

Compliance Agreement

Division of Public and Behavioral Health and Thomas Dermatology

This Compliance Agreement is made and entered into effective on the 10th day of Sept, 2024, by, between, and among the Division of Public and Behavioral Health (hereinafter "Division") and Thomas Dermatology (hereinafter "TD"), Registrant Number 4573.

RECITALS:

A. Electronic brachytherapy is a type of radiation therapy that uses X-rays which are electronically generated to deliver a radiation dose inside a patient's body or in contact with, or very close to, the body surface. The goal of this compliance agreement is to make electronic brachytherapy treatments for skin cancers more accessible to patients by reducing the annual registration fee for electron brachytherapy systems used by dermatologists and adding flexibility to the requirement for an authorized user to be present during treatments. This compliance agreement will allow TD:

(1) To register electron brachytherapy systems including systems that produce multiple treatment modalities such superficial radiation therapy for dermatology uses at the same fee as an accelerator radiation therapy system, which is currently \$550.00.

(2) To use a physician who is under the supervision of an authorized user, is identified in writing, and trained in the operation and emergency response for an electronic brachytherapy system to meet the requirement in Nevada Administrative Code Chapter 459 (NAC 459), section 459.5922.2(a) for an authorized user to be physically present during the initiation of all patient treatments.

B. NAC 459.161(1)(f) and (2), provides, in relevant part,

1. An application for the registration of a radiation machine submitted pursuant to NAC 459.154 must be accompanied by a nonrefundable fee for each X-ray tube, electron source or source of ionizing radiation, which is installed in the radiation machine, as follows:

[]

(f) Accelerator, \$550.

2. If the Division issues a registration certificate pursuant to NAC 459.156, the registrant must, for each year the certificate is valid, submit to the Division a nonrefundable renewal fee in an amount equal to the appropriate fee set forth in subsection 1.

NAC 459.5931(1), provides, in relevant part,

1. A registrant shall pay an annual fee for the registration and inspection of an electronic brachytherapy device in the amount of \$4,400.

When the regulations for electronic brachytherapy were developed, there were no electron brachytherapy systems in use for dermatology. Insurance reimbursements for electronic brachytherapy treatments by dermatologist is not enough to support the electron brachytherapy fee of \$4,400.00 per year due to the facility's cost to administer the treatment and the low number of patients treated. The application of radiation to treat skin cancer by dermatologist is similar to cancer treatments from accelerator radiation therapy systems because the radiation is applied from outside of the patient's body and does not involve inserting a source of radiation inside of the patient. For this reason, the registration fee of \$550.00 for a radiation therapy system better suits the dermatology uses of electron brachytherapy.

C. NAC 459.2922(2)(a), provides, in relevant part,

"An authorized user must be physically present during the initiation of all patient treatment or identify in writing an authorized medical physicist for electronic brachytherapy who is trained in the operation and emergency response for the system who will be physically present during the initiation of all patient treatments."

NAC 459.5922.2(a) requires an Authorized User (AU) or an Authorized Medical Physicist (AMP) to be physically present during the initiation of all patient treatments. The AMP develops the radiation treatment plan and performs tests and checks to ensure the electron brachytherapy system is operating correctly. The AU prescribes the radiation treatment, approves the treatment plan, and supervises the operation of the electronic brachytherapy system. The AU must be a physician who is certified in radiation oncology, therapeutic radiology, or radiation therapy. Dermatology offices do not treat enough patients to employ full time AUs or AMPs. To better facilitate treatments, the compliance agreement will allow TD to identify in writing a physician or authorized medical physicist for electronic brachytherapy who will be physically present during the initiation of all patient treatments. The physician or AMP must be trained in the operation and emergency response for the system. By allowing a physician in addition to an AMP to meet the requirement for an AU to be physically present will give the facility the flexibility to provide treatments using staff who work at the facility full time.

E. The Division supports TD's request to reduce the registration fee for electron brachytherapy for the treatment of skin cancer and other conditions by dermatologists and to use a physician who is under the supervision of an authorized user, is identified in writing, and trained in the operation and emergency response for an electronic brachytherapy system to meet the requirement in NAC 459.5922(2)(a) for an authorized user to be physically present during the initiation of all patient treatments. Further, the Division intends on bringing forward draft regulations to make this change in NAC Chapter 459.

F. Nevada Administrative Code (NAC) 439.280(3) provides the following: In those areas of the State which are not in a health district, or in case of a regulation enforced exclusively by the State Board of Health, the Chief Medical Officer may postpone the enforcement of and agree to a schedule for compliance with the regulation. If the period needed by such a person to comply exceeds 45 days, the schedule must be submitted to the Nevada State Board of Health for approval.

NOW, THEREFORE, it is hereby agreed as follows:

1. The Chief Medical Officer agrees to the above-described reduction in registration fees and the use of a physician who is under the supervision of an authorized user, is identified in writing, and trained in the operation and emergency response for an electronic brachytherapy system to meet the requirement in

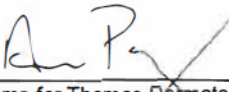
NAC 459.5922.2(a) for an authorized user to be physically present during the initiation of all patient treatments.

2. TERM OF AGREEMENT: This Agreement shall remain in effect for a period not to exceed 45 days or can go beyond the 45 days if presented at the earliest Nevada Board of Health meeting for approval. Once submitted to the Nevada Board of Health, and thereafter approved, the Agreement shall remain in effect until such time as the Chief Medical Officer revokes the Agreement, or the Division revises NAC 459 to establish a fee specific to electron brachytherapy for dermatology use and to allow for a physician

or AMP to meet the requirements for an AU to be physically present at the initiation of patient treatments, whichever is earlier.


IN WITNESS WHEREOF, the parties have executed this Agreement effective the day and year first above written.

THOMAS DERMATOLOGY

Signed:  Date: 9.10, 24
Name for Thomas Dermatology, Administrator
ANITA POMERANTZ, MD

Signed:

NEVADA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

Signed:  Date: Sept 18th, 24
IHSAN AZZAM, Nevada State Health Officer

Signed:

Approved by Board of Health on:

Signed: _____ Date: _____, 24
CODY PHINNEY, Administrator,
Division of Public and Behavioral Health,
Executive Officer of Board of Health

Signed: