One Citizens Plaza, 8th floor Providence, RI 02903:1345 Telephone 401:274:7200 Fax 401:751:0604 / 351:4607

175 Federal Street Boston, MA 02110-2210 Telephone 617-482-0600 Fax 617-482-0604

www.apslaw.com

February 21, 2013

Via E-Mail and Hand Delivery

Valentina D. Adamova Acting Chief Health Program Evaluator Rhode Island Department of Health Office of Health Systems Development 3 Capitol Hill, Room 410 Providence, RI 02908

Re: December 13, 2012 Corrected Conditions of Approval

Dear Ms. Adamova:

I am writing in response to your February 19, 2013 letter to Sarah J. Flaherty regarding the January 29, 2013 Change Order Request of Southern New England Regional Cancer Center, LLC ("SNERCC") and South County Radiation Therapy, LLC ("SCRT"). We respond as follows.

With respect to deficiency 1, as set forth below, SNERCC is seeking relief from conditions 9, 10, and 12 only with respect to the Lahey Clinic, due to the Lahey Clinic's corporate decision to no longer provide clinical oversight to any entity that it does not own or operate. In addition, SCRT, pursuant to corrected condition of approval 13, has petitioned the Department to terminate the services of the academic medical center, Massachusetts General Hospital, having met the prerequisite in condition 13, namely, the expiration of the three year period (it has been approximately eight years), having achieved ACRO accreditation since 2008 and in light of SCRT's demonstrated track record of providing quality care to its patients at the facility and the demonstrated financial viability of the facility. SNERCC, likewise, has a demonstrated track record of providing quality care to over a thousand patients and a demonstrated financial viability having been in operation since 2004 and accredited in 2008. Accordingly, consistent with condition 13, SNERCC is not proposing a replacement academic medical center. I

¹ Consistent with SCRT's December 13, 2012 condition of approval 13, the original clinical oversight requirement was intended to be a temporary measure subject to a proven demonstration of quality care and financial viability, both of which have occurred with respect to all of the facilities.

Valentina D. Adamova February 21, 2013 Page 2

Section I - General Conditions of Approval as corrected on December 13, 2012 (Deficiency 5):

1. that data, including but not limited to finances, utilization, and demographic patient information, be furnished to the state upon request by each facility;

Response: SNERCC, SCRT and RWRT are in compliance with condition 1.

2. that each facility will provide services to all patients without discrimination of payor source or ability to pay and that charity care shall have the same definitions, standards and requirements as set forth in the Rules and Regulations for Licensing of Hospitals (R23-17-HOSP) and Rules and Regulations Pertaining to Hospital Conversions (R23-17.14-HCA);

Response: SNERCC, SCRT and RWRT are in compliance with condition 2.

3. that each facility will establish a formal outreach program and strategy directed to reaching and providing notice to the referring physicians, and the uninsured and the underinsured populations of the availability of charity care; that the applicant shall provide a copy of the outreach program to the state agency within two months of licensure. The facilities shall make changes and adjustments to the outreach program where necessary to accomplish compliance with charity care requirement;

Response: SNERCC, SCRT and RWRT are in compliance with condition 3 and have provided a copy of the outreach program to the state agency as recently as September 10, 2012 by letter from me to Michael K. Dexter and Ana P. Novais including a certification from Bryan J. Carey. SNERCC, SCRT and RWRT do not have records going back to initial licensure.

4. that each facility shall submit to the state agency on an annual basis the total number of cancer cases, the number of charity care cancer cases (hospital) and the amount of charity care provided in \$ (charges) for cancer surgery (hospital), chemotherapy (hospital) and radiation oncology (OACF);

<u>Response:</u> SNERCC, SCRT and RWRT are in compliance with condition 4 and most recently submitted the data to the state agency on March 28, 2012.

5. that each facility shall maintain accreditation by the American College of Radiation oncology, or any successor thereto ("ACRO Accreditation") or the American College of Radiology or some other accreditation acceptable to the Director of Health such as the Joint Commission on Accreditation of Healthcare Organizations;

Valentina D. Adamova February 21, 2013 Page 3

Response: SNERCC, SCRT and RWRT are in compliance with condition 5. SNERCC and SCRT applied for ACRO accreditation in the first quarter of 2008, received provisional accreditation on December 4, 2008, and received full accreditation in September 2010 valid through August 31, 2013. RWRT applied for ACRO accreditation in January 2009, received provisional accreditation on October 14, 2009 and received full accreditation on September 1, 2010 that is valid through August 31, 2013.

6. that all physician radiation oncologists at the facilities be board certified or eligible for board certification in radiation oncology;

Response: SNERCC, SCRT and RWRT are in compliance with condition 6.

7. that the facility and equipment be in compliance with the Rules and Regulations for the Control of Radiation [R23-1.3-RAD] and Rules and Regulations for the Licensure of Organized Ambulatory Care Facilities (R23-17-OACF);

Response: SNERCC, SCRT and RWRT are in compliance with condition 7.

8. that each facility shall market its services as separate and separately licensure from their respective hospital partners.

Response: SNERCC, SCRT and RWRT are in compliance with condition 8.

II - SNERCC Conditions of Approval as corrected on December 13, 2012 (Deficiency 2)

SNERCC is in compliance with paragraphs 10 and 11, having provided the name and qualifications of the initial lead physician and oncology nurse coordinator of the radiation therapy service to the Department for prior review and approval, namely, Dr. Timothy Shafman and Maria Appenfeller. Nurse Appenfeller was replaced by Kathleen Scully, who was hired during the last year. A copy of Ms. Scully's C.V. is attached at **Tab A**.

REQUEST FOR RELIEF (Deficiency 2 and 3)

SNERCC seeks relief from conditions 9, 10 and 12 only to the extent that SNERCC was recently informed of Lahey Clinic's corporate decision to no longer provide clinical oversight and would not allow SNERCC physicians to renew their staff privileges. Accordingly, while SNERCC has consistently abided by conditions 9, 10 and 12 and remains in compliance with the criteria for Landmark medical staff, it can no longer indicate compliance with medical staff criteria at the Lahey Clinic. However, SNERCC is an established program that incorporated quality assurance policies, procedures and protocols that were maintained at the Lahey Clinic. Due to recent change in status with the Lahey Clinic and in light of the fact that SNERCC was granted ACRO

Valentina D. Adamova February 21, 2013 Page 4

initial accreditation on December 4, 2008 and it continues to provide quality services, SNERCC respectfully seeks to confirm that the Lahey Clinic requirements in conditions 9, 10 and 12 are no longer applicable and should be deleted. SNERCC does not believe that an alternative academic medical center should be required.² Consistent with SCRT's right to petition to terminate the academic medical center in corrected condition 13, SNERCC has been providing quality care to thousands of patients with board certified Rhode Island licensed physicians since 2004 with no reportable events to the Department, has demonstrated financial viability and has been ACRO accredited since 2008.

III - SCRT Conditions of Approval as Corrected on December 13, 2012 (Deficiency 2)

As set forth in Sarah Flaherty's January 29, 2013 letter to Raymond Rusin, SCRT is in compliance with corrected conditions 14, 15, 16, 17 and 18, as more fully set forth therein.

REQUEST FOR RELIEF (Deficiency 4)

SCRT seeks relief from corrected condition 13 requiring ACR accreditation to require ACRO accreditation. First, SCRT is ACRO accredited, having received provisional accreditation on December 4, 2008 consistent with general condition of approval 5 as corrected on December 13, 2012 and consistent with, and in reliance upon, the condition of approval in the February 2008 CEC Application. Second, ACRO accreditation is recognized by Medicare and ACRO accredits 153 radiation therapy centers across the country, including the Lahey Clinic. [ACR-433] Accordingly, SCRT requests that condition 13 be modified to include accreditation by ACRO consistent with the December 2012 general condition of approval 5 and the February 2008 CEC condition of approval. Finally, as set forth in Ms. Flaherty's November 12, 2012 letter, and pursuant to Corrected Condition 13, SCRT is petitioning to terminate the services of Massachusetts General Hospital, the academic medical center, based on its demonstrated track record in providing quality care to its patients and its demonstrated financial viability since commencing operations in 2005.

IV – RWRT Conditions of Approval as corrected on December 13, 2012

RWRT is in compliance with conditions 19 and 20.

² None of the physician owned practices providing radiation therapy services, including North Main Radiation Oncology or Maddock Center for Radiation Oncology are required to have clinical oversight, nor are they required to comply with the provisions of the Organized Ambulatory Care Facility Rules and Regulations applicable to the facilities here.

Valentina D. Adamova February 21, 2013 Page 5

If you have any questions or comments, please contact me. As always, thank you for your consideration.

Sincerely, / Rocha
PATRICIA K. ROCHA

Attachment

cc:

Greg Mercurio Sarah Flaherty

Norton L. Travis, Esq. Timothy Shafman, M.D.

637209.2

TAB A

Kathleen E. Scully RNP 10 Hill Avenue Smithfield, RI 02917

401-231-8903(H) 401-569-9462(C)

QUALIFICATIONS AND OBJECTIVE

With diverse experience within the field of Radiation Oncology, both as a registered nurse and nurse practitioner for multiple years, I am seeking a position as a nurse in the oncology setting utilizing these experiences and personal attributes.

- Eleven plus years as an Adult Nurse Practitioner in the field of Oncology.
- Specific Radiation Oncology experience, working collaboratively with physicians and residents managing patients through the trajectory of care.
- Senior staff person and mentor, advisor to nursing staff, protocol office and support services within the oncology department.
- Committed, self motivated and directed professional, possessing strong organizations and communications and analytical skills..

PROFESSIONAL EXPERIENCE

- 1971-2010 Tufts Medical Center, Boston Massachusetts
- 1999-2010 Rhode Island Hospital, Comprehensive Cancer Center, Tufts Division of Radiation Oncology, Providence Rhode Island.

Collaborative practice within the subspeciality of Radiation Oncology as a physician extender seeing new patient, consultations and follow-up patients.

Duties included:

- Obtaining History and Physicals on new patients. Perform dictation on all patients.
- Evaluates and monitoring on a weekly basis, all patients within the practice receiving radiation therapy.
- Symptom and side effect management for existing, new or follow-up patients.
- Pain management for existing, new or follow-up patients.
- Coordination of care and referrals for patients to other subspecialties, such as nutrition, social work and hospice.
- Protocol patient monitoring and management.

- Consultative resource for physicians in training in various aspects of symptom and pain management.
- Serve as collaborative point person, working with medical as well as surgical oncologists in multidisciplinary disease management.
- Providing patient, family and community education regarding health maintenance, promotion or health restoration through teaching, counseling.
- Also assists family members and significant others with resources and referrals.
- Assisted in coordination of organizing the CME credits for department.
- Preceptor/mentor for nurse practitioner students as well as basic nursing students.

1982-1999	STAFF NURSE- Department of Radiation Oncology
1979-1982	STAFF FLOAT NURSE (While enrolled in BSN program)
1979-1982	DATA COLLECTION-RESEARCH STUDY (part time)
1978-1979	STAFF NURSE-OUT PATIENT CLINICS
1976-1978	NURSE MANAGER-SURGICAL ONCOLOGY
1974-1976	EVENING SURGICAL SUPERVISOR
1971-1974	STAFF NURSE-SURGICAL

EDUCATION

•	Simmons College, Boston, MA	1994-1998
	Masters in Science Degree in Nursing/Adult Nurse Practitioner -	

Masters in Science Degree in Nursing/Adult Nurse Practitioner

o Part time

	Boston College, Chestnut Hill, MA	1979-1982
•	Boston Conege, Chestilut Hill, MA	17/7-1702

• Bachelor's in The Science of Nursing (BSN)-Part time

• Catherine Laboure School of Nursing, Dorchester, MA 1968-1971

• Diploma in Nursing

ORGANIZATIONS

- Massachusetts Nurses Association (MNA)
- Sigma Theta Tau
- Oncology Nursing Society
- American Society of Therapeutic Radiation Oncology (ASTRO)
- American Nurse Credentialing center

LICENSURE RN and ADVANCED PRCATICE

STATE OF MASSACHUSETTS 109738
STATE OF RI NPP36673
AMERICAN NURSES CREDENTIALING CENTER, certified Adult NP

REFERENCES AVAILABLE ON REQUEST