



STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

M. JODI RELL
GOVERNOR

CRISTINE A. VOGEL
COMMISSIONER

November 3, 2004

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.
One Century Tower
265 Church Street
New Haven, CT 06510

Re: Certificate of Need Determination, Report Number 04-30387-DTR
Michael Rubin Associates, L.L.C. d/b/a SŌNA® Laser Center
Proposal to Administer Cosmetic Injections

Dear Attorney Groves:

On October 21, 2004, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) Determination request regarding the proposal of Michael Rubin Associates, L.L.C. d/b/a SŌNA® Laser Center to administer cosmetic injections at locations in New Haven and Hartford counties. OHCA has reviewed the information contained in your request and makes the following findings:

1. Michael Rubin Associates, L.L.C. (“Petitioner”) is a franchisee of SŌNA® Laser Centers, Inc. (“SŌNA Center”). SŌNA Centers are also known as SŌNA® Med Spas.
2. In CON Determination Report 04-30232-DTR OHCA concluded that that the Petitioner’s proposed SŌNA Centers do not meet the definition of an outpatient surgical facility and CON approval is not required to establish the SŌNA Centers.
3. In addition to the performance of laser hair removal and anti-aging treatments, SŌNA Centers propose to offer Restylane and Botox® Cosmetic injections (“injections”). Restylane is injected into the skin by way of a very thin needle and serves to restore natural voumes underneath wrinklers. Botox® Cosmetic, is also administered by injection and works by temporarily reducing the contractions of muscles that cause persistent frownlines.
4. The injections will be performed by licensed physicians and do not involve the use of moderate or deep sedation, moderate or deep analgesia or general anesthesia.

5. The target population for the injections is the same as the target population for the SōNA Centers themselves, including men and women between the ages of 25 and 55.
6. No facility fee will be charged
7. There will be no third-party payer reimbursement for the injections. All such services must be paid for by the individuals to whom they are provided.
8. The proposal has no associated capital expenditure.
9. Section 1(a) of Public Act No. 04-249, "An Act Concerning Regulation of Outpatient Surgical Facilities", states that an outpatient surgical facility shall not include a medical office owned and operated exclusively by a person or persons licensed pursuant to Section 20-13, provided such medical office (1) has no operating room or designated surgical area;(2) bills no facility fees to third party payers;(3) administers no deep sedation or general anesthesia;(4) performs only minor surgical procedures incidental to the work performed in said medical offices...;(5) uses only light or moderate sedation or analgesia in connection with such incidental minor surgical procedures.

Based on the above findings, OHCA has determined that Certificate of Need approval is not required for Michael Rubin Associates, L.L.C. d/b/a SōNA® Laser Center, to administer Restylane and Botox® cosmetic injections at its locations in New Haven and Hartford counties.

Thank you for informing OHCA of your plans. If you have any questions concerning this letter, please contact Laurie Greci, Associate Research Analyst, at OHCA at (860) 418-7001.

Sincerely,

Signed by Cristine A. Vogel
Commissioner

cc: Rose McLellan, Licensing Examination Assistant, DHSR, DPH

CAV: lkg