**

CCMC 2RFP 0062

Department Coastal Carolina Medical Center Imaging Services	Policy Number	
Section MRI	Effective Date September 2006	Page: 1
Title Patient safety during a code in MRI	☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team	Review Date: September 2006 Revision Date:	

SCOPE. TO ENSURE PATIENT/STAFF SAFETY DURING A CODE

POLICY Refer to the Hospital/Radiology guidelines for all codes. There are additional duties in the MRI Dept. It is the responsibility of the MRI Technologist to remove the MRI patient from the magnet room in the event of a code or a patient requiring medical attention/assistance.

This is to ensure the safety not only of the patient but also the staff by preventing accidental missile effect of staff personal effects.

All individuals entering the magnet room must be screened for contraindications i.e. pacemakers, implanted metal and loose metal objects.

A non magnetic cart is always available for the MRI Technologist to use in removing/transporting the patient to a safe zone.

Radiologist _____

Director of Imaging: _____

Date _____

CCMC 2RFP 0063

Department Coastal Carolina Medical Center Imaging Services		Policy Number	
Section MRI		Effective Date September 2006	Page 1
Title MRI emergency button		☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team		Review Date: September 2006 Revision Date:	

POLICY TO MAKE ALL TECHNOLOGISTS AWARE OF THE LOCATION AND USE OF THE EMERGENCY BUTTON IN THE MRI COACH

POLICY The MRI Technologists are oriented as to the location (see following GE Manual Insert) and use of the emergency button

If the technologist becomes aware of a situation that would put either the patient or personnel in danger (e.g. frayed wire, fire, aberration of scanning sequence) the technologist should depress the emergency button remove the patient and/or personnel and notify the appropriate personnel (Engineering, Fire Dept etc)

Radiologist _____

Director of Imaging _____

Date _____

CCMC 2RFP 0064

Department Coastal Carolina Medical Center Imaging Services	Policy Number	
Section MRI	Effective Date: September 2006	Page: 1
Title Emergency supplies	☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team	Review Date: September 2006 Revision Date	

PURPOSE To assure adequate emergency supplies in the MRI Coach

POLICY An emergency drug tray is stored in the top cabinet in MRI. This tray will consist of drugs to treat allergic reaction. The tray will be examined monthly by a pharmacy aid. The drug box is sealed and the person who opens the tray will be responsible for notifying the pharmacy.

Airways and ambu bags in age appropriate sizes are available in the MRI Department at all times.

All techs in MRI are responsible for maintaining and replacing supplies replacing sharps boxes when full, and checking the condition and usability of said supplies.

Radiologist _____

Director of Imaging _____

Date _____

CCMC 2RFP 0065

Department Coastal Carolina Medical Center Imaging Services	Policy Number	
Section MRI	Effective Date September 2006	Page 1
Title Helium fill for MRI	☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team	Review Date September 2006 Revision Date	

PURPOSE TO SCHEDULE TIMELY AND EFFECTIVE HELIUM FILL FOR MR MACHINE

POLICY It is the duty of the MRI technologist to record the cryogen level daily. It is noted on the QA sheet and tracked daily. Each Tuesday AM Air Products is called with the magnet reading of that morning. If the level falls below 60% a fill is ordered. Air products also tracks the helium levels and subsequent calls are made to the site if the level falls precipitously. This ensures a double check on the level to preserve the integrity of the magnet.

Radiologist _____

Director of Imaging _____

Date _____

CCMC 2RFP 0066

Department Coastal Carolina Medical Center Imaging Services	Policy Number	
Section: MRI	Effective Date September 2006	Page 1
Title Identification of patient	☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team	Review Date: September 2006 Revision Date:	

POLICY IDENTIFICATION OF PATIENT

All patients must have appropriate identification bracelets for MRI procedure to be done. Nursing Unit personnel will be required to come to Radiology identify the patient and place the ID band of the patient.

The chart must accompany all inpatients to MRI Department for all exams.

All Out Patients must have ID bracelets issued by the Admissions office before being taken to the MRI department.

Radiologist: _____

Director of Imaging: _____

Date: _____

CCMC 2RFP 0067

Department Coastal Carolina Medical Center Imaging Services	Policy Number	
Section MRI	Effective Date, September 2006	Page. 1
Title Prevention of burns in the MRI department	☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team	Review Date: September 2006 Revision Date:	

SCOPE TO PREVENT BURNS FROM COILS IN/ON THE MRI EQUIPEMENT

POLICY Follow the guidelines as set forth by Frank Shellock MD in the MRI Safety book

NOTE Various types of implants and devices (e g monitoring equipment surface coils etc) may pose a hazard to the patient in the MRI environment as a result of excessive heat that may be generated during an MR procedure. Prevention of burns in the MR environment requires careful attention to understanding MR safety criteria for certain electrically-conductive implants and the proper use of monitoring equipment and accessories. Recommendations for protection of the patient from excessive heating and possible burns that may develop during the MRI procedure are as follows

MR compatible monitoring equipment is not available for use at this facility. Therefore, all monitoring equipment, cables, wires, electrodes must be removed before a patient enters the magnet room. See policy on the care of critical patients for MR exams

- 1 Follow all MR safety criteria for implants made from electrically conductive materials (See info sheet)
- 2 Use only devices and monitoring equipment that have been thoroughly tested and determined to be safe for patients during MR procedures
- 3 Allow only properly trained individuals to operate devices and monitoring equipment and to be responsible for the patient in the MRI environment
- 4 Before using the device or equipment check the integrity of the electrical insulation of the components or accessories of the device including monitoring leads, cables, and wires. Preventive maintenance should be practiced routinely.
- 5 Remove all electrically conductive materials from the MR system that is not required for the procedure (i.e. unused surface coils, cables, etc.)
- 6 Keep electrically conductive materials that must remain in the MR system from directly contacting the patient by placing thermal and/or electrical insulation (including air) between the conductive material and the patient.

CCMC 2RFP 0068

SUBJECT PREVENTION OF BURNS IN MRI DEPT	POLICY NO	PAGE 2 OF 2

- 7 Keep electrically conductive material (s) (e.g. leads, cables, wires, etc.) that must remain within the bore of the MR system from forming conductive loops. The patient's tissue is conductive and therefore may be involved in the formation of the conductive loop. Technologists should note that loops can be close, U shaped, or S shaped.
- 8 Position all cables to prevent "cross points" (a cross point is the point where a cable crosses another cable, where a cable loops across itself, or where a cable touches either the patient or side of the magnet bore more than once).
- 9 Position all cables and wires so that they exit as close as possible to the center of the table of the MRI system.
- 10 Position the patient so that there is no direct contact between the patient's skin and the bore of the MR system. This may be accomplished by having the patient place his/her arms over his/her head or by using elbow pads or foam padding between the patient's tissue and the bore of the MR system.
- 11 Do not position conductive leads, cables, or wires across the area of an external metallic prosthesis or similar device that is in contact with the patient.
- 12 Devices or equipment that do not appear to be operating properly during the MR procedure should be removed from the patient immediately.
- 13 If the patient reports feeling warm or hot in association with the use of monitoring equipment or other similar device, discontinue the MR procedure immediately and perform a thorough assessment of the equipment to determine proper functioning.
- 14 Use only MR system manufacturer recommended or monitoring equipment manufacturer-recommended ECG wires, leads, electrodes, as well as other components and accessories.
- 15 Follow all instructions for the proper operation of physiologic monitoring or other similar electronic equipment provided by the manufacturer of the device.

Radiologist _____

Director of Imaging _____

Date _____

CCMC 2RFP 0069

Department Coastal Carolina Medical Center Imaging Services	Policy Number	
Section: MRI	Effective Date: September 2006	Page: 1
Title Cleaning of MRI table and coils	☒ Non-Clinical ☐ Clinical	
Approved by: Administrative Team	Review Date: September 2006 Revision Date:	

PURPOSE TO ASSURE PROPER CLEANING OF MRI TABLE AND COILS

POLICY The MRI table should be cleaned after every patient with the disinfection solution used hospital wide. MRI coils and comfort pads should be cleaned in the same manner with caution being used not to damage the coils or wires.

Headphones used for the MRI Department should be cleaned after each use and disposable ear covers should be changed after each use.

Radiologist _____

Director of Imaging _____

Date _____

CCMC 2RFP 0070

Department Coastal Carolina Medical Center Imaging Services		Policy Number	
Section: MRI		Effective Date: September 2006	Page: 1
Title Charting of all contrast media reactions		☒ Non-Clinical ☐ Clinical	
Approval by Administrative Team		Review Date: September 2006 Revision Date:	

PURPOSE TO CHART ALL CONTRAST MEDIA REACTIONS AND CHECK FOR TRENDS

POLICY MRI Technologists will document all contrast media reactions on the Quality Assurance sheet. Reactions will be part of the continuing QA report and any trends or issues will be discussed with the Diagnostic Imaging Director and Radiologist

Radiologist _____

Director of Imaging _____

Date _____

CCMC 2RFP 0071

Department Coastal Carolina Medical Center Imaging Services		Policy Number	
Section MRI		Effective Date September 2006	Page 1
Title Prep for contrast media		☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team		Review Date: September 2006 Revision Date:	

SCOPE

PURPOSE TO SET GUIDELINES FOR CONTRAST MEDIA INJECTIONS

POLICY Patients requiring an injection of IV Contrast Media will be screened by the MRI Technologist following the guidelines as prescribed by the Radiologist

Due to the chance of allergic reaction, a physician, radiologist or ER physician must be present in the facility at the time of the injection

Patients with a history of renal disease/failure and/or a history of previous allergic reaction to contrast media will be further screened by the radiologist

Inpatients and emergency room patients requiring injection will of contrast media may have an intravenous catheter in place This may be used to introduce the contrast media The technologist must flush the IV line with saline prior to and after the injection of the Gadolinium

Outpatients will not have an IV line therefore a certified technologist or radiologist will establish venous access

The rate of dosage will be determined using the Gadolinium chart provided by the manufacturer This is determined by weight

Radiologist _____

Director of Imaging _____

Date _____

CCMC 2RFP 0072

Department: Coastal Carolina Medical Center Imaging Services	Policy Number:	
Section: MRI	Effective Date September 2006	Page: 1
Title: checking of implants before MRI	☒ Non-Clinical ☐ Clinical	
Approved by: Administrative Team	Review Date: September 2006 Revision Date:	

PURPOSE TO CHECK FOR SAFETY OF IMPLANTS/DEVICES BEFORE PATIENT IS ESCCORTEED TO MRI COACH

POLICY Each patient, after filling out the MRI Screening Questionnaire (see Policy 710 118) will be checked for the presence of medical implants. If the patient has such a device the device will be checked against the MRI Safety Book author Frank Sherlock Phd

If a patients presents with a stent implant, the patient should have a card from their physician stating type of implant and date of service. Guidelines as stated in the Sherlock book for MRI safety are followed at this institution. No patient is taken to the magnet room with a surgery less than 8 weeks old.

Pacemakers are an absolute contraindication as are cochlear implants

Radiologist _____

Director of imaging _____

Date _____

CCMC 2RFP 0073

Department Coastal Carolina Medical Center Imaging Services	Policy Number	
Section MRI	Effective Date September 2006	Page: 1
Title Prevent Missile effect in the MRI dept	☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team	Review Date: September 2006 Revision Date:	

PURPOSE TO PREVENT MISSILE EFFECT IN THE MRI DEPT

POLICY SEE INFO SHEET FOR DESCRIPTION OF MISSILE EFFECT

Patients will be screened outside the Gauss line and then once more before entering the magnet room

Guidelines and recommendations for preventing hazards related to "missile effects" in the MR environment are as follows

- 1 The technologist shall be the safety officer responsible for ensuring that proper procedures are in effect, enforced and updated to ensure safety in the MR environment
- 2 MRI safety policies shall be routinely reviewed and the level of compliance assessed by all staff members
- 3 All MR staff along with other personnel who have an opportunity or need to enter the MR environment (eg Transport personnel security officers housekeeping staff maintenance workers fire department personnel etc) with formal training on MR safety
- 4 All personnel should understand that the MR system's static magnetic field is always "on" and treat the MR environment accordingly
- 5 NO equipment shall enter the MR environment unless tested by the MR staff and labeled "MR Safe"
- 6 Patients shall be transported to MRI on the provided non ferromagnetic cart. Wheelchairs shall not enter the magnet room or any other transport device
- 7 No IV poles or infusion devices shall be brought into the MR environment

All patients undergoing MR procedures all metallic or other potentially problematic personal belongings (ie hearing aids analogue watches, jewelry etc) and devices must be removed as well as clothing items that have metallic fasteners or other metallic components (eg threads) It is recommended the patients undergoing MRI exams who cannot be screened adequately for metal objects should wear a gown

CCMC 2RFP 0074

No IV poles or infusion devices shall be brought into the MR environment
All patients undergoing MR procedures, all metallic or other potentially problematic personal belongings (I e hearing aids, analogue watches, jewelry etc) and devices must be removed as well as clothing items that have metallic fasteners or other metallic components (e g threads) It is recommended the patients undergoing MRI exams who cannot be screened adequately for metal objects should wear a gown

Radiologist. _____

Director of imaging _____

Date _____

CCMC 2RFP 0075

Department Coastal Carolina Medical Center Imaging Services	Policy Number	
Section MRI	Effective Date: September 2006	Page 1
Title Patient safety during evacuation	☒ Non-Clinical ☐ Clinical	
Approved by: Administrative Team	Review Date: September 2006 Revision Date:	

POLICY TO ENSURE PATIENT/STAFF SAFETY DURING EVACUATION

POLICY Refer to the Hospital/Radiology guidelines for evacuation guidelines
 There are additional duties in the MRI Dept It is the responsibility of the MRI
 Technologist to remove the MRI patient from the magnet room in the event of an
 evacuation

This is to ensure the safety not only of the patient but also the staff by preventing
 accidental missile effect of staff personal effects

All individuals entering the magnet room must be screened for contraindications
 i e pacemakers implanted metal and loose metal objects

A non magnetic cart is always available for the MRI Technologist to use in
 removing/transporting the patient to a safe zone

Radiologist. _____

Director of Imaging _____

Date _____

CCMC 2RFP 0076

Director of Imaging _____

Date _____

CCMC 2RFP 0077

Department Coastal Carolina Medical Center Imaging Services	Policy Number	
Section MRI	Effective Date September 2006	Page: 1
Title Event of power loss	☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team	Review Date September 2006 Revision Date	

PURPOSE SAFE REMOVAL OF THE PATIENT FROM MAGNET ROOM IN THE EVENT OF A LOSS OF POWER

POLICY In the event of a unanticipated power loss due to circumstances outside the technologist's control (e.g. high winds, power company fluctuation, inclement weather) the technologist shall remove the patient from the magnet room in the following manner:

- 1 The table release should be depressed by the first technologist in the room, the second technologist should grasp the table end and pull the patient from the magnet. The first technologist should reassure the patient and guide the patient's body from the magnet.
- 2 If the patient is ambulatory, the patient should be assisted from the table. If the patient requires help (e.g. wheelchair bound, cart patient, incapacitated patient) the technologists will bring the MRI compatible cart into the room and transfer the patient from the MRI table to the cart. The patient will then be escorted from the room. In the event the power does not return, the patient can be taken from the room via lift with the manual apparatus. The technologists can call Engineering for assistance with the lift if necessary.

Radiologist _____

Director of Imaging _____

Date _____

CCMC 2RFP 0078

Department Coastal Carolina Medical Center Imaging Services		Policy Number	
Section MRI		Effective Date: September 2006	Page: 1
Title Monitoring of temperature of MRI room		☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team		Review Date: September 2006 Revision Date:	

PURPOSE TO MONITOR THE MAGNET ROOM TEMPERATURE TO ENSURE PATIENT SAFETY AND COMFORT

POLICY The MRI Technologist should make note of the temperature in the magnet/scan room during an exam. The patient shall be monitored through communication with the speaker/headphones. If a patient reports over heating the exam can be cancelled or postponed until the patient and/or the scan room cools.

CCMC 2RFP 0079

Department Coastal Carolina Medical Center Imaging Services		Policy Number	
Section: MRI		Effective Date: September 2006	Page: 1
Title: Employee Pregnancy		☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team		Review Date: September 2006 Revision Date:	

POLICY To outline guidelines for pregnant employees assigned to the MRI area

PROCEDURE

- 1 All employees working in the MRI area must report their pregnancy to the Director of Imaging as soon as it is known. The pregnant employee shall complete a Declaration of Pregnancy form. A copy of this form is attached to this policy.
- 2 The pregnant employee will continue all duties required of her position, with the exception of occupying the magnet room during the activation of the systems's gradient and radio frequency subsystems until the termination of the pregnancy, unless the pregnant employee is responding to an emergency situation.
- 3 There currently are no established regulatory guidelines for occupational utilization of MRI systems by pregnant women.

Radiologist _____

Director of imaging _____

Date _____

CCMC 2RFP 0080

Department Coastal Carolina Medical Center Imaging Services		Policy Number	
Section MRI		Effective Date September 2006	Page: 1
Title Pregnant Patients and Contrast Media		☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team		Review Date: September 2006 Revision Date:	

POLICY It is the policy of Coastal Carolina Medical Center to ensure that no pregnant patient will receive an intervenous MR contrast agent unless approved by the radiologist-in-charge

PROCEDURE

- 1 If it is clinically indicated to administer a contrast agent for a procedure on a pregnant patient the technologist shall consult with the radiologist in charge and he shall determine whether it is medically appropriate to administer the contrast agent
- 2 If the radiologist has determined that it is medically appropriate to give the pregnant patient contrast, the technologist must note it in the patients MRI screening questionnaire form
- 3 Should it be necessary to administer an MRI contrast to a pregnant patient, the site shall obtain an executed written consent form from the patient indicating that she is aware of the risks, benefits, and alternatives to the procedure

Radiologist _____

Director of imaging _____

Date _____

CCMC 2RFP 0081

Department Coastal Carolina Medical Center Imaging Services		Policy Number	
Section: MRI		Effective Date: September 2006	Page: 1
Title Procedure for response to a fire in MRI		☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team		Review Date: September 2006 Revision Date:	

POLICY It is the policy of Coastal Carolina Medical Center to insure the safety of the staff patients, and visitors in the are in an expedient fashion should a fire occur in the MRI area

PROCEDURE

1 General

There are 4 basic steps that must be taken if a fire is discovered. The proper order is as follows

- Protect those immediately affected by the fire and smoke
- Confine the fire and smoke by closing doors that will isolate it in a given room or are
- Notify those responsible for responding to the fire scene by
 - Pulling the nearest/safest fire alarm pull station
 - Calling 5555 and reporting the location of the fire
- Attempt to extinguish or contain the fire without jeopardizing personal safety. Use appropriate fire extinguisher

2 Respond to a fire in the MRI room

- Disconnect electrical power to the MRI system by pressing the emergency "off" buttons
- Use only a non-magnetic fire extinguisher
- If the fire is not extinguished after emptying the available extinguisher, or jeopardizes person safety the magnetic field must be removed by pressing a "quench button" on the Emergency Rundown Unit.
- All personnel including fire fighters must be screened for entry to the restricted magnetic area before the magnetic field is removed

Radiologist _____

Director of imaging _____

Date _____

CCMC 2RFP 0082

Department Coastal Carolina Medical Center Imaging Services		Policy Number	
Section MRI		Effective Date: September 2006	Page: 1
Title Quench Evacuation		☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team		Review Date: September 2006 Revision Date:	

POLICY It is the policy of Coastal Carolina Medical Center to provide guidelines for proper action in the event of a sudden flooding of the unit with helium gas (a quench)>

PROCEDURE

- 1 Respond to visual or audible (each unit is equipped with a sensor and audible alarm system) warning of a quench by recognizing that patient safety is the first concern
- 2 Remove the patient from the unit and room quickly and carefully. Remain calm and reassure the patient. Helium is not toxic, the hazard is that it will displace the oxygen in the area and create a possibility of suffocation. Also be aware that gaseous helium will be very low temperature.
- 3 Close all doors when leaving the area.
- 4 Evacuate patients and personnel to a safe location
- 5 Notify the Plant Operations Manager of damage report and anticipated downtime
- 6 Notify the MRI manufacturer/service organization of the quench.
- 7 Notify the contracted site management and radiologist in charge
- 8 Complete and file Occurrence report to the Risk Manager

Radiologist _____

Director of imaging. _____

Date _____

CCMC 2RFP 0083

Department Coastal Carolina Medical Center Imaging Services		Policy Number	
Section MRI	Effective Date: September 2006	Page: 1	
Title Removal of Superconductive Magnetic field	☒ Non-Clinical ☐ Clinical		
Approved by Administrative Team		Review Date: September 2006 Revision Date:	

POLICY It is the policy of Coastal Carolina Medical Center to identify procedure for emergency removal of the superconducting magnetic field

PROCEDURE

- 1 The magnetic field should be promptly removed in the case of an urgent need by pressing the Emergency run down button. One such urgent case is that a person is pinned between the magnet and a ferromagnet object which cannot be removed without risking injury
- 2 Remove the patient from the magnet room.
- 3 Contact the Plant Operations manager and MRI service personnel
- 4 Submit Occurance report to the Risk management department

Radiologist _____

Director of imaging _____

Date _____

CCMC 2RFP 0084

Department Coastal Carolina Medical Center Imaging Services	Policy Number	
Section: Patient Care	Effective Date: September 2006	Page: 1
Title Emergency drug box & Crash Cart	☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team	Review Date: September 2006 Revision Date	

SCOPE

There is an emergency drug box & crash cart located in the Imaging Department. The location is known by all personnel in the Imaging Department. A content list, date and checklist will be folders near on each box. These boxes will have a **RED** plastic lock. The only time this lock is to be removed is during a patient drug reaction or patient necessity during an emergency.

The box is checked daily and the checklist signed. When the lock is broken, this means someone has used something from the emergency drug box. The Nursing Supervisor on duty will place a **YELLOW** lock on the box to signify the box has been used.

This is to be reported to the Imaging Manager or his assistant so the contents can be restocked to its original contents. The Pharmacy will re-supply the box and **RED** lock. The new lock is secured and the new number is then added to the list that is signed daily.

Radiologist _____

Director of Imaging _____

Date _____

CCMC 2RFP 0085

Department Coastal Carolina Medical Center Imaging Services	Policy Number	
Section MRI	Effective Date September 2006	Page: 1
Title Dangers of Liquid Helium and Liquid Nitrogen	☒ Non-Clinical ☐ Clinical	
Approved by Administrative Team	Review Date: September 2006 Revision Date:	

POLICY It is the policy of Coastal Carolina Medical Center to identify effects of improper handling of liquid helium and liquid nitrogen.

PROCEDURE

- 1 Liquid Helium and/or Liquid Nitrogen will cause freezing of human tissues. Use protective gloves. Injuries caused by freezing must be washed with water and treated as burns.
- 2 There is danger of suffocation if helium and nitrogen leak into the room as their vapors will dilute the oxygen in the air. Always keep the ventilation of the examination room and the storage room for liquid gases running. A 5 times per hour air exchange is required.
- 3 Filling liquid nitrogen and liquid helium should be done only by authorized personnel.

Radiologist _____

Director of imaging _____

Date _____

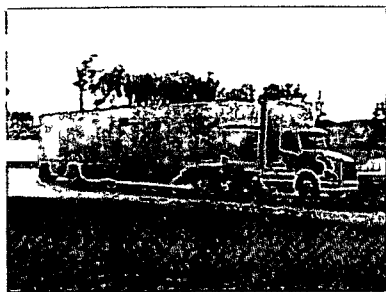
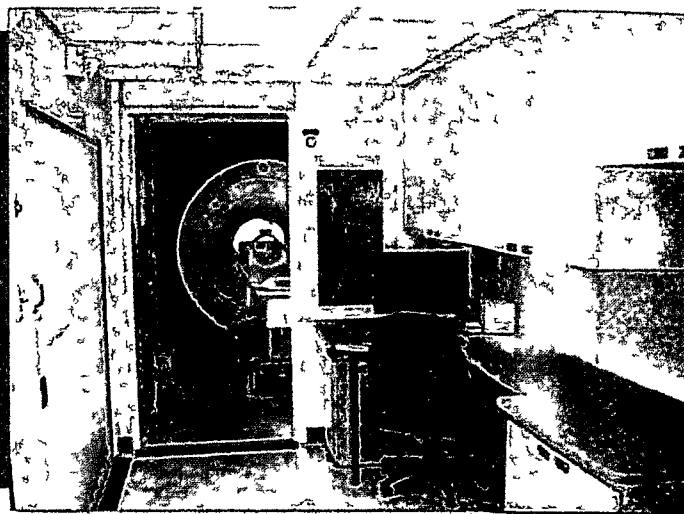
CCMC 2RFP 0086



Mobile MRI GE SIGNA 1.5T SYSTEM

A TRADITION OF ENGINEERING INNOVATION

The Ellis & Watts mobile MRI is an innovative combination of engineering and practical application which is a result of years of experience and multiple user input. This new design is built upon the past generations of excellence, which has been synonymous with the Ellis & Watts name.



MAJOR FEATURES

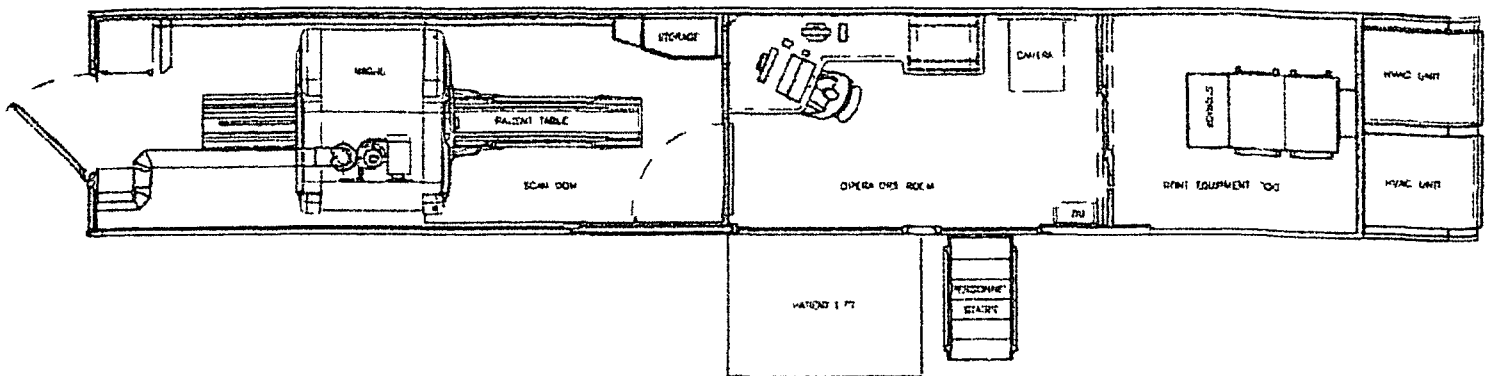
- Redesigned interior
- Site compatible with most existing mobile sites
- Improved Patient Lift
- Easy to clean wall surfaces
- 102" Wide trailer for maximum operator and patient space
- Improved quiet generator housing
- Easy access sliding patient entry door minimizes exposure to outside elements
- Magnetic shielding in walls encloses the 5-Gauss exclusion zone within the scan room
- MRI System and magnet are factory installed at Ellis & Watts
- Site planning and start-up assistance are available from Ellis & Watts
- Lightweight entry stairs and safety rails
- Increased lower compartment storage space
- Operator's Viewing Window
- RFI tested and approved
- Smoke Alarms
- Fire Extinguishers
- Interior Emergency Lighting
- Shore Power Phase Monitor
- Coil Storage Cabinet in scan room
- On-Board Storage
- ABS Braking System
- Tandem Axle Air-ride Suspension



INTERIOR FEATURES

- Bright, cheerful color scheme pleasant for operators and patients
- Operator's work surface faces scan room for efficient patient care
- Coil and patient accessories cabinet in scan and equipment rooms
- Two (2) individual phone and data connection lines plus dedicated line for GE service connection
- Single piece FRP sub flooring
- Flat floor front to rear
- AM/FM/CD stereo receiver

Mobile MRI GE SIGNA 1.5T SYSTEM



EXTRA FEATURES

- Generator in sound attenuated/ weatherproof enclosure to keep road dirt and salt out
- Rig of one-piece lower compartment doors are less susceptible to damage
- Completely enclosed lift compartment ensures lift stays clean and protected during transit
- Patient lift doors are removable for close quarters operation

SAFETY

- Exterior entry lighting
- Trailer backup lights
- Patient lift alarm
- MRI system emergency off button located in multiple locations including both fore and aft of magnet
- Interior Emergency Lighting
- Smoke detectors in every room
- Automatic and manually operated helium exhaust venting system
- Non-ferrous hand held fire extinguishers

HYDRA

- Custom designed chiller and air conditioning system is vibration isolated to meet GE heat load and vibration specifications
- Entire mobile unit is environmentally tested for operation at temperatures from -20°F to +110°F

- Dedicated chiller unit in lower compartment is on slideouts for ease of service
- New air ducting design provides quiet pleasant atmosphere for operator and patients
- Simplified electrical mechanical and control circuits allow ease of service

TRAILER GRAPHICS

- Optional custom graphic design assistance and application available

SERVICEABILITY & WARRANTY

- Shore Power phone cord and data connections are accessible from either side of trailer
- Oversized roof hatch for service accessibility
- Equipment layout allows easy access to front and back of computer cabinets
- Dedicated line for GE INSITE service connection
- Service and operators manuals plus laminated schematics provided
- One (1) year warranty Extended service contracts available
- Contact Ellis & Watts Service Manager for details
- Warranty service provided by Ellis & Watts' Service Network

OPTIONAL ITEMS AVAILABLE

- Patient Entertainment System
- Sink with Hot & Cold Water
- Patient Transport Gurney
- Film Illuminator
- Decal Graphics Packages
- Built-In Oxygen/Suction
- Ceiling Mounted I V Track
- Patient Valuables Lock Box
- Fire Suppression System
- Changing Area
- Contrast Injector Mobile Mounting Kit

RECOMMENDED TRACTOR SPEC'S

- Tractor weight of 20,000 lbs. or less
- Air Ride Suspension required
- DC wiring to include back-up capability
- 34,000 lbs. rear bogie rating
- 12,000 lbs. front axle rating

TRAILER SPECIFICATIONS

- Overall Length 48 ft
- Overall Width 102 in
- Overall Height 13 ft. 6 in
- Power Requirements 480V 3-phase @ 150 amp service
- On-Board Generator for Environmental Systems
- Generator Fuel Tank Capacity 80 Gallons
- Patient Lift Entry Width 75 in
- A/C—Heating Capacity Accommodates GE SIGNA system heat load and ensures comfort



ELLIS & WATTS

Ellis & Watts International, Inc.
4400 Glen Willow Lake Lane,
Dayton, OH 45103
Phone 513.752.9000
FAX 513.752.4113
www.getmobile.com

NOTE: Product specifications are subject to change without notice. Please consult your Ellis & Watts representative for the latest revision of this data.

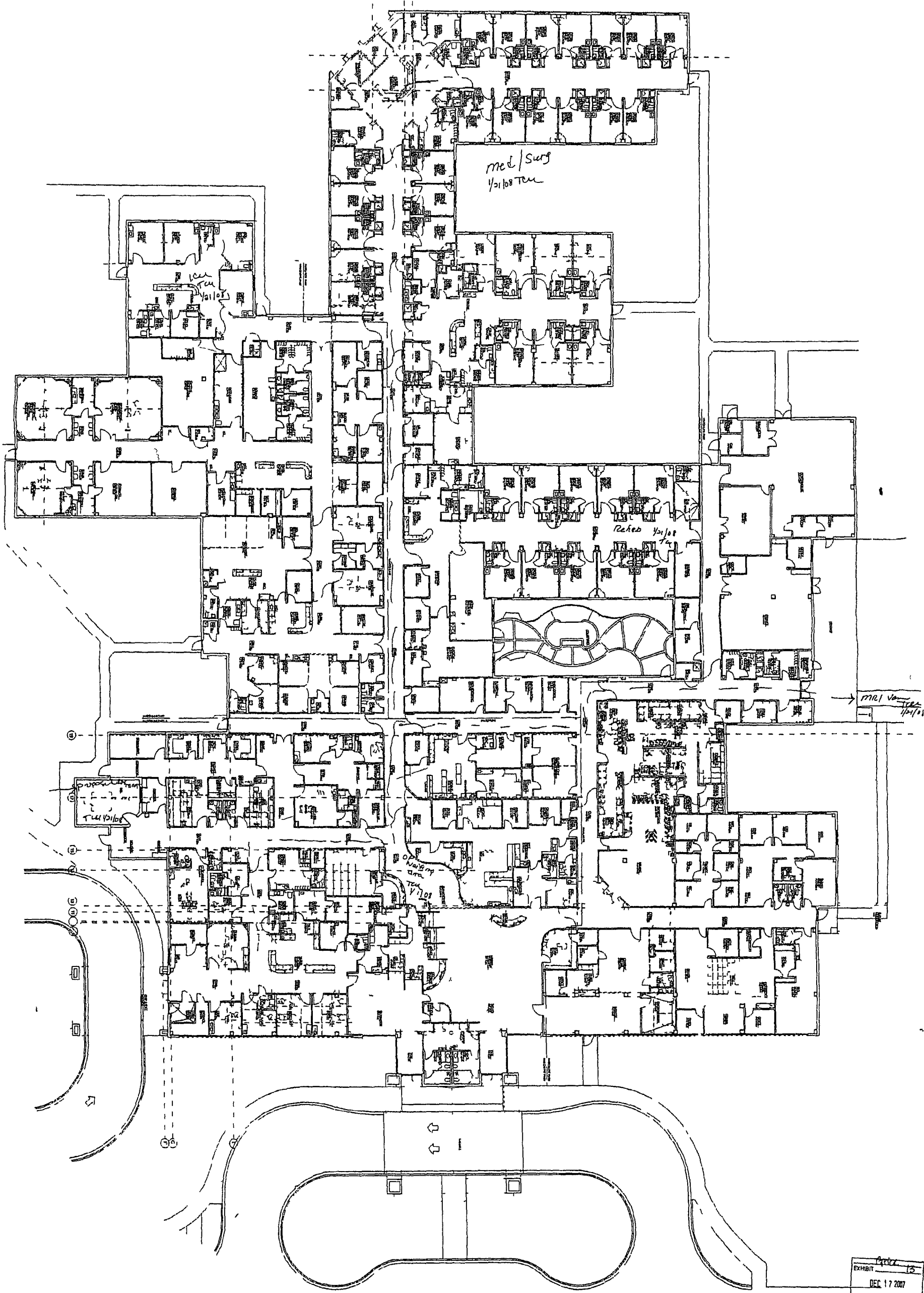


EXHIBIT 15
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