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JUN 13 2017
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY



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PO Box 55727
Birmingham, AL 35255-5727

June 13, 2017

VIA E-MAIL (shpda.online@shpda.alabama.gov)

Alva M. Lambert
Executive Director
State Health Planning and Development Agency
100 North Union Street, Suite 870
Montgomery, AL 36140

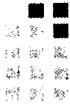
**Re: *University of South Alabama Mitchell Cancer Institute
Request for Non-Reviewability Determination
("RV2017-023 Request")
Additional Information Response***

Dear Mr. Lambert:

INTRODUCTION

This letter is written in response to your letter, a copy of which is attached hereto as Exhibit A, requesting additional information from the University of South Alabama Mitchell Cancer Institute ("USAMCI") regarding the USAMCI RV2017-023 Request for a determination that the ownership, installation, and operation of the Elekta Versa HD 2017 Linear Accelerator, major medical equipment that will not be owned by or located in a health care facility, but instead will be owned by USAMCI and located in its Fairhope, Alabama Physician office, is exempt from Certificate of Need review under the physician office exemption codified at Alabama Code § 22-21-260(6) (the "POE").

USAMCI initially filed the USAMCI RV2017-023 Request with the State Health Planning and Development Agency ("SHPDA") on May 9, 2017, requesting a determination that the RV2017-023 Request is **not subject to CON review** under Alabama Code § 22-21-260, *et seq.*, and the CON Rules, and **does not require a CON** because it does not involve a new institutional health service or any health care facility expenditures in excess of the statutory thresholds requiring CON Review. The USAMCI RV2017-023 Request has still not been published as required in CON Rule 410-1-7-.02, making time of the essence.



Alva M. Lambert
June 13, 2017
Page 2

SHPDA REQUESTED INFORMATION

SHPDA responded to USAMCI's Request on May 22, 2017, requesting additional information regarding: (1) the ownership of USAMCI; (2) the financial breakdown of the anticipated first year annual operating costs; and (3) capital costs, including leases, land/building, and construction costs, if any, for the Proposal.¹

USAMCI hereby submits the following additional requested information in support of its RV2017-023 Request.

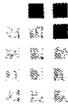
DISCUSSION

1. Ownership Structure of USAMCI

1.1 USAMCI is a division of USA Health, which is a division of the University of South Alabama ("USA"), a University System created under the laws of the State of Alabama with multiple operating divisions, much like the Sacred Heart System, as described in *Ex Parte Sacred Heart Health Sys., Inc.*, 155 So. 3d 980 (Ala. 2012), setting forth the POE test.² Two of the USA operating divisions are licensed and certified "health care facilities": USA Medical Center and USA Children's and

¹ Defined terms used herein have the same definition as included in the RV2017-023 Request unless otherwise noted.

² The *Sacred Heart* litigation has a long and complicated procedural history. The case began when South Baldwin Regional Medical Center ("South Baldwin") filed a petition for a declaratory ruling with SHPDA, requesting that SHPDA declare that Sacred Heart was required to obtain a CON in order to offer health-care services in the medical office building ("MOB") it was developing in south Baldwin County. Infirmiry Health System ("IHS") intervened in support of South Baldwin's petition. When the CONRB failed to rule on South Baldwin's petition, South Baldwin and IHS filed a petition for judicial review in the circuit court. The circuit court ruled that the Sacred Heart project fell under the statutory POE and that Sacred Heart was not required to secure a CON to offer health-care services in the building. The circuit court later amended its judgment to state that the exemption applied only to the three SHMG physicians who were relocating their south Baldwin County-area offices into the MOB, and that if any additional physicians or services were added, Sacred Heart would need to obtain a CON for those physicians or services. Sacred Heart appealed that judgment to the Alabama Supreme Court, and the opposing parties cross-appealed. The Alabama Supreme Court transferred the appeal and cross-appeal to the Court of Civil Appeals, which then reversed the judgment of the circuit court and determined that the MOB did not qualify for the POE. See *Sacred Heart Health Sys., Inc. v. Infirmiry Health Sys.*, 155 So. 3d 969, 979 (Ala. Civ. App. 2010). Sacred Heart then appealed to the Alabama Supreme Court, which set out a modified four-part test to be used to determine whether a proposed medical facility or project qualifies for the POE. It then reversed and remanded the case with instructions that the trial court apply the modified POE test to SHMG and the SHMG space. See *Ex parte Sacred Heart Health Sys., Inc.*, 155 So. 3d 980, 988 (Ala. 2012). On remand, the trial court found that the MOB did not meet the POE test. Sacred Heart appealed to the Alabama Court of Civil Appeals, which reversed the trial court and found that the project did qualify for the POE and that the trial court had exceeded the scope of the remand order. See *Sacred Heart Health Sys., Inc. v. Infirmiry Health Sys.*, 155 So. 3d 989, 1001-02 (Ala. Civ. App. 2013). South Baldwin petitioned the Supreme Court for a writ of certiorari, and the Supreme Court denied the writ without opinion. See *Ex parte S. Baldwin Reg'l Med. Ctr.*, 155 So. 3d 1002 (Ala. 2014).



Alva M. Lambert
June 13, 2017
Page 3

Women's Hospital; however, these two USA operating divisions are unrelated to USAMCI's operation of a physicians' office and this Proposal.

1.2 The USA Physician oncology group practice office division, known as USAMCI, is much like the Sacred Heart Medical/Physician Group ("SHMG"), whose physicians were all employed by the **Sacred Heart Health System** and not by the **Sacred Heart Hospital**.

1.3 USA, the University System, is **not** a "health care facility," just like the Sacred Heart Health System was **not** a "health care facility," as the Court of Civil Appeals ruled that the SHMG Physician office qualified for the CON Review exemption under the POE test set forth by the Alabama Supreme Court in *Ex Parte Sacred Heart*.

1.4 Similarly, USAMCI is also **not** a "health care facility," but a physician office oncology group practice operating division of USA in an academic medical center environment. The six physicians who will practice at the Fairhope USAMCI Physician office, and who are identified in Exhibit 1 to USAMCI's RV2017-023 Request, are employed by USA/USA Health Care Management, LLC ("HCM"), USA's single member LLC which handles all USA employees. All of the USAMCI Physicians bill under the same billing/USAMCI Group NPI number for USAMCI; all USAMCI Physicians have uniform contracts; all USAMCI billing is consolidated; and third party providers consider USAMCI a medical physician group practice, just like the SHMG Physician group, as described in the *Sacred Heart* litigation.

1.5 In response to your request that USAMCI "disclose any other health care facilities or groups holding an interest in USAMCI," there are no health care facilities or groups holding an interest in USAMCI.

2. Financial Breakdown of Costs³

2.1 As to the costs associated with USAMCI's RV2017-023 Request, the estimated cost of the new linear accelerator is **\$2,100,000.00**.

³ Costs are being provided as requested, but are not relevant to the POE and the RV2017-023 Request because USA and USAMCI are **not** health care facilities and do **not** involve a new institutional health service or any health care facility expenditures in excess of the statutory thresholds requiring CON Review. Even if costs were relevant, which clearly they are not, the costs associated with the RV2017-023 Request are, nevertheless, below the health care facility expenditure thresholds set forth in SHPDA's "New Certificate of Need Application Fee and Monetary Threshold for Review Effective October 1, 2016" Memorandum dated September 19, 2016. This Memorandum provides that the health care facility expenditure threshold for major medical equipment is \$2,923,059.00; the threshold for new annual operating costs is \$1,169,223.00; and the threshold for other capital expenditure is \$5,846,117.00. The RV2017-023 Request does not involve any expenditures in excess of these thresholds.



Alva M. Lambert
June 13, 2017
Page 4

2.2 There are no construction costs associated with the purchase and installation of the linear accelerator in the new leased Fairhope Physician office space of USAMCI.

2.3 The anticipated first year new annual operating costs related to RV2017-023 Request are **\$224,536.00**. See Chart, New Operating Costs Related to USAMCI RV2017-023 Request, attached hereto as Exhibit B, for complete breakdown of the new operating costs associated with the USAMCI RV2017-023 Request.

2.4 The only other capital costs associated with the RV2017-023 Request, other than the cost of the linear accelerator, will be a CT Simulator with an estimated cost of **\$591,182.00**.⁴

3. No Health Care Facility Interest in USAMCI

3.1 The Elekta Versa HD 2017 that USAMCI will own, install, and operate in its Fairhope Physician office will **not** be owned by or located in a health care facility, but instead will be owned by USAMCI and located in the USAMCI private oncology physician office in Fairhope, Alabama. The Proposal of RV2017-023 has **no** health care facility interest or involvement and is operated independently of any health care facility.

4. Legal Analysis

4.1 In *Ex Parte Sacred Heart*, the Alabama Supreme Court enumerated four specific factors that physician offices must meet in order to qualify for the POE.

The POE factors are:

(1) The proposed services are to be provided, and related equipment used, **exclusively** by the physicians identified as owners or employees of the **physicians' practice for the care of their patients**.

(2) The proposed services are to be provided, and related equipment used, at **any office** of such **physicians**.

(3) **All patient billings related to such services** are through, or expressly on behalf of, **the physicians' practice**.

⁴ Alternatively, USAMCI is considering leasing the CT Simulator pursuant to a five year lease with an annual estimated lease cost of \$103,956.00.



Alva M. Lambert
June 13, 2017
Page 5

(4) The equipment shall not be used for inpatient care, nor by, through, or on behalf of a health-care facility.

Ex parte Sacred Heart, 155 So. 3d at 988 (emphasis added).

4.2 USAMCI satisfies each of these factors and qualifies for the POE, as set out in its RV2017-023 Request, just as SHMG was found to satisfy the POE in the *Sacred Heart* litigation. The ownership, installation, and operation of the Elekta Versa HD 2017 is **not** subject to CON review, and **no** CON is required for this proposal.

4.3 You stated in your May 22, 2017 letter that:

[T]he radiation and medical oncology services offered through USAMCI are being provided in the offices of physicians employed by the University of South Alabama, and not by private physicians, and are thus an extension of such health care facility.

The University of South Alabama is **not** a health care facility, and hence the USAMCI Physicians cannot be an “extension of” a health care facility. Like Sacred Heart Health System and SHMG, neither USA nor USAMCI is a “health care facility.” Furthermore, the Physician offices of USAMCI are **not an extension** of any health care facility, but are private physician offices operated **independently** of any “health care facility.” The four-part test for determining whether a proposal qualifies for the POE does not include an analysis of the **ownership** of the private physician office. Indeed, the POE, Alabama Code § 22-21-260(6), explicitly provides that the offices of private physicians are excluded from the definition of a health care facility “whether for individual or group practices and **regardless of ownership**” (emphasis added).

4.4 Likewise, the first factor of the four-part test set out in *Ex parte Sacred Heart* indicates that a Proposal qualifies for the POE if the services are to be provided “by the physicians identified as owners **or employees** of the physicians’ practice for the care of **their patients.**” (emphasis added). The USAMCI Physicians who have been identified in Exhibit 1 to USAMCI’s RV2017-023 Request are clearly deemed employees of the USAMCI oncology group practice even though USAMCI is not a separate legal entity and the USAMCI Physicians are employees of USA/USA HCM, just as the SHMG Physicians were deemed employees of the SHMG practice even though SMHG was **not** a separate legal entity and even though the SHMG Physicians were employees of the Sacred Heart Health System. Consequently, factor one of the four-part test is satisfied by the USAMCI RV2017-023 Request.

4.5 USA is a nationally recognized research University System, with multiple operating divisions, like the Sacred Heart Health System. It is **not** a “health care facility.” USA’s ownership of its physician office oncology practice division known as USAMCI is irrelevant to whether USAMCI



Alva M. Lambert
June 13, 2017
Page 6

qualifies as a private physician office, which is clearly exempted from the definition of “health care facilities.”

4.6 As stated here and above, the physician group that was ultimately recognized as qualifying for the POE in the *Sacred Heart* litigation, SMHG, is very similar to the USAMCI Physician group that will work at the Fairhope office of USAMCI in Baldwin County.

4.7 In the *Sacred Heart* litigation, the Alabama Supreme Court identified the organizational structure of the Sacred Heart Medical Group physician office as follows:

Sacred Heart is an out-of-state, charitable, nonprofit corporation that provides health-care services in the panhandle of Florida and in southern Baldwin County. Sacred Heart also owns Sacred Heart Medical Group (“SHMG”), consisting of 143 multi-specialty physicians who practice in the area served by Sacred Heart. SHMG is not a separate legal entity. All SHMG physicians have uniform employment contracts with SHMG; billing for all patients is consolidated and handled by SHMG employees; third-party providers consider SHMG a medical group; and its physicians share the same billing number.

Ex parte Sacred Heart, 155 So. 3d at 982 (emphasis added).

Likewise, the Alabama Court of Civil Appeals explained:

Sacred Heart Health System Inc. is a Florida based operator of hospitals and other health care facilities. Sacred Heart Health System also employs approximately 143 physicians, including approximately six physicians who practice in Baldwin County. The physician practices operate under the moniker of the Sacred Heart Medical Group (“SHMG”). However, the SHMG is not a legal entity but a unit of Sacred Heart Health System Inc., and all operating income and expenses of the SHMG are included in the consolidated financial statement for Sacred Heart Health System, Inc.

Sacred Heart Health Sys., Inc. v. Infirmary Health Sys., 155 So. 3d 989, 994 (Ala. Civ. App. 2013) (quoting trial court’s findings and conclusions on remand) (emphasis added).

4.8 With respect to USAMCI, the physicians who will practice at the Fairhope USAMCI Physician office will all operate under the name or “moniker” of USAMCI. USAMCI, like SHMG, is not a legal entity in and of itself, but a physician office operating division of the University of South



Alva M. Lambert
June 13, 2017
Page 7

Alabama System, like the Sacred Heart Health System.⁵ USAMCI, like SHMG, operates as a private physician group practice office, independent of any health care facility; third party providers recognize USAMCI as a physician office group practice; all USAMCI Physicians have uniform contracts; all USAMCI billing is consolidated; and all USAMCI Physicians use the USAMCI billing/NPI number.

4.9 In the *Sacred Heart* litigation, the Alabama Court of Civil Appeals ultimately concluded that SMHG qualified for the POE. Following this decision, South Baldwin petitioned the Alabama Supreme Court for a writ of certiorari. The Supreme Court denied the writ without opinion; however, in a special concurrence, Justice Stuart approved of the Court of Civil Appeals' analysis and application of the POE test. Justice Stuart stated, "The Court of Civil Appeals properly interpreted our holding in *Ex parte Sacred Heart Health System* and applied that holding to the facts of this case." *Ex parte S. Baldwin Reg'l Med. Ctr.*, 155 So. 3d 1002, 1004 (Ala. 2014) (Stuart, J., concurring specially).

4.10 Accordingly, **SHMG qualified for the POE** under the Court of Civil Appeal's analysis, regardless of whether it was an operating division of the Sacred Heart Health System, which had **other operating divisions that included a health care facility**. Similarly, **USAMCI**, an operating physician office oncology group practice division of USA, also **qualifies for the POE**, regardless of whether it is an operating division of the USA University System, which has **other operating divisions** that include two licensed and certified **health care facilities which operate independently from USAMCI**.

4.11 Pursuant to the precedent set by *Sacred Heart*, SHPDA is limited to applying the factors set out by the Alabama Supreme Court in *Ex parte Sacred Heart*. When the *Sacred Heart* case was reversed and remanded by the Supreme Court, the trial court deviated from the four-part test and considered factors other than those enumerated by the Alabama Supreme Court. In finding that this deviation was error, the Court of Civil Appeals stated:

In its order on remand, the trial court considered facts such as the different build-out costs of the various leases, which, it said, indicated that "Sacred Heart clearly does not treat these facilities as one physician's office, but as separate facilities." The POE application test does not contain a factor for which the build-out costs of the various leases would be a relevant consideration. Thus, we have not considered the build-out costs of the various leases in determining whether the evidence supported the trial court's conclusion that the SHMG leased space does not qualify for the POE.

⁵ Like the SHMG operating division income and expenses were included in the consolidated financial statement for the Sacred Heart Health System, all operating division income and expenses of USAMCI are included in the consolidated financial statement for USA.



Alva M. Lambert
June 13, 2017
Page 8

Sacred Heart Health Sys., Inc. v. Infirmary Health Sys., 155 So. 3d at 1000 (emphasis added).

4.12 The Court of Civil Appeals also found that by considering whether applying the POE to the medical park would “circumvent the statutory language in §§ 22-21-260(6), 22-21-260(8), 22-21-263, and 22-21-265,” the trial court had “**injected a subjective factor** into a test that our supreme court has indicated **should be limited to the four objective factors set out in its opinion.**” *Sacred Heart Health Sys., Inc. v. Infirmary Health Sys.*, 155 So. 3d at 1000-01.

4.13 The Court further explained, “The trial court’s only function on remand was to consider the POE application test set out in *Ex parte Sacred Heart* and to apply the factors of that test to the facts in the record or those facts developed in any proceedings held on remand.” *Id.* at 1001.

4.14 SHPDA, too, must apply the factors of the four-part test as set out in *Ex parte Sacred Heart*. Consideration of any factors other than those enunciated in this four-part test would go against the clear direction provided by the Alabama Supreme Court.

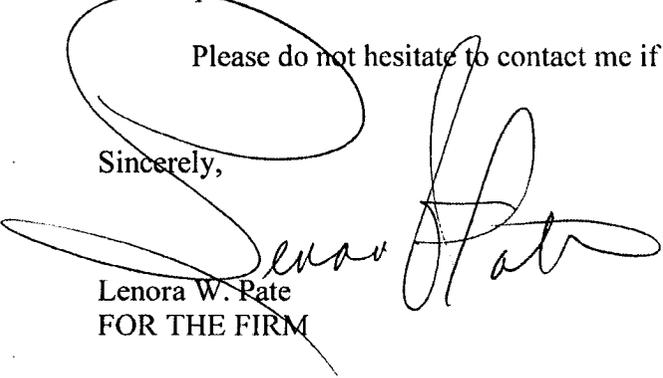
CONCLUSION

Pursuant to the physicians’ office statutory exemption in Alabama Code § 22-21-260(6) and the precedent set by the *Sacred Heart* litigation, USAMCI, therefore, respectfully requests that, SHPDA issue a determination that the ownership, installation, and operation of the Elekta Versa HD 2017 in the private USAMCI oncology physician group practice office in Fairhope, Alabama is **not** subject to CON review, and that **no** CON is required for USAMCI’s Proposal, as set out in USAMCI’s RV2017-023 Request.

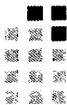
We trust that this additional information completes the factual and legal information set forth in RV2017-023, so that SHPDA can deem it complete and immediately publish the USAMCI RV2017-023 Request in accordance with CON Rule 410-1-7-.02.

Please do not hesitate to contact me if you have any further questions.

Sincerely,


Lenora W. Pate
FOR THE FIRM

LWP/lcc

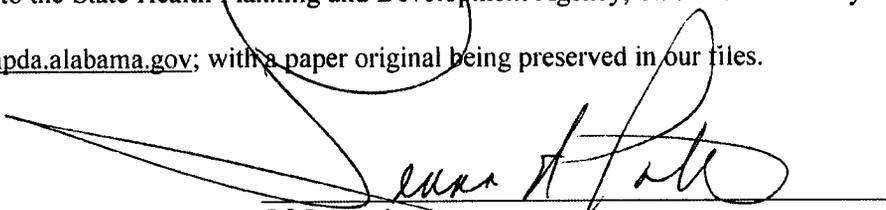


Alva M. Lambert
June 13, 2017
Page 9

c: Alyse N. Gillman, Esq.
Jean W. Tucker, Esq.
Deborah Compton

CERTIFICATE OF SERVICE

I hereby certify that, in accordance with CON Rule § 410-1-3-.09, a PDF text searchable copy of this Letter is being submitted to the State Health Planning and Development Agency, on this the 13th day of June, 2017, to shpda.online@shpda.alabama.gov; with a paper original being preserved in our files.



Of Counsel

EXHIBIT A



STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

100 NORTH UNION STREET, SUITE 870
MONTGOMERY, ALABAMA 36104

May 22, 2017

Lenora W. Pate, Esq.
Sirote & Permutt, P.C.
2311 Highland Avenue South
P.O. Box 55727
Birmingham, Alabama 35255-5727

RE: RV2017-023
University of South Alabama
Mitchell Cancer Institute

Dear Ms. Pate:

This is written in response to your May 9, 2017, request for a reviewability determination on behalf of the University of South Alabama Mitchell Cancer Institute ("USAMCI"), regarding USAMCI's plans to purchase, install and operate a new Elekta Versa HD 2017 Linear Accelerator in its Fairhope, Alabama physician offices, pursuant to the exemption from Certificate of Need review provided to the "offices of private physicians" under ALA. CODE § 22-21-260(6) (1975 as amended) (the "POE").

According to your letter, USAMCI has operated as a "Physician office oncology group practice" at offices located in the city of Mobile in Mobile County and in Fairhope, in Baldwin County, Alabama. Currently, both offices provide medical oncology services, but radiation oncology services are offered only in the Mobile office. You state that USAMCI is expanding its radiation oncology services to a new USAMCI physician office in Fairhope, which will require the purchase, installation and operation of a new linear accelerator. USAMCI's existing office in Fairhope will be consolidated into the new location. The estimated cost of the new accelerator is \$2,100,000.00.

In your correspondence, you have represented that you meet each of the requirements of the POE adopted by the Alabama Supreme Court in *Ex parte Sacred Heart Health Sys., Inc.*, 155 So. 3d 980, 988 (Ala. 2012). However, the Agency's records reflect that USAMCI is a d/b/a for the University of South Alabama and that the radiation and medical oncology services offered through USAMCI are being provided in the offices of the physicians employed by the University of South Alabama, and not by private physicians, and are thus an extension of such health care facility.

MAILING ADDRESS: P.O. BOX 303025, MONTGOMERY, ALABAMA 36130-3025
PHONE: (334) 242-4103 FAX: (334) 242-4113

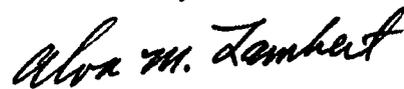
Lenora W. Pate, Esq.
May 22, 2017
Page Two

Please provide ownership information for USAMCI, including any physician owners, and a financial breakdown of the anticipated first year annual operating costs and capital costs, including leases, land/building, and construction costs, for the proposed project. Please also disclose any other health care facilities or groups holding an interest in USAMCI.

Upon receipt of the requested information, additional review will be conducted regarding your request.

Should you have any questions regarding this letter, please do not hesitate to contact the Agency at (334) 242-4103.

Sincerely,

A handwritten signature in black ink that reads "Alva M. Lambert". The signature is written in a cursive style with a large, stylized initial "A".

Alva M. Lambert
Executive Director

EXHIBIT B

New Operating Costs Related to USAMCI RV2017-023 Request

I. New USAMCI Lease

Total New USAMCI Lease	\$167,400.00
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Total New USAMCI Lease Consists of:

USAMCI Medical Oncology Relocated Space	\$108,181.00
USAMCI New Radiation Oncology Space	\$59,219.00

II. Total New USAMCI Operating Costs Related to RV2017-023 Request

Lease of USAMCI Radiation Oncology/ RV2017-023 Request Lease Space	\$59,219.00
<u>New USAMCI Employee Costs</u>	
Radiation Therapist	\$63,000.00
Benefits (22%)	\$13,860.00
Total New USAMCI Compensation and Benefits	\$76,860.00
<u>Other USAMCI RV2017-023 Request Operating Expenses</u>	
Medical Supplies	\$23,704.00
Office Supplies	\$3,951.00
Utilities	\$15,802.00
Marketing/Advertising	\$20,000.00
Contract Labor	\$25,000.00
Total Other USAMCI Operating Expenses	\$88,457.00
Total New USAMCI/RV2017-023 Request Operating Costs	\$224,536.00



MAY 09 2017

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May 9, 2017

VIA E-MAIL (shpda.online@shpda.alabama.gov)

Alva M. Lambert
Executive Director
State Health Planning and Development Agency
100 North Union Street, Suite 870
Montgomery, AL 36140

Re: *University of South Alabama Mitchell Cancer Institute
Request for Non-Reviewability Determination*

Dear Mr. Lambert:

On behalf of the University of South Alabama Mitchell Cancer Institute ("USAMCI") and pursuant to the Alabama Certificate of Need ("CON") Program Rules and Regulations ("CON Rules") § 410-1-7-.02 and § 410-1-3-.09, attached hereto as **Exhibit A** is a Request for your determination that the ownership, installation, and operation of the Elekta Versa HD 2017, major medical equipment which will not be owned by or located in a healthcare facility but owned by USAMCI and located in the private USAMCI Physician office in Fairhope, Alabama, is **not** subject to Certificate of Need ("CON") review under Alabama Code § 22-21-260 *et. seq.* and the CON Rules, and does **not** require a CON in that it does not involve a new institutional health service or any health care facility expenditures in excess of the statutory thresholds requiring CON Review.

In accordance with CON Rule § 410-1-3-.09, a pdf copy of this Request is being submitted electronically on the 9th day of May, 2017, to shpda.online@shpda.alabama.gov; a paper original will be preserved in our files; and a filing fee of \$1,000.00 is being sent via overnight FedEx to SHPDA on the 9th day of May, 2017, for delivery on the next business day, May 10th, 2017.

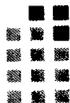
Please give me a call if you have any questions.

With kindest personal regards,

Lenora W. Pate
FOR THE FIRM

LWP/lcc
Enclosure

Birmingham Huntsville Mobile Pensacola



Alva M. Lambert
May 9, 2017
Page 2

c: Deborah Crompton
Jean W. Tucker, Esq.

EXHIBIT A

**BEFORE THE STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY OF THE STATE OF ALABAMA**

IN THE MATTER OF:)	
)	
UNIVERSITY OF SOUTH ALABAMA)	REQUEST FOR
)	NON-REVIEWABILITY
MITCHELL CANCER INSTITUTE)	DETERMINATION
("USAMCI"))	
)	RV-_____

REQUEST FOR NON-REVIEWABILITY DETERMINATION

On behalf of the University of South Alabama Mitchell Cancer Institute ("USAMCI") and pursuant to the Alabama Certificate of Need Program Rules and Regulations ("CON Rules") § 410-1-7-.02 and § 410-1-3-.09 and Alabama Code § 22-21-260, *et. seq.*, this Request is hereby filed with the State Health Planning and Development Agency ("SHPDA") for a determination by SHPDA's Executive Director that the USAMCI ownership, installation, and operation of major medical equipment – Elekta Versa HD 2017- which will not be owned by or located in a healthcare facility but owned by USAMCI and located in the private USAMCI Physician office in Fairhope, Alabama, is **not** subject to CON review for the reasons stated below, and that **no** CON is required for this USAMCI proposal ("Proposal").

The following factual and legal information is hereby included in support of this Request, and a check in the amount of \$1,000.00 made payable to the State Health Planning and Development Agency is being filed in accordance with CON Rule § 410-1-3-.09 as the required filing fee for this Request pursuant to CON Rule § 410-1-7-.02.

PROPOSAL

1. Facts

1.1 USAMCI, a division of USA Health, which is a division of the University of South Alabama ("USA"), a public body corporate created under the laws of the State of Alabama, is a physician office oncology group practice in an academic medical center environment. USAMCI combines the cumulative knowledge and expertise of its USAMCI employed physicians ("USAMCI Physicians") and, its employed researchers to integrate basic research and clinical cancer programs to achieve an inter-disciplinary approach to cancer treatment through dedicated patient care and research utilizing the most advanced technologies.

1.2 USAMCI has operated as a USAMCI Physician office oncology group practice since 2008 at its 1660 Springhill Avenue, Mobile, Alabama physician office. USAMCI currently provides advanced, comprehensive physician office medical oncology and radiation oncology therapy services to USAMCI Physician office patients from the Gulf Coast region in its Springhill Avenue Office in Mobile, Alabama. USAMCI is currently comprised of eleven (11) practicing USAMCI Physicians, all of whom are licensed in the State of Alabama. A list of the current practicing USAMCI Physicians is attached hereto and incorporated herein as **Exhibit 1**, with the location of where each USAMCI Physician will practice once this Proposal is fully implemented.

1.3 As a part of the total scope of the USAMCI Physician office services currently, certain medical oncology USAMCI Physicians are practicing in both the Mobile USAMCI Physician office and in the current Fairhope, Alabama USAMCI Physician office in Baldwin County. There have been no USAMCI radiation oncology services provided in Baldwin County at the current USAMCI Physician office in Fairhope, Alabama. As a result, USAMCI patients residing in Baldwin County are currently receiving medical oncology physician office services at the existing Fairhope USAMCI Physician office practice, but must drive to Mobile to receive radiation oncology services at the USAMCI Physician office located at 1660 Springhill Avenue in Mobile, Alabama.

1.4 USAMCI is expanding its USAMCI Physician office radiation oncology services in Mobile to a new USAMCI Physician office in Fairhope, utilizing the same USAMCI Physicians who are radiation oncologists currently providing radiation oncology services to USAMCI patients only at its USAMCI Physician office in Mobile. This Proposal will better serve USAMCI's radiation oncology patients residing in Baldwin County, and reduce the burden on the existing and future USAMCI Baldwin County oncology patients of driving to Mobile on a daily basis to receive radiation oncology therapy services.

1.5 Hence, this Request seeks SHPDA's determination of non-reviewability, pursuant to CON Rule § 410-1-7-.02, of the ownership, installation, and operation of the following major medical equipment which will not be owned by or located in a healthcare facility, but owned by USAMCI and located in the new leased USAMCI Physician office in Fairhope, Alabama:

Type: Linear Accelerator
Brand: Elekta
Model: Versa HD
Model Year: 2017
("Elekta Versa HD Linear Accelerator")

1.6 The Elekta Versa HD Linear Accelerator, like other 2017 competitive linear accelerators, is a multi-functional and versatile state of the art system. It has the same functionality and ability as other competitive 2017 model linear accelerators such as the Varian Medical Systems. It is equipped with sophisticated conformal beam-shaping technology and high dose rate mode delivery. The Elekta Versa HD Linear Accelerator gives cancer management professionals the flexibility to employ conventional therapies to treat the broad spectrum of tumors throughout the body. It has a state of the art beam-shaping for accuracy, capable of achieving the smallest target and sparing healthy tissue, with advanced technological speed and versatility to potentially reduce the duration of each treatment, and the number of treatments.

1.7 The Elekta Versa HD Linear Accelerator has all the necessary technological advances that will benefit USAMCI patients in Baldwin County, and the cost is approximately **\$2,100,000.00**.

1.8 The Elekta Versa HD Linear Accelerator will be installed in a new USAMCI Physician office in Baldwin County located in USAMCI leased space in a medical office building at 1047 Fairhope Avenue in Fairhope, Alabama. USAMCI will also consolidate all of its existing USAMCI Physician office medical oncology services from USAMCI's existing leased space in Fairhope to one new USAMCI Physician office space at 1047 Fairhope Avenue, resulting in an integrated and accessible new USAMCI Physician office to provide comprehensive USAMCI medical and radiation oncology services by USAMCI Physicians and professionals to USAMCI patients in Baldwin County.

1.9 The Elekta Versa HD Linear Accelerator will be used exclusively by, through, and on behalf of USAMCI and its USAMCI Physicians. All billing for the Elekta Versa HD Linear Accelerator will involve only the professional and technical component of the Elekta Versa HD, with no additional facility fee billing of any type. All Elekta Versa HD Linear Accelerator services billing will be for USAMCI Physician office services in accordance with Federal and State laws and regulations and various third-party payor requirements.

1.10 A linear accelerator, like the proposed Elekta Versa HD Linear Accelerator, uses precisely focused beams of radiation to treat patients with cancer. Each USAMCI patient will be treated based on unique treatment protocols developed by a USAMCI Physician radiation oncologist with a USAMCI radiation dosimetrist. The USAMCI patient will be monitored by a USAMCI radiation physicist, USAMCI radiation technologist, and by the USAMCI Physician radiation oncologist. The radiation will be administered by trained USAMCI radiation technologists. All such required USAMCI Physician radiation oncologists, professionals, and staff are USAMCI employed personnel. They will be providing such radiation oncology services exclusively to USAMCI Physician office patients, utilizing the Elekta Versa HD Linear Accelerator once it is installed in the USAMCI Physician office located at 1047 Fairhope Avenue in Fairhope, Alabama.

1.11 The Elekta Versa HD Linear Accelerator will be used at all times exclusively by USAMCI in its Fairhope physician office for USAMCI physician office patients only, and exclusively by the USAMCI Physicians listed on Exhibit 1 and USAMCI employed personnel and staff.

1.12 This Proposal is necessary to provide USAMCI Physician office radiation oncology services to USAMCI patients in Baldwin County, Alabama, so that USAMCI oncology patients will not have to travel to the USAMCI Physician office in Mobile, Alabama, for USAMCI Physician office radiation oncology therapy services.

2. Legal Analysis

2.1 This Proposal does not involve a “new institutional health service”, by or on behalf of a health care facility, subject to CON review as set forth in § 22-21-263 of the Alabama Code and CON Rule § 410-1-01, in that the Proposal does not include:

- (a) the construction, development, acquisition through lease or purchase or other establishment of a new health care facility or health maintenance organization; or
- (b) any expenditure by or on behalf of a health care facility which as a capital expenditure exceeds the CON statutory threshold for major medical equipment, new annual operating costs, or any other capital expenditure by or on behalf of a health care facility; or
- (c) the addition of any new healthcare facility bed or stations; or
- (d) any health service which is proposed to be offered in or through a healthcare facility which was not offered on a regular basis in or through a healthcare facility within the preceding twelve (12) month period; or
- (e) any other reviewable event under the existing CON Laws, Rules, or Regulations in the State of Alabama.

2.2 Alabama Code §22-21-260(6) exempts from the CON review process and the definition of “healthcare facility”, the “offices of private physicians..., whether for individual or group practices and regardless of ownership.” The private USAMCI Physician office in Fairhope will

operate exclusively as a group practice of USAMCI Physicians to provide medical and radiation oncology services to USAMCI patients only.

2.3 In 2012, the Alabama Supreme Court adopted the following four-part test to be used to determine whether a Proposal qualifies for the Alabama statutory CON Physician Office Exemption, as follows:

(a) The proposed services are to be provided, and related equipment used exclusively by the physicians identified as owners or employees of the physicians' practice for the care of their patients.

(b) The proposed services are to be provided and related equipment used at any office of such physicians.

(c) All patients billings related to such services are through, or expressly on behalf of the physicians' practice.

(d) The equipment shall not be used for inpatient care, nor by, through, or expressly on behalf of the health care facility.

Ex parte Sacred Heart Health Sys., Inc., 155 So. 3d 980, 988, (Ala. 2012).

2.4 This Proposal meets all of the four-part Physician Office Exemption test, as follows:

- The Elekta Versa HD 2017 Linear Accelerator services are to be provided and the equipment used exclusively by the USAMCI Physicians listed on the attached **Exhibit 1** as providing radiation oncology services in the Fairhope Avenue, Fairhope, Alabama, USAMCI Physician office for the care of their USAMCI Physician office out-patients;
- The Elekta Versa HD 2017 Linear Accelerator services are to be provided, and related equipment used, exclusively at the Fairhope Avenue USAMCI Physician office in Fairhope, Alabama;

- All patient billings related to the Elekta Versa HD 2017 Linear Accelerator services will be through, or expressly on behalf of, the USAMCI Physician group practice and the USAMCI Physicians listed on Exhibit 1 as providing radiation oncology services in the Fairhope USAMCI Physician office;
- The Elekta Versa HD 2017 Linear Accelerator shall not be used for in-patient care, nor by, through, or on behalf of a health care facility.

3. Conclusion and Request

3.1 This Proposal does not involve a new institutional health service subject to CON review pursuant to CON Rules § 410-1-4-.01 *et. seq.* and § 22-21-260 *et. seq.* of the Alabama Code. USAMCI is merely requesting a determination by SHPDA's Executive Director that its ownership, installation, and operation of the Elekta Versa HD 2017 Linear Accelerator, which will not be owned by or located in a healthcare facility but owned by USAMCI and located in the Fairhope Avenue USAMCI Physician office in Fairhope for use exclusively by USAMCI professional staff and personnel and USAMCI Physicians as listed on Exhibit 1 for USAMCI Physician office out-patients only, is **not** subject to CON review, and that **no** CON is required for the Proposal.

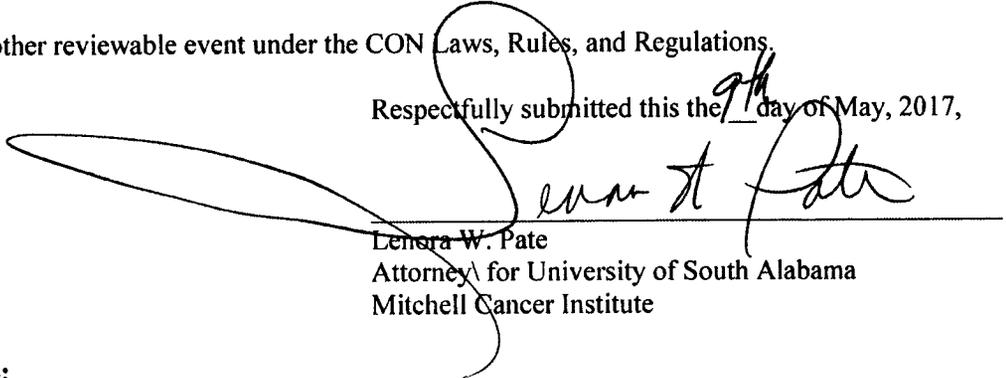
3.2 Alabama Code § 22-21-260(6) excludes from the definition of a "health care facility" the "offices of private physicians... whether for individual group practice and regardless of ownership."

3.3 CON Rule § 410-1-2-.05(2)(a) provides that the term "health care facility" shall not include the private offices of any duly licensed physicians whether for individual or group practice and regardless of ownership.

3.4 Also, Alabama Code § 22-21-260(8) excludes from the definition of "health services" the "lawful practice of any profession or vocation conducted independently of a health care facility."

3.5 Therefore, this Proposal is due to be determined as non-reviewable in accordance with the Alabama CON Laws, Rules, and Regulations in that it does not involve any new institutional health services or any health care facility expenditure in excess of the statutory thresholds requiring CON Review or any other reviewable event under the CON Laws, Rules, and Regulations.

Respectfully submitted this the 9th day of May, 2017,



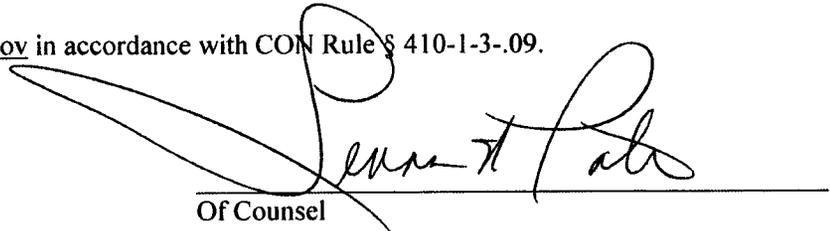
Lehera W. Pate
Attorney for University of South Alabama
Mitchell Cancer Institute

OF COUNSEL:

Sirote & Permutt, P.C.
2311 Highland Avenue South
Birmingham, Alabama 35205
205.930.5162

CERTIFICATE OF SERVICE

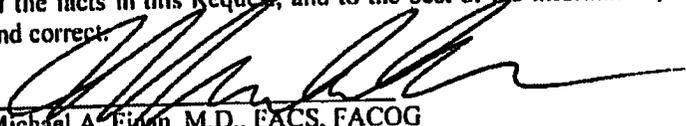
I hereby certify that a PDF copy of the above and foregoing Exhibit A was electronically filed this the 9th day of May, 2017, with the State Health Planning and Development Agency via shpda.online@shpda.alabama.gov in accordance with CON Rule § 410-1-3-.09.



Of Counsel

Affirmation of Requesting Party:

The Undersigned, being first duly sworn, hereby makes oath or affirms that he, Michael A. Finan, M. D., FACS, FACOG, Director, of the University of South Alabama Mitchell Cancer Institute, has knowledge of the facts in this Request, and to the best of his information, knowledge and belief such facts are true and correct.


Michael A. Finan, M.D., FACS, FACOG
Director of the University of South Alabama Mitchell Cancer Institute

Seal

Subscribed and Sworn to before me this the 9 day of May, 2017.


(Notary Public)
My Commission Expires: 04/23/18

**NOTARY PUBLIC STATE OF ALABAMA AT LARGE
MY COMMISSION EXPIRES 04/23/18**

EXHIBIT 1 TO EXHIBIT A

USAMCI PHYSICIAN EMPLOYEES

- I. ***Radiation Oncology*** – Each will practice in both Mobile and Fairhope USAMCI Physician Offices

Elesyia Outlaw, M.D.

Weisi Yan, M.D., Ph.D.

Clayton Smith, M.D., Ph.D.

- II. ***Medical Oncology*** – Each will practice in both Mobile and Fairhope USAMCI Physician Offices

Daniel Cameron, M.D.

David Clarkson, M.D.

William Taylor, M.D.

- III. ***Medical Oncology*** – Will practice in Mobile USAMCI Physician Office only

Moh'd Khushman, M.D.

Thomas Butler, M.D.

Thaddeus Beeker, M.D.

Carole Norden, M.D.

Sachin Pai, M.D.

USAMCI remains in the physician recruiting process and may add other USAMCI physician employees in the future.