



North Carolina Department of Health and Human Services
 Division of Health Service Regulation

Pat McCrory
 Governor

Aldona Z. Wos, M.D.
 Ambassador (Ret.)
 Secretary DHHS

Drexdal Pratt
 Division Director

July 1, 2015

Terrill Johnson Harris
 300 N. Greene Street, Suite 1400
 Greensboro, NC 27401

No Review

Record #: 1622
Facility Name: Highlands-Cashiers Hospital
FID #: 943256
Business Name: Highlands-Cashiers Hospital, Inc.
Business #: 926
Project Description: Transfer control of 80-bed nursing home on hospital license to wholly owned subsidiary and license it separately
County: Macon

Dear Ms. Harris:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter on June 1, 2015 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

Moreover, you need to contact the Agency's Construction Section, Acute and Home Care Licensure and Certification Section, and Nursing Home Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

An Equal Opportunity/ Affirmative Action Employer



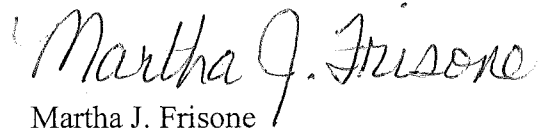
original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility ID # (FID) if the facility is licensed.

Sincerely,

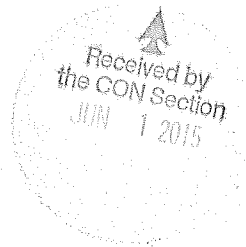


Julie Halatek
Project Analyst



Martha J. Frisone
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Nursing Home Licensure and Certification Section, DHSR
Assistant Chief, Healthcare Planning



May 29, 2015

Martha Frisone, Assistant Chief of CON
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Highlands-Cashiers Hospital, Inc. (License No. H0193)
No review request to transfer control of Eckerd Living Center to wholly owned subsidiary

Dear Martha:

Our firm represents Highlands-Cashiers Hospital, Inc., a North Carolina non-profit corporation. It operates a critical access hospital in Highlands, Macon County, with 24 acute care beds as well as an 80 bed nursing facility under the hospital license. The nursing facility is physically attached to the hospital, but there is a separate entrance for the nursing facility, which is known as the Eckerd Living Center. Highlands-Cashiers Hospital, Inc. is part of the Mission Health System.

Highlands-Cashiers Hospital, Inc. has determined that it would enhance financial viability and better position it to serve the community by transferring ownership of the Eckerd Living Center to a wholly-owned subsidiary which it has created, Fidelia Eckerd Living Center, LLC, a North Carolina limited liability company. Highlands-Cashiers Hospital, Inc. is the sole member of Fidelia Eckerd Living Center, LLC. See Articles of Organization attached as Exhibit A.

Following receipt of confirmation that this proposal is not subject to Certificate of Need review, Fidelia Eckerd Living Center, LLC will apply for a separate license for the nursing facility and operate it as a separately licensed nursing facility. As you know, a no review letter is needed as part of the license application process.

The CON law provides that transfer of ownership or control of a CON would constitute grounds for withdrawal of the CON if it occurs during the course of development of a project before the project is complete. N.C. Gen. Stat. § 131E-189. There is no CON project under development at the Eckerd Living Center. Furthermore, Agency rules provide that neither ownership nor control of a CON is transferred when the holder of a certificate is a corporation and the identity of the holder changes because of a corporate reorganization. 10A N.C.A.C.

Ms. Martha Frisone, Assistant Chief of CON
May 29, 2015
Page 2

14C.0502(b)(1) and (c). Transferring ownership to a wholly-owned subsidiary in this case is part of a corporate reorganization.

In this instance, the entity that owns Eckerd Living Center will not change, and the same building, staff, and equipment will be used to provide the same services at the same location to the Eckerd Living Center residents. Highlands-Cashiers Hospital, Inc. will control the disposition of the Eckerd Living Center assets. Eckerd Living Center already has its own separate NPI and is certified to participate in the Medicare and Medicaid programs.

The proposed transaction does not involve the offering or expansion of any new facility, service, or equipment, and the State's inventory of nursing home beds will not change. No new or additional nursing home beds will be acquired or placed in operation as a result of this transaction.

This proposal is the same as the Hugh Chatham Memorial proposal to transfer 100% of its ownership interest in Hugh Chatham Memorial Nursing Center to a wholly-owned subsidiary of the hospital and license it separately. Attached as Exhibit B is a copy of the CON Section's no review letter issued to Hugh Chatham Memorial Hospital and the accompanying request. Included in the exhibits to that request is another similar no review letter determining that a perfusion company could hold heart-lung bypass equipment in two separate wholly-owned subsidiaries without undergoing CON review.

Based on these facts, the CON law allows the transfer of Eckerd Living Center to a wholly-owned subsidiary of Highlands-Cashiers Hospital, Inc. without a CON because the transfer does not involve the development or acquisition of a new facility or services within the meaning of N.C. Gen. Stat. § 131E-176(16) or 10A N.C.A.C. 14C.0502. The subsidiary has no control over the services or equipment independent of its parent entity, and the ultimate ownership and control of the facility and services will not change as a result of this proposal. No new beds or facility will be constructed, and there is no activity which constitutes the offering or development of a new institutional health service. Accordingly, we request that you issue a no review letter confirming that a CON is not required for Highlands-Cashiers Hospital, Inc. to transfer 100% of its interest in Eckerd Living Center to a wholly-owned subsidiary to permit it to obtain a separate license.

Ms. Martha Frisone, Assistant Chief of CON
May 29, 2015
Page 3

Please let me know if you need any other information to evaluate this request.

With kindest regards, I am

Very truly yours,

SMITH MOORE LEATHERWOOD LLP



Terrill Johnson Harris

Enclosures

cc: Brian Moore, Mission Health
Lisa D'Agostino, Mission Health

Exhibit A

*State of North Carolina
Department of the Secretary of State*

Limited Liability Company
ARTICLES OF ORGANIZATION

Pursuant to §57D-2-20 of the General Statutes of North Carolina, the undersigned does hereby submit these Articles of Organization for the purpose of forming a limited liability company.

1. The name of the limited liability company is: The Fidelia Eckerd Living Center, LLC
(See Item 1 of the Instructions for appropriate entity designation)
2. The name and address of each person executing these articles of organization is as follows: (State whether each person is executing these articles of organization in the capacity of a member, organizer or both. Note: This document must be signed by all persons listed.)
Ann Y. Young, Organizer
509 Biltmore Avenue
Asheville, NC 28801
3. The name of the initial registered agent is: Ann Y. Young.
4. The street address and county of the initial registered agent office of the limited liability company is:
Number and Street 509 Biltmore Avenue
City Asheville State: NC Zip Code: 28801 County: Buncombe
5. The mailing address, if different from the street address, of the initial registered agent office is:
Number and Street _____
City _____ State: NC Zip Code: _____ County: _____
6. Principal office information: (Select either a or b.)
 - a. X The limited liability company has a principal office.
The principal office telephone number: 828-526-1315
The street address and county of the principal office of the limited liability company is:
Number and Street: 190 Hospital Drive
City: Highlands State: NC Zip Code: 28741 County: Macon

The mailing address, if different from the street address, of the principal office of the company is:

Number and Street: _____

City: _____ State: _____ Zip Code: _____ County: _____

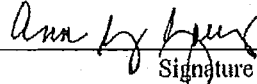
b. The limited liability company does not have a principal office.

7. Any other provisions which the limited liability company elects to include (e.g., the purpose of the entity) are attached.

8. (Optional): Please provide a business e-mail address: _____
The Secretary of State's Office will e-mail the business automatically at the address provided above at no cost when a document is filed. The e-mail provided will not be viewable on the website. For more information on why this service is offered, please see the instructions for this document.

9. These articles will be effective upon filing, unless a future date is specified:

This is the 22nd day of May, 2015.


Signature

Ann Y. Young, Organizer

Type or Print Name and Title

The below space to be used if more than one organizer or member is listed in Item #2 above.

Signature

Type and Print Name and Title

Signature

Type and Print Name and Title

Signature

Type and Print Name and Title

Signature

Type and Print Name and Title

NOTES:

1. Filing fee is \$125. This document must be filed with the Secretary of State.

Exhibit B



North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

March 11, 2014

S. Todd Hemphill
3105 Glenwood Avenue, Suite 300
Raleigh, North Carolina 27612

No Review

Facility: Hugh Chatham Memorial Nursing Center
Project Description: Transfer by Hugh Chatham Memorial Hospital, Inc. (HCMH) of 100% of its ownership interests in Hugh Chatham Memorial Nursing Center to Hugh Chatham Nursing Center, LLC, a wholly-owned subsidiary of HCMH and license it separately from the hospital
County: Surry
FID #: 955375

Dear Mr. Hemphill:

The Certificate of Need Section (CON Section) received your letter of February 18, 2014, regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

Moreover, you need to contact the Acute and Home Care Licensure and Certification Section and the Nursing Home Licensure and Certification Section of the Division of Health Service Regulation to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

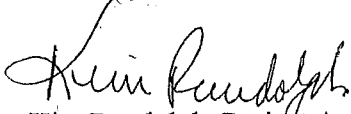
An Equal Opportunity/ Affirmative Action Employer



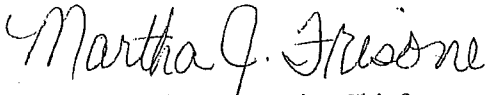
S. Todd Hemphill
March 11, 2014
Page 2

Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID) if the facility is licensed.

Sincerely,



Kim Randolph, Project Analyst



Martha J. Frisone, Interim Chief
Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR
Nursing Home Licensure and Certification Section, DHSR
Medical Facilities Planning Branch, DHSR

JOHN T. BODE
S. TODD HEMPHILL
MATTHEW A. FISHER
DAVID R. BROYLES

*John
Kim*

BODE HEMPHILL, L.L.P.

ATTORNEYS AT LAW
3105 GLENWOOD AVENUE, SUITE 300
RALEIGH, NORTH CAROLINA 27612

TELEPHONE (919) 881-0338
FACSIMILE (919) 881-9548

WWW.BCS-LAW.COM

MAILING ADDRESS

POST OFFICE BOX 6338
RALEIGH, NORTH CAROLINA
27628-6338

Writer's E-mail: HEMPHILL@BCS-LAW.COM

February 18, 2014

Received by
the CON section
FEB 19 2014

VIA HAND DELIVERY

Martha J. Frisone, Interim Chief
Kim Randolph, Project Analyst
Certificate of Need Section
N.C. Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Hugh Chatham Memorial Hospital, Inc. (License No. H0049)
No review request to transfer control of Hugh Chatham Nursing Center to wholly
owned-subsiary

Dear Ms. Frisone and Ms. Randolph:

We are writing you on behalf of our client, Hugh Chatham Memorial Hospital, Inc. ("HCMH"), a North Carolina non-profit corporation. HCMH owns and operates Hugh Chatham Nursing Center (the "Nursing Center"), a combination facility with 99 nursing beds and 28 assisted living beds (20 Alzheimer's or special care unit beds and 8 general beds), under the hospital's license. HCMH has determined that it is in its best interest to transfer ownership of the Nursing Center to a wholly-owned subsidiary which it has created, Hugh Chatham Nursing Center, LLC, a North Carolina limited liability company ("HCNC"). HCMH is the sole member of HCNC. See HCNC Articles of Organization, Exhibit 1 hereto.

We also understand that as part of this transfer, the Nursing Center will need to be operated as a separately-licensed nursing facility. I have already spoken about this subject with Becky Wertz, Nurse Consultant with the Nursing Home Licensure and Certification Section, and our client is in the process of preparing the Nursing Home Licensure Application and other related documentation which she has provided. However, before that documentation can be filed, we first need to confirm with your office that this proposal is not subject to certificate of need review.

The CON law provides that transfer of ownership or control of a CON would constitute grounds for withdrawal of the CON if it occurs during the course of development of a project before the project is complete. N.C.G.S. § 131E-189. There is no CON project under development at the Nursing Center. Furthermore, Agency rules provide that neither ownership nor control of a certificate of need is transferred when the holder of the certificate is a corporation and the identity of the holder changes because of a corporate reorganization, such as transferring ownership to a wholly-owned subsidiary. 10A N.C.A.C. 14C.0502(b)(1) and (c).

In this instance, the entity that owns the Nursing Center will not change, and the same building, staff and equipment will be used to provide the same services at the same location. HCMH will continue to own the Nursing Center assets that were authorized under the CON and have been used to furnish skilled nursing care to the Nursing Center's residents. The proposed transaction does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of nursing home beds will not change. No new or additional nursing home beds will be acquired or placed in operation in the State. The Nursing Center already has its own separate NPI number and Medicare number.

This proposal is similar to other proposals involving transfer of assets to wholly owned subsidiaries that the CON Section has found in the past did not require CON review. For example, the CON Section determined that a perfusion company could hold heart-lung bypass equipment in two separate wholly owned subsidiaries without undergoing CON review. See enclosed Exhibit 2 (without exhibits to original request letter).

For these reasons, we believe that the CON law allows the transfer of the Nursing Center to a wholly-owned subsidiary of HCMH, without the requirement of a CON, because such a transfer does not constitute the development or acquisition of a new facility or services by the subsidiary, within the meaning of G.S. 131E-176(16) or 10A N.C.A.C. 14C.0502. The subsidiary has no control over those services independent of its parent entity. The ultimate ownership and control of the service does not change. The beds already exist in the inventory in the State Medical Facilities Plan and there is no new facility constructed. Thus, there has been no action which constitutes the offering or development of a new institutional health service within the meaning of G.S. 131E-178(a), and no CON is required.

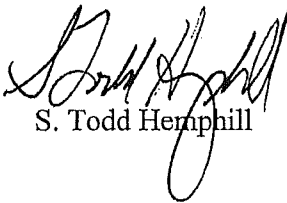
We request that you provide a letter of no review confirming that our interpretation of the CON law and applicable rules is correct and that this proposal is not subject to certificate of need review.

Ms. Frisone and Ms. Randolph
February 18, 2014
Page 3

Please let us know if you need further information or if there are questions we can answer.

Very truly yours,

BODE HEMPHILL, L.L.P.



S. Todd Hemphill

STH:sh
Enclosure
cc w/enc.:

Becky Wertz, Nurse Consultant (via hand delivery)
Paul Hammes/Don Trippel (via e-mail only)

State of North Carolina
Department of the Secretary of State

Limited Liability Company
ARTICLES OF ORGANIZATION

Pursuant to §57D-2-20 of the General Statutes of North Carolina, the undersigned does hereby submit these Articles of Organization for the purpose of forming a limited liability company.

1. The name of the limited liability company is: Hugh Chatham Nursing Center, LLC
(See Item 1 of the Instructions for appropriate entity designation)
2. The name and address of each person executing these articles of organization is as follows: (State whether each person is executing these articles of organization in the capacity of a member, organizer or both. Note: This document must be signed by all persons listed.)
S. Todd Hemphill (Organizer)
Post Office Box 6338, Raleigh, NC 27628
3. The name of the initial registered agent is: Raymond A. Parker
4. The street address and county of the initial registered agent office of the limited liability company is:
Number and Street 131 Colony Lane
City Elkin State: NC Zip Code: 28621 County: Surry
5. The mailing address, if different from the street address, of the initial registered agent office is:
Number and Street _____
City _____ State: NC Zip Code: _____ County: _____
6. Principal office information: (Select either a or b.)
 - a. The limited liability company has a principal office.
The principal office telephone number: (336) 527-7000
The street address and county of the principal office of the limited liability company is:
Number and Street 180 Parkwood Drive
City Elkin State: NC Zip Code: 28621 County: Surry



The mailing address, if different from the street address, of the principal office of the company is:

Number and Street Post Office Box 580

City Elkin State: NC Zip Code: 28621 County: Surry

b. The limited liability company does not have a principal office.

7. Any other provisions which the limited liability company elects to include (e.g., the purpose of the entity) are attached.

8. (Optional): Please provide a business e-mail address Privacy Redaction
The Secretary of State's Office will e-mail the business automatically at the address provided above at no cost when a document is filed. The e-mail provided will not be viewable on the website. For more information on why this service is offered, please see the instructions for this document.



9. These articles will be effective upon filing, unless a future date is specified:

This is the 12th day of February, 2014.

S. Todd Hemphill
Signature

S. Todd Hemphill, Organizer
Type or Print Name and Title

The below space to be used if more than one organizer or member is listed in Item #2 above.

Signature

Type and Print Name and Title

Signature

Type and Print Name and Title

Signature

Type and Print Name and Title

Signature

Type and Print Name and Title

NOTES:

1. Filing fee is \$125. This document must be filed with the Secretary of State.

**ATTACHMENT TO ARTICLES OF ORGANIZATION
HUGH CHATHAM NURSING CENTER, LLC**

NAME AND ADDRESS OF INITIAL MEMBER

The sole member of Hugh Chatham Nursing Center, LLC is Hugh Chatham Memorial Hospital, Inc.

Hugh Chatham Memorial Hospital, Inc.'s address is 180 Parkwood Drive, Blkin, NC 28621



North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

Craig R. Smith, Section Chief
Phone: 919-855-3875
Fax: 919-733-8139

December 9, 2011

William R. Shenton
Poyner Spruill
P.O. Box 1801
Raleigh, NC 27602-1801

RE: No Review:

- o Transfer by CSA Medical Services, LLC (CSA) of 100% of its ownership interests in five (5) existing heart lung bypass machines in use at WakeMed to CSAMS New Bern Avenue, LLC, a wholly-owned subsidiary of CSA
- o Transfer by CSA Medical Services, LLC (CSA) of 100% of its ownership interests in three (3) existing heart lung bypass machines in use at Rex Hospital to CSAMS Lake Boone Trail, LLC, a wholly-owned subsidiary of CSA

Wake County

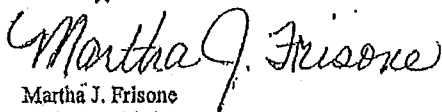
Dear Mr. Shenton:

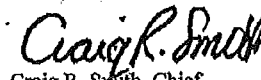
The Certificate of Need (CON) Section received your letter of November 21, 2011 regarding the above referenced proposals. Based on the CON law in effect on the date of this response to your request, the proposals described in your correspondence are not governed by, and therefore, do not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposals would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposals when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the proposals or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a proposal include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# (FID) if the facility is licensed.

Sincerely,


Martha J. Frisone
Assistant Chief


Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR



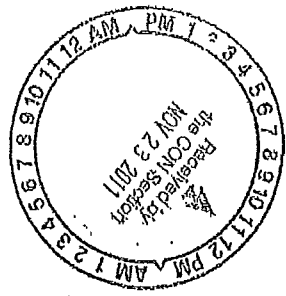
Location: 809 Ruggles Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603
An Equal Opportunity / Affirmative Action Employer



EXHIBIT

2

Martha



Poyner Spruill^{LLP}

November 21, 2011

Wilson Hayman
Partner
D: 919.783.1140
whayman@poynerspruill.com
William R. Shenton
Partner
D: 919.783.2947
F: 919.783.1076
wshenton@poynerspruill.com

VIA U.S. MAIL AND E-MAIL/
Craig.smith@dhhs.nc.gov
Martha.frison@dhhs.nc.gov

Mr. Craig R. Smith, Chief
Ms. Martha Frisone, Assistant Chief
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, North Carolina 27696-2704

RE: CSA Medical Services, LLC; No Review Request regarding Transfer of Heart-Lung Bypass Machines to Wholly Owned Subsidiaries

Dear Mr. Smith and Ms. Frisone:

This letter is submitted on behalf of CSA Medical Services, LLC ("CSA"), and two subsidiary limited liability companies to be formed and wholly owned by CSA and to be named "CSAMS New Bern Avenue, LLC" (CSA New Bern), and "CSAMS Lake Boone Trail, LLC" (CSA Lake Boone), upon receipt of your approval of this request. CSA currently owns and operates eight (8) heart-lung bypass ("HLB") machines. Five (5) of the HLB machines are operated at WakeMed and three (3) of the HLB machines are operated at Rex Hospital, Inc. ("Rex"). The purpose of this letter is to provide notice to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "Agency"), and confirm that the transfer of CSA's interests in these eight (8) HLB machines and the operation of the same to two wholly owned subsidiaries of CSA is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law.

The Agency has recently approved a similar transfer in an August 18, 2011 Declaratory Ruling regarding Radiation Oncology Centers of the Carolinas, Inc. ("ROCC"). That Declaratory Ruling concerned the transfer of interests in two radiation oncology facilities from ROCC to two wholly owned subsidiaries of ROCC. Attached hereto as Exhibits 1 and 2 are the ROCC Declaratory Ruling Request and the ROCC Declaratory Ruling. The ruling requested by CSA here is directly analogous to the ROCC ruling, the only difference being that ROCC involved the *per se* reviewable items of linear accelerators and simulators and CSA's request involves the *per se* reviewable items of heart-lung bypass machines.

I. BACKGROUND AND FACTS

CSA directly owns eight (8) Terumo Corporation Series 8000 HLB machines. Five (5) of these HLB machines are located and used by CSA to provide perfusion services at WakeMed, located at 3000 New Bern Avenue, Raleigh, NC 27620. Three (3) of these HLB machines are located and used by CSA to provide perfusion services at Rex, located at 4420 Lake Boone Trail, Raleigh, NC 27607. CSA also owns

Mr. Craig R. Smith, Chief
Ms. Martha Frisone, Assistant Chief
November 21, 2011
Page 2

seven (7) cell saver machines located at WakeMed in Raleigh, and two (2) located at WakeMed-Cary. These cell saver machines are Baylor Rapid Autologous Transfusion (BRAT) machines manufactured by Sorin Corporation and are not subject to CON review. CSA does not own the BRAT machines at Rex, which are owned by the hospital. CSA also provides the hospitals with the services of seven (7) licensed perfusionists, who are employed by CSA's affiliate Carolina MSO, L.L.C. (MSO) but work for CSA pursuant to its Management Services Agreement with MSO.

The five (5) HLB machines at WakeMed are labeled A, B, C, D, and E, and the three (3) at Rex are labeled 1, 2, and 3. Each HLB machine consists of the following: (a) a four (4) or five (5) pump Terumo Base; (b) three (3) or four (4) Terumo 8000 roller pump modules (8000 roller pump modules); (c) one (1) Medtronic Bio-Medicus arterial pump series 550 (Bio pump); (d) one (1) Medtronic TX 50 Flowmeter (Flowmeter); and (e) one (1) Sechrist air/oxygen mixer (Sechrist). Similarly, the seven (7) BRAT machines at WakeMed in Raleigh are labeled A, B, C, D, E, F and G, and the two at WakeMed-Cary are labeled 1 and 2. Each HLB machine (and its components) and BRAT machine is identified by its serial numbers (SN), model numbers and the hospital where it is located, as described in Exhibit 3 to this letter.

The surgeons of Carolina Cardiovascular Surgical Associates, P.A. (Practice), started performing open heart surgery and providing their own perfusion services at WakeMed in 1979 and at Rex in 1989, through either the Practice itself or a perfusion company owned by the same physicians. Each of the eight (8) HLB machines currently owned by CSA is replacement equipment for a machine owned by CSA (or a predecessor entity) prior to the year 1993, when acquisition of an HLB machine became subject to CON review regardless of its cost. W. Charles Helton, M.D., founded the Practice in 1979 and Cardinal Bio-Medical Associates, Inc. (Cardinal Bio-Medical), in 1980. Cardinal Bio-Medical was the perfusion company predecessor to CSA that like CSA was owned by the shareholders of the Practice. The two hospitals have never owned the HLB machines used at their facilities. Before 1989, Cardinal Biomedical had acquired and operated three (3) HLB machines at WakeMed and two (2) at Rex. Another cardiothoracic surgery practice in Raleigh, Atkinson & Zeok, M.D., P.A., had two (2) additional HLB machines at WakeMed and one (1) additional HLB machine at Rex. Atkinson & Zeok, M.D., P.A. merged with the Practice in 1993, and its two (2) surgeon shareholders, Alvan W. Atkinson, M.D., and John V. Zeok, M.D., joined the Practice. At the same time their three (3) HLB machines were acquired by Cardinal Bio-Medical, and they become shareholders of that perfusion company. Cardinal Bio-Medical or its successor company has continued to own and operate these eight (8) HLB machines (or their replacements) at their same respective locations at WakeMed and Rex since that time. In 1997, the shareholders of Cardinal Bio-Medical reorganized the company by forming CSA and transferring the operations and all eight (8) machines to CSA, which was owned by the same surgeons.

By 2001, CSA needed to replace all eight (8) of its HLB machines. There was a fourth HLB machine at Rex owned by surgeons Abdul G. Chaudhry, M.D. and James H. Davis, M.D. This one (1) HLB machine had been loaned to them by the manufacturer in the late 1990's to replace one they had provided for use at Rex which had become obsolete. At that time, CSA bought this fourth loaned HLB machine, which had already been used at Rex, from the manufacturer to replace one of CSA's older machines at Rex. Thereafter, Drs. Chaudhry and Davis no longer provided perfusion services or a HLB machine for use at Rex. CSA's purchase of this machine thus resulted in a net decrease in useable HLB machines at Rex from four (4) to three (3).

The same year, CSA obtained replacement equipment for its other seven (7) HLB machines at WakeMed and Rex, at a total capital cost of \$322,695. CSA's obsolete machines were subsequently removed out of North Carolina. By letter dated June 25, 2004, the Agency approved CSA's acquisition of the seven (7)

Mr. Craig R. Smith, Chief
Ms. Martha Frisone, Assistant Chief
November 21, 2011
Page 3

new HLB machines at WakeMed and Rex as replacement equipment. The Agency's "no review" letter of that date is attached and labeled as Exhibit 4.

CSA would like to transfer its interest in the eight (8) HLB machines into two wholly owned subsidiary limited liability companies. The first wholly owned subsidiary will be named "CSAMS New Bern Avenue, LLC" and will own the five (5) HLB machines currently operated at WakeMed. The second wholly owned subsidiary will be named "CSAMS Lake Boone Trail, LLC" and will own the three (3) HLB machines currently operated at Rex. The transfer of CSA's interests in the eight (8) HLB machines into two (2) wholly owned subsidiaries is not a CON reviewable event because it will have the following results:

- (1) No increase in the HLB machine inventory in Wake County;
- (2) No physical relocation of any HLB machines in Wake County;
- (3) No creation of any new health service facilities; and
- (4) No asset purchases of any per se reviewable equipment, consistent with the ROCC Declaratory Ruling.

This letter requests your confirmation that such a proposed transfer of interests would not trigger any of the new institutional health service provisions in the CON statute, and the transaction may proceed without first acquiring a CON.

II. ANALYSIS

The CON law provides that the "acquisition by purchase, donation, lease, transfer or comparable arrangement" of an HLB machine constitutes a "new institutional health service" that is subject to CON review. N.C. Gen. Stat. § 131E-176(16)f1; § 131E-178(a). However, we believe the creation of these two wholly owned subsidiaries is not a reviewable event because CSA, the owner of the CON rights for the eight (8) HLB machines, is not undergoing any direct change in its ownership status. Rather, this is merely a type of reorganization in the nature of those which the CON rules recognize as non-reviewable.

Until 1993, the acquisition of an HLB machine was not regulated under the CON law unless it involved the obligation of a capital expenditure exceeding two million dollars (\$2,000,000), which far exceeds the cost of this equipment. See N.C. Sess. Laws 1993, c. 7, § 2 (adding the acquisition of HLB machines and any "major medical equipment" costing more than \$750,000 as "new institutional health services" requiring a CON). However, effective March 18, 1993, the General Assembly amended the CON law to make the acquisition of HLB machines constitute a "new institutional health service" requiring a CON regardless of its cost. N.C. Gen. Stat. § 131E-176(10a), (16)f1.5., as amended by N.C. Sess. Laws 1993, c. 7, § 2.

Under the CON law, transfer of ownership or control of a CON prior to completion of a project or operation of the facility constitutes grounds for withdrawal of a CON. N.C. Gen. Stat. § 131E-189. However, the Agency's rules provide that in that situation, neither ownership nor control of a CON is transferred when the holder of the certificate is a corporation and the identity of the holder changes because of corporate reorganization, including transferring ownership to wholly owned subsidiaries. 10A N.C.A.C. 14C.0502(b)(1) and (c).

Mr. Craig R. Smith, Chief
Ms. Martha Frisone, Assistant Chief
November 21, 2011
Page 4

Specifically, the provisions of N.C. Gen. Stat. § 131E-189(c) state by analogy that the Department of Health and Human Services may immediately withdraw any CON if the holder of the certificate, before completion of the project or operation of the facility, transfers ownership or control of the facility, the project, or the certificate of need." Further, the Agency's rules at 10A N.C.A.C. 14C.0502(b) state as follows:

Ownership of a certificate of need is transferred when any person acquired a certificate from the holder by purchase, donation, lease, trade, or any comparable arrangement, except that ownership of a certificate of need is not transferred when:

- (1) the holder of the certificate is a corporation and the identity of the holder changes because of a corporate reorganization; or
- (2) the holder of the certificate is a partnership and the identity of the holder changes because the same partners reorganize as a new partnership.

10A N.C.A.C. 14C.0502(b) (emphasis added).

Here, CSA's right to own and operate the HLB machines is not a CON project that is not yet completed or operational. Nonetheless, if the CON law permits the transfer of a CON for an undeveloped project to a subsidiary of the applicant without a new CON or other sanction, then it would make no sense to interpret the law to prevent an existing provider from transferring a service to a wholly-owned subsidiary after the project has been developed. This principle has been affirmed by the Agency on a very similar set of facts in the ROCC Declaratory Ruling referenced above and attached as Exhibit 2.

Moreover, N.C. Gen. Stat. § 131E-189(c) acknowledges that completed projects may be transferred without CON review. It states that "[a]ny transfer after [the project is completed or becomes operational] will be subject to the requirement that the service be provided consistent with the representations made in the application and any applicable conditions." That statute does not require that a CON first be acquired before such a transfer takes place. Clearly, the reorganization of CSA's assets and CON exemption into two wholly owned subsidiaries would not constitute the "offering or development of a new institutional health service" within the definition of N.C. Gen. Stat. § 131E-178(a).

III. CONCLUSION

Based on the foregoing information, we hereby request the Agency's confirmation that the following transactions are not subject to CON review as a new institutional health service:

- (1) CSA's proposed transfer of its ownership interest in, and operation of, five (5) HLB machines, operated at WakeMed, to CSA Lake Boone, a wholly owned subsidiary of CSA; and
- (2) CSA's proposed transfer of its ownership interest in, and operation of, three (3) HLB machines, operated at Rex, to CSA New Bern, a wholly owned subsidiary of CSA.

If you require additional information to consider this request, please contact us as soon as possible. We thank you for consideration of this request.

Poyner Spruill^{LLP}

Mr. Craig R. Smith, Chief
Ms. Martha Frisone, Assistant Chief
November 21, 2011
Page 5

Very truly yours,

A handwritten signature in cursive script, appearing to read "Wilson Hayman", with a long horizontal line extending to the right.

Wilson Hayman
Partner
William R. Shenton
Partner

Attachments