Executive Committee Meeting

Virginia Board of Medicine

December 1, 2017

8:30 a.m.

PERIMETER CENTER CONFERENCE CENTER
EMERGENCY EVACUATION OF BOARD AND TRAINING ROOMS
(Script to be read at the beginning of each meeting.)

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Board Room 4

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Executive Committee

Friday, December 1, 2017 @ 8:30 a.m.
9960 Mayland Drive, Suite 200
Richmond, VA 23230
Board Room 4

Page

Call to Order of the Executive Committee—Kevin O'Connor, MD, President, Chair

Emergency Egress Procedures ..... **i**

Public Hearing – Proposed Regulations on the Prescribing of Opioids **9-22**

Roll Call

Approval of Minutes – August 4, 2017 1-8

Adoption of Agenda

Public Comment on Agenda Items

DHP Director's Report – David Brown, DC

President's Report - Kevin O'Connor, MD

Executive Director's Report – Jennifer Deschenes, JD

NEW BUSINESS:

1. Regulatory Actions – Ms. Yeatts
   - Chart of Regulatory Actions 23
   - Proposed regulations for performance of and for supervision and direction of laser Hair removal 24
   - Guidance Document on the completion of Form B 46

Announcements

Next scheduled meeting: April 13, 2018

Adjournment

--- DRAFT UNAPPROVED --

VIRGINIA BOARD OF MEDICINE

EXECUTIVE COMMITTEE MINUTES

Friday, August 4, 2017 | Department of Health Professions | Henrico, VA

CALL TO ORDER: The meeting convened at 8:34 AM.

ROLL CALL: Ms. Opher called the roll; a quorum was established.

MEMBERS PRESENT:
Kevin O'Connor, MD, President & Chair
Randy Clements, DPM
Alvin Edwards, MDiv, PhD
Jane Hickey, JD
Maxine Lee, MD
Nathaniel Tuck, Jr., DC, Vice-President

MEMBERS ABSENT:
Syed Salman Ali, MD
Lori Conklin, MD, Secretary-Treasurer

STAFF PRESENT:
William L. Harp, MD, Executive Director
Jennifer Deschenes, JD, Deputy Director, Discipline
Alan Heaberlin, Deputy Director, Licensure
Barbara Matusiak, MD, Medical Review Coordinator
Colanthia Morton Opher, Operations Manager
Sherry Gibson, Administrative Assistant
Erin Barrett, JD, Assistant Attorney General

OTHERS PRESENT:
Scott Johnson, JD, MSV
B. Tilman Jolly, MD, Specialists on Call

EMERGENCY EGRESS INSTRUCTIONS

Dr. O'Connor provided the emergency egress instructions.

APPROVAL OF MINUTES OF APRIL 7, 2017

Dr. Edwards moved to approve the meeting minutes of April 7, 2017 as presented. The motion was seconded and carried unanimously.

ADOPTION OF AGENDA

Dr. Edwards moved to adopt the agenda as presented. The motion was seconded and carried unanimously.

PUBLIC COMMENT

There was no public comment.

DHP DIRECTOR'S REPORT

In Dr. Brown's absence, Dr. Harp provided the comments that Dr. Brown wanted to convey to the Committee. He told the Committee about HB 2161, which authorizes the Secretary of Health and Human Resources to convene a workgroup with representatives from the Department of Behavioral Health and Developmental Services, Department of Health, Department of Health Professions, State Council on Higher Education for Virginia, and at least one representative from each medical school, dental school, pharmacy school, physician assistant program, and nursing program located in the Commonwealth. The task of the workgroup will be to develop educational standards and curricula for training health care providers in the safe and appropriate use of opioids to treat pain while minimizing the risk of addiction and substance abuse. Such educational standards and curricula shall include education and training on pain management, addiction, and the proper prescribing of controlled substances. The workgroup shall report its progress and the outcomes of its activities to the Governor and the General Assembly by December 1, 2017. DHP is the lead agency for this workgroup, and meetings have already occurred.

Dr. Harp also said that SB 1230 requires the Secretary of Health and Human Resources to convene a workgroup to review the actions necessary for the implementation of electronic prescriptions for controlled substances containing an opioid. On July 1, 2020, all opioid prescriptions will have to be transmitted electronically. The workgroup first met on August 2, 2017. DHP is also the lead agency for this workgroup.

PRESIDENT'S REPORT

Dr. O'Connor reported on his attendance at the Tri-Regulator Symposium held in Chicago. He said the meeting was hosted by the Federation of State Medical Boards (FSMB), the National Association of Boards of Pharmacy (NABP) and the National Council of State Boards of Nursing (NCSBN). These organizations represent approximately 6 million healthcare providers. Dr. O'Connor stated that it was a great opportunity to exchange ideas and explore common concerns and potential solutions. He said that the majority of the time was spent on the opioid crisis and its significance to all the professions. It became clear that the way in which Virginia boards could have the most impact is in educating legislators. Dr. O'Connor said that it is his belief that the process Virginia undertook to create workable opioid regulations will be a model for many states as they tackle this critical issue.

EXECUTIVE DIRECTOR'S REPORT

Quarterly Performance Measurements

Dr. Harp reviewed the Board's performance report on the clearance rate of cases, the pending caseload, and time to disposition. He gave great credit to the Board members and Dr. Matusiak. Dr. Edwards asked how Virginia stacked up with other states. Ms. Deschenes said

that Medicine cases are to be closed in 250 days and that Virginia is one of the few states that has required timeframes for closure. In querying other states, she learned that a number averaged 3-5 years for closure of cases. In recent years, Virginia has been much faster in closing cases than it used to be.

Dr. O'Connor thanked Dr. Matusiak and the Board members for their good work.

Revenue and Expenditures

Dr. Harp reported that the cash balance as of June 30, 2017 was $10 million and that the Board came in $18,000 under budget in FY2017. He commended Charles Giles and Elaine Yeatts for their great forecasting.

New Board Liaison Representative

Dr. O'Connor announced that he was the new Board liaison to FSMB. Claudette Dalton, former Virginia Board President and current FSMB Board Member, will continue as the liaison from FSMB to the Virginia Board. Dr. O'Connor said that the Interstate Medical Licensure Compact and the Board's regulations for Endorsement would probably be topics of discussion.

NEW BUSINESS

Telemedicine Licensure and FORM B's

Dr. Harp introduced this topic by saying that telemedicine practitioners applying for a Virginia license are seeking the same consideration that tele-radiology and tele-pathology have in regards to FORM B's. The Board previously granted tele-radiology and tele-pathology applicants an exemption to getting a FORM B from every hospital or facility where he/she had provided services in the last 5 years. A FORM B and a letter listing the locations and signed by the program director of the tele-radiology or tele-pathology company were deemed acceptable to the Board.

Dr. Jolly, Chief Medical Officer for Specialists on Call, provided a brief presentation on the services provided by the telemedicine practitioners employed by the company. He made several points about the company for the Committee to consider. Specialists on Call:

- Is the largest provider of acute telemedicine services in rural as well as large hospitals
- Has been accredited by the Joint Commission since 2006
- Provides services in over 36 states, approximately 400 hospitals, and employs 140 physicians
- Does physician-to-physician consults in neurology, psychiatry, and critical care

Dr. Jolly stated that Specialists on Call has several physicians awaiting licensure in Virginia and that the speedbump is getting a FORM B submitted from each and every site of service.

Dr. O'Connor asked if there were currently enough Virginia critical care physicians to fill the need.

Dr. Jolly said his company provides physicians to hospitals that don't have a critical care physician, or to those that only have one and have no coverage in the physician's absence.

Dr. O'Connor said that one concern is that an unscrupulous medical director might hire practitioners that may not be prepared to provide the best medical care.

Dr. Jolly stated that would be a concern for his company as well, but at Specialists on Call, quality is paramount. Returning to the FORM B's, he pointed out that the work of the Board staff might be reduced, since there would be less documentation submitted for each telemedicine practitioner.

Dr. O'Connor asked if there was a fundamental difference between the services of an in-person critical care encounter and a telemedicine encounter.

Dr. Jolly said that there is a difference but the qualifications to provide either should be the same.

Dr. O'Connor pointed out that telemedicine x-ray and imaging studies are generally re-read or over-read in the facility as a follow-up to the telemedicine read. He inquired as to whether such a second look occurred after a tele-neurologist provided services.

Dr. Jolly said the first point of contact for Specialists on Call is with a physician, not the patient. One or more physicians are already caring for the patient in the acute setting, and follow-up with a neurologist on staff has usually been ordered.

Dr. O'Connor stated that Specialists on Call sounds like the best of the best, but the concern lies with those companies that may hire physicians that are borderline in their oversight of their practitioners and processes.

Dr. Jolly agreed that it's like the Wild Wild West for anyone that has access to a phone and the Internet. He shares that concern and will work with the Board to get past its skepticism and assist with setting standards regarding licensing if need be.

Dr. O'Connor acknowledged that our telemedicine document does not allow the use of audio-only for direct-to-consumer visits.

Ms. Hickey stated there was a Virginia study that showed a shortage of psychiatrists, particularly in the rural areas. It has been suggested that tele-psychiatry would help fill that gap. She then asked if the physicians have to be privileged at each hospital.

Dr. Jolly said that Specialists on Call has approximately 40 psychiatrists, but Psychiatry is not the company's primary focus. He advised that the physicians are privileged at every hospital.

Ms. Hickey asked what purpose does it serve to request a FORM B from every hospital or facility if the physician is licensed and already practicing in other states. Does every FORM B actually provide some value to the Board?

Ms. Deschenes said that getting all FORM B's is an incredible amount of work for the staff. If the applicant's chronological dates don't correspond to the dates on the FORM B submitted by the facility, staff has to go back and forth to get the information aligned. Ms. Deschenes reminded the Committee that the Board recently decided to accept the National Practitioner Data Bank (NPDB) report which the Board was not getting before. She also pointed out that if a telemedicine physician was working alone in his/her home and applies for a license, we ask him/her to have a colleague complete a FORM B on his/her behalf. This constitutes less oversight than what Specialists on Call is requesting.

Dr. Harp agreed with Ms. Deschenes acknowledging that a solitary practitioner providing direct-to-consumer services to 300 people in different states is under a less stringent application requirement than the physicians that work for a company accredited by the Joint Commission. The initiation of the NPDB is going to provide more information than is gathered from the FORM B's, AMA profile, and FSMB discipline report, which are required currently. The NPBD report will include hospital actions, which it does not get direct source verification from current documents. The current application does query the applicant about current/past investigations, which could also be disclosed in the NPDB data. Dr. Harp said the Board would need to develop a policy that deals with companies that are Joint Commission accredited, those that are not, and the solitary physician that does not work for a company.

Dr. O'Connor said that the question is two-fold: 1) how many FORM B's are really required, and 2) whether the Board should consider issuing a "telemedicine only" license.

Dr. Harp quoted data from FSMB that 48 state boards require a telemedicine physician to be licensed to practice into the state. Fifteen boards issue a special purpose license for telemedicine. He said that a telemedicine license was discussed by the Virginia Board in the 90's and not supported. His comment was that the Board should want just as much information about a physician who will be sitting in another state providing services to Virginia residents as someone who is moving to Virginia to set up an office. Telemedicine is new to all of us, and the perception is that it is not as safe as in-office visits. However, the Board gets more complaints about in-office visits than telemedicine. When patients decide to engage in telemedicine, it is by their choice for convenience and cost. Making such a choice might promote a greater sense of shared responsibility with the physician.

Mr. Heaberlin confirmed that the NPDB provides information on hospital privileges and professional societies. He pointed out that the FORM B issue is not just for telemedicine practitioners, but also for those who practice locum tenens.

Dr. O'Connor suggested that this item be sent to the Credentials Committee to look at the issues with the FORM B and determine not only the number that should be requested for sufficient review, but the entire concept of what should be required.

Ms. Deschenes said that the Credentials Committee met on July 26th and is forwarding their recommendation to the Executive Committee. The goal of the Board for applicants and staff is to reduce the complexity of licensure if possible. While most facilities will complete the evaluation, a good number of them provide the position held and dates of employment, perhaps completed by a HR representative.

Mr. Heaberlin said that, in the main, the FORM B is the least helpful of the supporting documents required by the application.

Dr. O'Connor stated that the consensus seems to be that the Board doesn't need 50 FORM B's. He said the Credentials Committee needs to provide a specific recommendation regarding the FORM B and its applicability in the licensing process.

Dr. Clements asked if we have access to the FORM B information through the NPDB report. What novel information do we get from the FORM B? Is it similar to a letter of recommendation?

Mr. Heaberlin agreed that it's a letter of recommendation. He also said that it wouldn't do much harm to lower the 5-year requirement for the FORM B to 3 or even 2 years. The NPDB provides information on actionable conduct about which the Board is most concerned. If a physician was dismissed from a practice, but the termination was not reported to the Data Bank, that may be picked up by a FORM B.

Dr. Lee stated that Mr. Heaberlin does not seem to be in favor of totally getting rid of FORM B.

Mr. Heaberlin advised that he has received some FORM B's with notes that say "call me to discuss". He would prefer not to require 30 FORM B's from sites at which a physician may have practiced for a week.

MOTION: After a lengthy discussion, Dr. Tuck moved that the FORM B topic be referred back to the Credentials Committee for a definitive suggestion on its use to include the number required. The motion was seconded and carried unanimously.

Chart of Regulatory Actions

Dr. Harp reviewed the status of pending regulatory matters.

This report was for informational purposes only.

Regulatory Action on Postgraduate Training for International Graduates

Dr. Harp said that Ms. Deschenes, Mr. Heaberlin and he along with Ms. Yeatts put together the draft regulations in the packet. The draft regulations include revisions to bring the regulations into compliance with the law. The amendments capture: 1) the elimination of 2 years of postgraduate training replacing it with 1 year; and 2) deletion of the options that previously could constitute 1 year of the prior 2-year requirement.

Ms. Barrett advised that this has been put in as exempt action, and it is reflective of the changes in the Code.

Ms. Deschenes pointed out that there might be confusion due to the international graduate being allowed to count a fellowship postgraduate year. American and Canadian graduates need to do one year as an intern or resident. Dr. Harp said that most of the international graduates that wish to submit a fellowship year have already done a residency in another country.

MOTION: Ms. Hickey moved to adopt the amendment to 18VAC85-20-122 as an exempt action. The motion was seconded and carried unanimously.

Proposed Regulatory Action – Nurse Practitioners

Dr. Harp stated that when the Code was amended in 2016 regarding nurse practitioner practice agreements, the requirement for agreements to be submitted to the Board of Nursing was eliminated. Other sections of the nurse practitioner regulations were amended, but Section 120 was inadvertently left unchanged. He noted that this change can be accomplished through a fast-track action.

MOTION: Dr. Edwards moved to adopt the proposed amendments to 18VAC90-40-120 by a fast-track action. The motion was seconded and carried unanimously.

Request of the Board to Approve Chiropractic Continuing Education

Dr. Harp advised that Kris Fetterman of Fetterman Events (FE) requested that the Board consider its company "any other organization" as per the regulations. He said that the Board has not approved individual coursework when requested to do so, and only a few short years ago did the Board approve the PACE program of continuing education provided by the Federation of Chiropractic Licensing Boards.

Dr. O'Connor said that his sense of "any other organization" approved by the Board was to allow for emergencies.

Dr. Tuck agreed and suggested that all organizations offering chiropractic continuing education should go through PACE.

MOTION: Dr. Tuck moved to deny the request and requested Board staff to notify Kris Fetterman of the decision. The motion was seconded and carried unanimously.

US Department of Veterans Affairs Request for Comment on Telemedicine

Dr. Harp said that Poonam Alaigh, MD, Acting Under Secretary for Health in the Department of Veterans Affairs, sent a letter to Humayun Chaudhry, DO, President of FSMB, asking for support in communicating to the state licensing boards the VA's plans to amend its

telemedicine regulations to remove barriers and enhance access to health care services for its veterans.

Dr. O'Connor posed the question how the expansion of VA telemedicine is going to impact the Commonwealth. If the VA is taking care of its patients and staying within their scope/jurisdiction, that is laudable. The only concern is the prescribing aspect and whether controlled substance prescriptions will be presented at non-VA pharmacies.

Dr. Harp stated that the VA notifies the states of their processes, some of which may already be in place. Dr. Harp raised the question of who has jurisdiction over the practitioner based in another state.

Ms. Deschenes said that if they are not licensed in Virginia, then the Board will have no jurisdiction. And even if they are licensed in Virginia, it would be up to the VA to give the Board access to the records to properly investigate the case.

The Committee instructed Dr. Harp to send a message to Dr. Kevin Galpin, Director of Telehealth Services, thanking the VA for informing the Board of its plans, that the Board believes the plans will enhance care to veterans, and best of luck with the implementation of this new telemedicine approach.

ANNOUNCEMENTS

The next meeting of the Committee will be December 1, 2017 at 8:30 a.m.

Ms. Opher reminded the members of the $50.00 per diem for attendance at official meetings of the Board. All travel reimbursement vouchers submitted since July 1st have already been amended.

Ms. Opher also informed the Committee of the direct-billing option for lodging in Richmond when attending Board meetings. She will send out a memo to all Board members advising them of this option.

ADJOURNMENT

With no additional business, the meeting adjourned at 10:05 a.m.

_____ _____

Kevin O'Connor, MD
President, Chair

William L. Harp, MD
Executive Director

_____

Colanthia M. Opher
Recording Secretary

Copy of Proposed Regulation on Prescribing of Opioids

Public Hearing – December 1, 2017

Comment period – November 27, 2017 to January 26, 2018

Project 5033 - Proposed

BOARD OF MEDICINE

Initial regulations

CHAPTER 21

REGULATIONS GOVERNING PRESCRIBING OF OPIOIDS AND BUPRENORPHINE

Part I

General Provisions

18VAC85-21-10. Applicability.

A. This chapter shall apply to doctors of medicine, osteopathic medicine, and podiatry and to physician assistants.

B. This chapter shall not apply to:

1. The treatment of acute or chronic pain related to (i) cancer, (ii) a patient in hospice care, or (iii) a patient in palliative care;

2. The treatment of acute or chronic pain during an inpatient hospital admission or in a nursing home or an assisted living facility that uses a sole source pharmacy; or

3. A patient enrolled in a clinical trial as authorized by state or federal law.

18VAC85-21-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Acute pain" means pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances may be prescribed for no more than three months.

"Board" means the Virginia Board of Medicine.

"Chronic pain" means nonmalignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.

"Controlled substance" means drugs listed in The Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) in Schedules II through IV.

"FDA" means the U.S. Food and Drug Administration.

"MME" means morphine milligram equivalent.

"Prescription Monitoring Program" means the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

"SAMHSA" means the federal Substance Abuse and Mental Health Services Administration.

Part II

Management of Acute Pain

18VAC85-21-30. Evaluation of the acute pain patient.

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days.

B. Prior to initiating treatment with a controlled substance containing an opioid for a complaint of acute pain, the prescriber shall perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia, and conduct an assessment of the patient's history and risk of substance misuse.

18VAC85-21-40. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

1. A prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record. This shall also apply to prescriptions of a controlled substance containing an opioid upon discharge from an emergency department.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine are present.

C. Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these

substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

D. Buprenorphine is not indicated for acute pain in the outpatient setting, except when a prescriber who has obtained a SAMHSA waiver is treating pain in a patient whose primary diagnosis is the disease of addiction.

18VAC85-21-50. Medical records for acute pain.

The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan, and the medication prescribed or administered to include the date, type, dosage, and quantity prescribed or administered.

Part III

Management of Chronic Pain

18VAC85-21-60. Evaluation of the chronic pain patient.

A. Prior to initiating management of chronic pain with a controlled substance containing an opioid, a medical history and physical examination, to include a mental status examination, shall be performed and documented in the medical record, including:

1. The nature and intensity of the pain;

2. Current and past treatments for pain;

3. Underlying or coexisting diseases or conditions;

4. The effect of the pain on physical and psychological function, quality of life, and activities of daily living;

5. Psychiatric, addiction, and substance misuse history of the patient and any family history of addiction or substance misuse;

6. A urine drug screen or serum medication level;

7. A query of the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia;

8. An assessment of the patient's history and risk of substance misuse; and

9. A request for prior applicable records.

B. Prior to initiating opioid treatment for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment to include securely storing the drug and properly disposing of any unwanted or unused drugs. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective.

18VAC85-21-70. Treatment of chronic pain with opioids.

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.

B. In initiating and treating with an opioid, the practitioner shall:

1. Carefully consider and document in the medical record the reasons to exceed 50 MME/day;

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist;

3. Prescribe naloxone for any patient when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine are present; and

4. Document the rationale to continue opioid therapy every three months.

C. Buprenorphine mono-product in tablet form shall not be prescribed for chronic pain.

D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medications if prescribed.

E. The practitioner (i) shall regularly evaluate the patient for opioid use disorder and (ii) shall initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation and treatment if indicated.

18VAC85-21-80. Treatment plan for chronic pain.

A. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including pain relief and improved physical and psychosocial function, quality of life, and daily activities.

B. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

C. The prescriber shall document in the medical record the presence or absence of any indicators for medication misuse or diversion and shall take appropriate action.

18VAC85-21-90. Informed consent and agreement for treatment for chronic pain.

A. The practitioner shall document in the medical record informed consent, to include risks, benefits, and alternative approaches, prior to the initiation of opioids for chronic pain.

B. There shall be a written treatment agreement signed by the patient in the medical record that addresses the parameters of treatment, including those behaviors that will result in referral to a higher level of care, cessation of treatment, or dismissal from care.

C. The treatment agreement shall include notice that the practitioner will query and receive reports from the Prescription Monitoring Program and permission for the practitioner to:

1. Obtain urine drug screens or serum medication levels when requested; and

2. Consult with other prescribers or dispensing pharmacists for the patient.

D. Expected outcomes shall be documented in the medical record including improvement in pain relief and function or simply in pain relief. Limitations and side effects of chronic opioid therapy shall be documented in the medical record.

18VAC85-21-100. Opioid therapy for chronic pain.

A. The practitioner shall review the course of pain treatment and any new information about the etiology of the pain and the patient's state of health at least every three months.

B. Continuation of treatment with opioids shall be supported by documentation of continued benefit from such prescribing. If the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

C. The practitioner shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

D. The practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter.

E. The practitioner (i) shall regularly evaluate the patient for opioid use disorder and (ii) shall initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation for treatment if indicated.

18VAC85-21-110. Additional consultations.

A. When necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment.

B. When a prescriber makes the diagnosis of opioid use disorder, treatment for opioid use disorder shall be initiated or the patient shall be referred for evaluation and treatment.

18VAC85-21-120. Medical records for chronic pain.

The prescriber shall keep current, accurate, and complete records in an accessible manner readily available for review to include:

1. The medical history and physical examination;

2. Past medical history;

3. Applicable records from prior treatment providers or any documentation of attempts to obtain those records;

4. Diagnostic, therapeutic, and laboratory results;

5. Evaluations and consultations;

6. Treatment goals;

7. Discussion of risks and benefits;

8. Informed consent and agreement for treatment;

9. Treatments;

10. Medications (including date, type, dosage, and quantity prescribed and refills);

11. Patient instructions; and

12. Periodic reviews.

Part IV

Prescribing of Buprenorphine for Addiction Treatment

18VAC85-21-130. General provisions pertaining to prescribing of buprenorphine for addiction treatment.

A. Practitioners engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a SAMHSA waiver and the appropriate U.S. Drug Enforcement Administration registration.

B. Practitioners shall abide by all federal and state laws and regulations governing the prescribing of buprenorphine for the treatment of opioid use disorder.

C. Physician assistants and nurse practitioners who have obtained a SAMHSA waiver shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a waivered doctor of medicine or doctor of osteopathic medicine.

D. Practitioners engaged in medication-assisted treatment shall either provide counseling in their practice or refer the patient to a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance misuse counseling. The practitioner shall document provision of counseling or referral in the medical record.

18VAC85-21-140. Patient assessment and treatment planning for addiction treatment.

A. A practitioner shall perform and document an assessment that includes a comprehensive medical and psychiatric history, substance misuse history, family history and psychosocial supports, appropriate physical examination, urine drug screen, pregnancy test for women of

childbearing age and ability, a check of the Prescription Monitoring Program, and, when clinically indicated, infectious disease testing for human immunodeficiency virus, hepatitis B, hepatitis C, and tuberculosis.

B. The treatment plan shall include the practitioner's rationale for selecting medication-assisted treatment, patient education, written informed consent, how counseling will be accomplished, and a signed treatment agreement that outlines the responsibilities of the patient and the prescriber.

18VAC85-21-150. Treatment with buprenorphine for addiction.

A. Buprenorphine without naloxone (buprenorphine mono-product) shall not be prescribed except:

1. When a patient is pregnant;

2. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days;

3. In formulations other than tablet form for indications approved by the FDA; or

4. For patients who have a demonstrated intolerance to naloxone; such prescriptions for the mono-product shall not exceed 3.0% of the total prescriptions for buprenorphine written by the prescriber, and the exception shall be clearly documented in the patient's medical record.

B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed opioid treatment programs. With the exception of those conditions listed in subsection A of this section, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use off site from the program.

C. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

D. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

E. Prior to starting medication-assisted treatment, the practitioner shall perform a check of the Prescription Monitoring Program.

F. During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on no more than eight milligrams of buprenorphine per day. The patient shall be seen by the prescriber at least once a week.

G. During the stabilization phase, the prescriber shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

H. Practitioners shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of the Prescription Monitoring Program. The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

I. Documentation of the rationale for prescribed doses exceeding 16 milligrams of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 milligrams of buprenorphine per day shall not be prescribed.

J. The practitioner shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance misuse counseling.

18VAC85-21-160. Special populations in addiction treatment.

A. Pregnant women may be treated with the buprenorphine mono-product, usually 16 milligrams per day or less.

B. Patients younger than the age of 16 years shall not be prescribed buprenorphine for addiction treatment unless such treatment is approved by the FDA.

C. The progress of patients with chronic pain shall be assessed by reduction of pain and functional objectives that can be identified, quantified, and independently verified.

D. Practitioners shall (i) evaluate patients with medical comorbidities by history, physical exam, appropriate laboratory studies and (ii) be aware of interactions of buprenorphine with other prescribed medications.

E. Practitioners shall not undertake buprenorphine treatment with a patient who has psychiatric comorbidities and is not stable. A patient who is determined by the prescriber to be psychiatrically unstable shall be referred for psychiatric evaluation and treatment prior to initiating medication-assisted treatment.

18VAC85-21-170. Medical records for opioid addiction treatment.

A. Records shall be timely, accurate, legible, complete, and readily accessible for review.

B. The treatment agreement and informed consent shall be maintained in the medical record.

C. Confidentiality requirements of 42 CFR Part 2 shall be followed.

D. Compliance with 18VAC85-20-27, which prohibits willful or negligent breach of confidentiality or unauthorized disclosure of confidential Prescription Monitoring Program information, shall be maintained.

Agenda Item: **Regulatory Actions - Chart of Regulatory Actions**

Staff Note: Attached is a chart with the status of regulations for the Board as of November 20, 2017

Board **Board of Medicine**

Chapter		Action / Stage Information
[18 VAC 85 - 20]	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic	Supervision and direction for laser hair removal [Action 4860] NOIRA - *Register Date: 10/2/17* *Comment ended: 11/1/17* *Exec. Comm. to adopt proposed regulations: 12/1/17*
[18 VAC 85 - 20]	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic	Licensure by endorsement [Action 4716] Proposed - *At Governor's Office for 17 days*
[18 VAC 85 - 20]	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic	Renewal fee reduction [Action 4942] Final - *Register Date: 11/27/17* *Effective: 12/27/17*
[18 VAC 85 - 21]	Regulations Governing Prescribing of Opioids and Buprenorphine	Initial regulations [Action 4760] Proposed - *Register Date: 11/27/17* *Comment period ends:* 1/26/18
[18 VAC 85 - 50]	Regulations Governing the Practice of Physician Assistants	Definitions of supervision and weight loss rules [Action 4943] NOIRA - *At Governor's Office for 13 days*
[18 VAC 85 - 80]	Regulations for Licensure of Occupational Therapists	NBCOT certification as option for CE [Action 4461] Proposed - *Stage Withdrawn 6/28/2017* [Stage 7756]
[18 VAC 85 - 80]	Regulations for Licensure of Occupational Therapists	Elimination of CE form and change in title of regulation [Action 4849] Fast-Track - *Register Date: 10/30/17* *Effective: 12/14/17*
[18 VAC 85 - 130]	Regulations Governing the Practice of Licensed Midwives	Practical experience under supervision [Action 4944] Fast-Track - *DPB Review in progress* [Stage 8115]

Agenda Item:

Proposed regulations for performance of and for supervision and direction of laser hair removal

Repeal of Guidance document on laser hair removal

Included in the agenda package:

A copy of HB2119
Copies of comments on the Notice of Intended Regulatory Action
Copy of Proposed Regulations as recommended by the Regulatory Advisory Panel
Guidance document 85-7 – to be deleted

Staff note:

Since the statutory language requires laser hair removal by a *properly trained person under the direction and supervision of a licensed doctor of medicine or osteopathic medicine or a physician assistant,* regulations for doctors of medicine and osteopathy, physician assistants and nurse practitioners need to be amended to define "direction and supervision" in this context and provide guidance about the practitioner responsibility relative to a "properly trained."

Action:

Adoption of proposed regulations to implement HB2119 in 18VAC85-20 (Regulations for Doctors of Medicine, Osteopathic Medicine, Podiatry and Chiropractic) and 18VAC85-50 (Regulations for Physician Assistants) as recommended by the RAP.

VIRGINIA ACTS OF ASSEMBLY -- 2017 SESSION

CHAPTER 390

An Act to amend and reenact § 54.1-700 of the Code of Virginia and to amend the Code of Virginia by adding in Article 6 of Chapter 29 of Title 54.1 a section numbered 54.1-2973.1, relating to the practice of laser hair removal.

[H 2119]

Approved March 13, 2017

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-700 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding in Article 6 of Chapter 29 of Title 54.1 a section numbered 54.1-2973.1 as follows:

§ 54.1-700. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Barber" means any person who shaves, shapes or trims the beard; cuts, singes, shampoos or dyes the hair or applies lotions thereto; applies, treats or massages the face, neck or scalp with oils, creams, lotions, cosmetics, antiseptics, powders, clays or other preparations in connection with shaving, cutting or trimming the hair or beard, and practices barbering for compensation and when such services are not performed for the treatment of disease.

"Barbering" means any one or any combination of the following acts, when done on the human body for compensation and not for the treatment of disease, shaving, shaping and trimming the beard; cutting, singeing, shampooing or dyeing the hair or applying lotions thereto; applications, treatment or massages of the face, neck or scalp with oils, creams, lotions, cosmetics, antiseptics, powders, clays, or other preparations in connection with shaving, cutting or trimming the hair or a beard. The term "barbering" shall not apply to the acts described hereinabove when performed by any person in his home if such service is not offered to the public.

"Barber instructor" means any person who has been certified by the Board as having completed an approved curriculum and who meets the competency standards of the Board as an instructor of barbering.

"Barbershop" means any establishment or place of business within which the practice of barbering is engaged in or carried on by one or more barbers.

"Board" means the Board for Barbers and Cosmetology.

"Body-piercer" means any person who for remuneration penetrates the skin of a person to make a hole, mark, or scar, generally permanent in nature.

"Body-piercing" means the act of penetrating the skin of a person to make a hole, mark, or scar, generally permanent in nature.

"Body-piercing salon" means any place in which a fee is charged for the act of penetrating the skin of a person to make a hole, mark, or scar, generally permanent in nature.

"Body-piercing school" means a place or establishment licensed by the Board to accept and train students in body-piercing.

"Cosmetologist" means any person who administers cosmetic treatments; manicures or pedicures the nails of any person; arranges, dresses, curls, waves, cleanses, cuts, shapes, singes, waxes, tweezes, shaves, bleaches, colors, relaxes, straightens, or performs similar work, upon human hair, or a wig or hairpiece, by any means, including hands or mechanical or electrical apparatus or appliances unless such acts as adjusting, combing, or brushing prestyled wigs or hairpieces do not alter the prestyled nature of the wig or hairpiece, and practices cosmetology for compensation.

"Cosmetology" includes, but is not limited to, the following practices: administering cosmetic treatments; manicuring or pedicuring the nails of any person; arranging, dressing, curling, waving, cleansing, cutting, shaping, singeing, waxing, tweezing, shaving, bleaching, coloring, relaxing, straightening, or similar work, upon human hair, or a wig or hairpiece, by any means, including hands or mechanical or electrical apparatus or appliances, but shall not include hair braiding or such acts as adjusting, combing, or brushing prestyled wigs or hairpieces when such acts do not alter the prestyled nature of the wig or hairpiece.

"Cosmetology instructor" means a person who has been certified by the Board as having completed an approved curriculum and who meets the competency standards of the Board as an instructor of cosmetology.

"Cosmetology salon" means any commercial establishment, residence, vehicle or other establishment, place or event wherein cosmetology is offered or practiced on a regular basis for compensation and may include the training of apprentices under regulations of the Board.

"Esthetician" means a person who engages in the practice of esthetics for compensation.

"Esthetics" includes, but is not limited to, the following practices of administering cosmetic treatments to enhance or improve the appearance of the skin: cleansing, toning, performing effleurage or other related movements, stimulating, exfoliating, or performing any other similar procedure on the skin of the human body or scalp by means of cosmetic preparations, treatments, *or* any nonlaser device, *whether by* electrical, mechanical, or manual *means*, for care of the skin; applying make-up or eyelashes to any person, tinting or perming eyelashes and eyebrows, and lightening hair on the body except the scalp; and removing unwanted hair from the body of any person by the use of *any nonlaser device, by* tweezing, *or by use of* chemical~~,~~ or mechanical means. However, "esthetics" is not a healing art and shall not include any practice, activity, or treatment that constitutes the practice of medicine, osteopathic medicine, or chiropractic. The terms "healing arts," "practice of medicine," "practice of osteopathic medicine," and "practice of chiropractic" shall mean the same as those terms are defined in § 54.1-2900.

"Esthetics instructor" means a licensed esthetician who has been certified by the Board as having completed an approved curriculum and who meets the competency standards of the Board as an instructor of esthetics.

"Esthetics spa" means any commercial establishment, residence, vehicle, or other establishment, place, or event wherein esthetics is offered or practiced on a regular basis for compensation under regulations of the Board.

"Master esthetician" means a licensed esthetician who, in addition to the practice of esthetics, offers to the public for compensation, without the use of laser technology, lymphatic drainage, chemical exfoliation, or microdermabrasion, and who has met such additional requirements as determined by the Board to practice lymphatic drainage, chemical exfoliation with products other than Schedules II through VI controlled substances as defined in the Drug Control Act (§ 54.1-3400 et seq.), and microdermabrasion of the epidermis.

"Nail care" means manicuring or pedicuring natural nails or performing artificial nail services.

"Nail salon" means any commercial establishment, residence, vehicle or other establishment, place or event wherein nail care is offered or practiced on a regular basis for compensation and may include the training of apprentices under regulations of the Board.

"Nail school" means a place or establishment licensed by the board to accept and train students in nail care.

"Nail technician" means any person who for compensation manicures or pedicures natural nails, or who performs artificial nail services for compensation, or any combination thereof.

"Nail technician instructor" means a licensed nail technician who has been certified by the Board as having completed an approved curriculum and who meets the competency standards of the Board as an instructor of nail care.

"Physical (wax) depilatory" means the wax depilatory product or substance used to remove superfluous hair.

"School of cosmetology" means a place or establishment licensed by the Board to accept and train students and which offers a cosmetology curriculum approved by the Board.

"School of esthetics" means a place or establishment licensed by the Board to accept and train students and which offers an esthetics curriculum approved by the Board.

"Tattoo parlor" means any place in which tattooing is offered or practiced.

"Tattoo school" means a place or establishment licensed by the Board to accept and train students in tattooing.

"Tattooer" means any person who for remuneration practices tattooing.

"Tattooing" means the placing of designs, letters, scrolls, figures, symbols or any other marks upon or under the skin of any person with ink or any other substance, resulting in the permanent coloration of the skin, including permanent make-up or permanent jewelry, by the aid of needles or any other instrument designed to touch or puncture the skin.

"Wax technician" means any person licensed by the Board who removes hair from the hair follicle using a physical (wax) depilatory or by tweezing.

"Wax technician instructor" means a licensed wax technician who has been certified by the Board as having completed an approved curriculum and who meets the competency standards of the Board as an instructor of waxing.

"Waxing" means the temporary removal of superfluous hair from the hair follicle on any area of the human body through the use of a physical (wax) depilatory or by tweezing.

"Waxing salon" means any commercial establishment, residence, vehicle or other establishment, place or event wherein waxing is offered or practiced on a regular basis for compensation and may include the training of apprentices under regulations of the Board.

"Waxing school" means a place or establishment licensed by the Board to accept and train students in waxing.

§ 54.1-2973.1. Practice of laser hair removal.

The practice of laser hair removal shall be performed by a properly trained person licensed to practice medicine or osteopathic medicine or a physician assistant as authorized pursuant to § 54.1-2952 or a nurse practitioner as authorized pursuant to § 54.1-2957 or by a properly trained

person under the direction and supervision of a licensed doctor of medicine or osteopathic medicine or a physician assistant as authorized pursuant to § 54.1-2952 or a nurse practitioner as authorized pursuant to § 54.1-2957 who may delegate such practice in accordance with subdivision A 6 of § 54.1-2901.

AmSpa AMERICAN MED SPA ASSOCIATION

Alex Thiersch, Director
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312.981.0991

November 1, 2017

william.harp@dhp.virginia.gov
William L. Harp, M.D.
Executive Director, Board of Medicine
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Jay P. Douglas, R.N.
Executive Director, Board of Nursing
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Richmond, VA 23233-1463

Re: Comments on NOIRA for supervision and direction for laser hair removal

To Whom It May Concern:

The American Med Spa Association (AmSpa) is the primary national trade group for medical spas, laser centers, and non-invasive medical aesthetic centers in the United States. It is comprised of more than 850 members consisting of free-standing medical spas, laser centers, franchises, plastic surgeons, dermatologists, and other aesthetic professionals.

AmSpa, headquartered in Chicago, was created to provide compliance, legal and business resources to the non-invasive aesthetic industry. Its main product offering is a state-by-state summary of the regulations governing medial spas and aesthetic centers, including the regulations governing lasers, light-based devices, and laser hair removal. Currently, AmSpa has information on the current aesthetic regulations for 32 of the 50 states. More information can be found at http://www.americanmedspa.org/page/state_regulations.

AmSpa is supported by a national healthcare law firm, ByrdAdatto, which is based in Dallas. The attorneys at ByrdAdatto provide AmSpa with access to research, guidance, and legal support to accurately advise its membership on relevant regulatory issues facing the industry in all 50 states.

AmSpa has also recently begun working closely with the International Aesthetic & Laser Association (IALA), who is jointly submitting an Impact Statement to the State of Virginia, in reviewing state-based aesthetic regulations and providing guidance to states looking to develop or refine existing guidelines.

Accordingly, AmSpa is in a unique position to provide guidance and information to states like Virginia as they attempt to develop, refine, and define the regulations governing light-based devices used for hair removal, skin-tightening, and other aesthetic purposes. We would be happy to provide information any resources to this state of Virginia, including current regulations recognized by other jurisdictions, trends, statistical data and information about new technology.

Additionally, AmSpa would like to adopt and incorporate the Impact Statement made by IALA as AmSpa's own Impact Statement relative to the current regulations being considered. IALA's statement accurately portrays the current regulatory landscape and offers a sound, reasoned opinion on the issues of supervision as it relates to light-based hair removal treatments.

Please let me know if you have any questions about AmSpa or if you would like further information about how AmSpa can assist in this process.

Sincerely,

Alex Thiersch
Founder/Director
American Med Spa Association (AmSpa)

INTERNATIONAL AESTHETIC & LASER ASSOCIATION

October 31, 2017

Impact Statement of International Aesthetic & Laser Association Regarding the NOIRA for Direction and Supervision of Laser Hair Removal

This Impact Statement is made by the International Aesthetic & Laser Association ("IALA") in relation to the Notice of Intended Regulatory Action related to the direction and supervision of laser hair removal ("NOIRA") submitted by the Virginia Boards of Medicine and Nursing.

1. **IALA Background.** IALA is a non-profit med spa association. Its membership is comprised of over 500 health care professionals, including physicians, nurse practitioners, physician assistants and registered nurses. Many members live in Virginia and own small businesses and will likely be impacted by any changes contemplated under this NOIRA.

2. **Brief Summary of State or Federal Laws Governing the Profession**

   a. **Direction and Supervision.** Approximately forty-eight states provide for general supervision for laser hair removal. General supervision means a supervising practitioner, often a physician or independent nurse practitioner, may be off-site but readily available via telecommunication methods to assist other providers, such as nurse practitioners, physician assistants, or registered nurses. Typically, on-site or direct supervision is required for non-licensed health care providers such as medical assistants, aestheticians or cosmetologists, whereby the supervising practitioner is required to be physically present in the same location where the provider is performing the medical function.

   b. **Training.** Most states mandate that physicians, nurse practitioners, physician assistants or registered nurses may perform laser hair removal with their general medical or nursing background, while some states require that the supervising practitioner have adequate training in the devices used for the procedure. IALA understands the need for additional training and most, if not all, its members have training on the following topics: laser basics, laser settings, treatment policies, and risk management.

3. **Current State Regulatory Oversight of the Profession.** There is currently a Virginia Medical Board Guidance Document ("Guidance Document") for light-based hair removal in physician practices (see attached). According to the Guidance Document, it is within a physician's authority to delegate laser hair removal to "personnel supervised by him," so long as the physician assumes full responsibility for the

provider's actions.[1] The Guidance Document suggests that physicians maintain written policies and procedures that "indicate the level of discretion granted to staff, as well as criteria that necessitate physician involvement."[2] It also suggests these written policies and procedures include training and/or certification for staff involved in laser hair removal treatments, including the initial assessment of the patient, informed consent, energy or fluence setting, management of complications, emergency preparedness and procedures, procedure if treatment results in an adverse reaction, and post-treatment follow-up.[3]

4. **Recommendation.** Based on the current national regulatory landscape and the existing Virginia Guidance Document, Virginia falls in line with the clear majority of states allowing for off-site supervision by a supervising practitioner. Any regulations developed by the two Boards to define the terms "direction and supervision," as used in § 54.1-2973.1, should provide for a general supervision regulatory framework, consistent with the existing Guidance Document, that allows a supervising practitioner to observe standard delegation protocol and scope of practice responsibilities while delegating the practice of laser hair removal to other licensed healthcare practitioners, including registered nurses, without being on-site.

   Moreover, the regulations should require on-site or direct supervision by a healthcare practitioner for non-licensed health care providers such as medical assistants, aestheticians or cosmetologists whereby the supervising practitioner is required to be physically present in the same location where the provider is performing the medical function. Additional training on laser hair removal topics such as those recommended in the 2008 Guidance Document would be useful for the providers.

Respectfully submitted,

International Aesthetic & Laser Association, Inc.

Nicole Strothman, President

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[1] Va. Bd. of Med., *Guidance Document for Light-Based Hair Removal in Physician Practices*, http://www.dhp.virginia.gov/medicine/guidelines/85-7Laser.doc (Feb. 21, 2008).
[2] Id.
[3] Id.

November 1, 2017

William L. Harp, MD
Executive Director
Virginia Board of Medicine
9960 Mayland Drive, Suite 300
Henrico, VA 23233
Submitted electronically: william.harp@dhp.virginia.gov

Re: 18VAC85-20, Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic
18VAC85-50, Regulations Governing the Practice of Physician Assistants

Dear Dr. Harp,

On behalf of the undersigned organizations, representing 14,000 dermatologists nationwide, we appreciate the opportunity to provide comments in response to the Virginia Board of Medicine's consideration of amending **18VAC85-20, Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic and 18VAC85-50, Regulations Governing the Practice of Physician Assistants.** We are concerned with weakening supervision and oversight requirements for laser hair removal, which would jeopardize patient safety and disregard adequate and appropriate medical training.

The Safety of Virginia Patients is at Risk
Our organizations believe that allowing "properly trained personnel" who may have no medical experience would jeopardize patient safety and disregard adequate and appropriate medical training.[1, 2] While these lasers are extremely safe and effective when used by medical professionals with appropriate training and oversight, in the wrong hands they can cause painful burns and permanent scarring.

Quality patient care includes evaluating a patient's needs and current condition, selecting an appropriate course of treatment, and providing adequate information and follow-up care. When non-physician practitioners are given legal approval to do the same procedures dermatologists spend years in medical and surgical training to perform, patient safety is seriously compromised. Short term, basic training is in no way equivalent to a physician's training and understanding of a medical procedure and its implications for each patient. Ultimately, patient safety and quality of care are seriously compromised.

Additionally, laser hair removal causes more complications than any other medical laser treatment. According to a study published in *Skin and Aging*, hair reduction was the most commonly treated condition that resulted in complications (46%), followed by laser/light leg vein treatments (21%) and non-facial photorejuvenation (11%).[3] Lower extremities were the most common location of complications (36%), followed by the face (22%) and neck (12%). Physicians performing these procedures have years of training in residencies to medically recognize and address complications, in addition to evaluating the patient to determine the most appropriate treatment. For example, laser hair removal procedures are less effective on individuals with light-colored hair and those with tanned or dark skin may be more susceptible to burning.

With multiple medical laser devices available on the market, and as more devices become available, it is critical to ensure that patient safety remains the primary objective. We feel strongly that cosmetic medical procedures, such as laser hair removal, are more safely performed in a dermatologist's office by the physician or under direct, on-site supervision by the physician. Non-ablative procedures, defined as a medical procedure using a laser, ultrasound, intense pulsed light, cryolipolysis, microwave or radio frequency device that is not expected or intended to remove, burn or vaporize the live epidermal surface of the skin, but may damage the live epidermal surface or underlying tissue if used inappropriately, should only be delegated to non-physicians through the use of a written protocol.[4]

According to a study by Mathew M. Avram, MD, JD, the percentage of medical malpractice lawsuits involving the non-physician use of medical lasers has grown steadily over the past four years, from just 38 percent of lawsuits in 2008 to 78 percent of lawsuits in 2011. According to this same data, 89 percent of laser hair removal-related medical malpractice lawsuits in the year 2011 involved non-physicians performing laser hair removal.[5]

The Use of Medical Lasers is the Practice of Medicine

Any procedure, including hair removal, which utilizes energy-based devices capable of damaging living tissue performed on human beings for cutaneous conditions should be considered as the practice of medicine. Consideration of laser and light-based hair removal as the practice of medicine is consistent with the American Medical Association and the American College of Surgeon's definition of surgery.[6]

Moreover, it is important to consider that in addition to the use of medical lasers themselves, laser hair removal also requires the use of a medical-grade topical anesthetic. In at least two cases, the dispension of this anesthetic without appropriate supervision has resulted in patient deaths. In 2007, and again in 2009, the Food and Drug Administration (FDA) issued public advisories cautioning consumers about this issue. As stated in the advisory:

> *FDA is aware of two instances where women, aged 22 and 25 years old, applied topical anesthetics to their legs to lessen the pain of laser hair removal. These women then wrapped their legs in plastic wrap, as they were instructed, to increase the creams' numbing effect. Both women had seizures, fell into comas, and subsequently died from the toxic effects of the anesthetic drugs. The skin numbing creams used in these two cases were made in pharmacies and contained high amounts of the anesthetic drugs lidocaine and tetracaine. The FDA also has received reports of serious and life-threatening side effects such as irregular heartbeat, seizures*

and coma, and slowed or stopped breathing following the use of these numbing products. These effects happened in both children and adults and when the anesthetic drug was used both for approved and unapproved conditions.[7]

In order to protect the people of Virginia from adverse events and to ensure quality care, **we urge the Virginia Board of Medicine to define "properly trained personnel" and "delegation and supervision" to include the direct, on-site supervision of non-physician providers and to ensure quality care by only allowing adequately trained providers to perform laser hair removal.** Should you have any questions, please contact Kristin Hellquist, ASDSA Director of Advocacy and Practice Affairs, at *khellquist@asds.net* or at (847) 956-9144.

Sincerely,

Henry W. Lim, MD, FAAD, President
American Academy of Dermatology Association

Lisa M. Donofrio, MD, President
American Society for Dermatologic Surgery Association

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[1] ASDSA *Position Statement on Delegation.* http://asdsa.asds.net/uploadedFiles/ASDSA/Policymakers/ASDSA%20-%20Regulation%20of%20Physician%20Assistants%20Position%20Statement(1).pdf

[2] *AAD Position Statement on the Practice of Dermatology – Protecting Patient Safety Quality Care.* https://www.aad.org/Forms/Policies/Uploads/PS/PS-Practice%20of%20Dermatology-Protecting%20Preserving%20Patient%20Safety%20Quality%20Care.pdf

[3] Narurkar, V. 2005, September. "Complications from Laser Procedures Performed by Non-Physicians." *Skin & Aging*. Volume 13 - Issue 9: 70 – 71.

[4] *Safe Laser and Energy-Based Device Act*. Retrieved Nov. 1, 2017. http://asdsa.asds.net/uploadedFiles/Safe%20Laser%20and%20Energy-Based%20Device%20Act.pdf

[5] Jalian HR, Jalian, CA, Avram M. Increased risk of litigation associated with laser surgery by nonphysician operators. JAMA Dermatol 2014; 150(4):407-11.

[6] Definition of surgery (2007). Retrieved Nov. 1, 2017. https://policysearch.ama-assn.org/policyfinder/detail/surgery?uri=%2FAMADoc%2FHOD.xml-0-4317.xml

[7] Food and Drug Administration. 2007, February 6. "Public Health Advisory: Life-Threatening Side Effects with the Use of Skin Products Containing Numbing Ingredients for Cosmetic Procedures." Retrieved from: https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm054718.htm

AMERICAN SOCIETY OF PLASTIC SURGEONS
THE PLASTIC SURGERY FOUNDATION

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October 23, 2017

The Honorable William L. Harp, MD, *Executive Director*
The Honorable Kevin O'Connor, MD, *President*
Virginia Board of Medicine
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233

RE: Recommendations for regulatory implementation of 2017 House Bill 2119

Dear Members of the Virginia Board of Medicine:

On behalf of the American Society of Plastic Surgeons (ASPS) I would like to submit comments to assist the Board in crafting regulations to implement 2017 House Bill 2119. ASPS is the largest association of plastic surgeons in the world, representing more than 7,000 members and 94 percent of all board-certified plastic surgeons in the United States. Our mission is to advance quality care for plastic surgery patients and promote public policy that protects patient safety.

House Bill 2119 restricts the practice of laser hair removal to physicians, physician assistants, nurse practitioners, and properly trained persons under the direction and supervision of one of the aforementioned medical professionals. While ASPS believes that physician assistants and nurse practitioners should perform these procedures under the supervision of a physician, we understand that HB 2119 is a considerable improvement to patient safety and appreciate the commitment of the legislature to improve such standards.

The law requires supervision and appropriate training for persons performing laser hair removal procedures. Due to the fact that these terms are not currently defined under Virginia law, we recommend the following for the Board's consideration:

Supervision

With respect to supervision, ASPS recommends the following supervision standards for physician assistants, nurse practitioners, and properly trained persons: the physician should be immediately available by electronic communication, be no further than fifty (50) miles away, and must be available to physically see the patient within twenty-four (24) hours. These supervision requirements are considerate of the fact that certain physician specialties like plastic surgeons are going to be in-hospital performing surgeries on some days, but also will provide a mechanism to protect the public from medispas with physician supervisors in name only.

Properly Trained

ASPS recommends that physicians be deemed as properly trained due to their existing medical training. For physician assistants and nurse practitioners, we recommend training that includes – at minimum – a formal laser safety course. Additional training in skin physiology, skin types, and device decision-making may be necessary. The paradigm of this additional training should be at the discretion of the supervising physician.

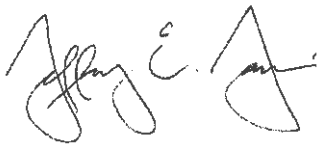
As for the new designation of 'properly trained persons' who lack formal medical education, we recommend certification that includes the following elements:

- Skin physiology and histology;
- Skin type analysis and patient selection;
- Laser and intense light physics and safety;
- Practical application to skin problems treated with medical laser and intense light devices; and
- A number of proctored patient cases (5-10) for each of the devices the individual will be operating.

There are several courses available that incorporate the above and award a certificate upon completion.

Thank you for your consideration of our recommendations. Please do not hesitate to contact Patrick Hermes, Senior Manager of Advocacy and Government Affairs, at phermes@plasticsurgery.org or (847) 228-3331 with any questions or concerns.

Sincerely,



Jeffrey E. Janis, MD, FACS
President, American Society of Plastic Surgeons

Yeatts, Elaine J. (DHP)

From: Henry Wilson <hbwilson1@gmail.com>
Sent: Sunday, May 21, 2017 8:04 PM
To: Harp, William L. (DHP); Yeatts, Elaine J. (DHP)
Subject: House Bill 2119

Dr. William Harp

Executive Director, Board of Medicine

9960 Mayland Drive

Suite 300

Henrico, Virginia 23233

Dr. Harp,

On behalf of the Virginia Society of Plastic Surgeons I would like to offer comments to assist the Board in drafting regulations to implement House Bill 2119.

House Bill 2119 restricts the practice of laser hair removal to physicians, physician assistants, nurse practitioners, and properly trained persons under the direction and supervision of one of the previous three. The legislation mandates both supervision and appropriate training for those performing laser hair removal procedures. As these terms are not defined we would offer the following recommendations for the Board's consideration.

Supervision

The Virginia Society of Plastic Surgeons would recommend that supervision be defined as immediately available to include by electronic or telephonic means but shall not be construed to mean physically present.

Properly Trained

The Virginia Society of Plastic Surgeons would recommend that physicians should be deemed as properly trained due to their existing medical training. For physician assistants and nurse practitioners, we recommend training that will include at a minimum a formal laser safety course. Additional training in skin physiology, skin types, and device decision-making may be necessary and this judgement should rest with their supervising/collaborating physician. For those performing laser hair removal who do not have formal medical education, we would recommend a formal certificate course that includes the following elements:

- Skin physiology and histology
- Skin type analysis and patient selection
- Laser and intense light physics and safety
- Practical application to skin problems treated with medical laser and intense light devices
- A number of proctored patient cases (5-10) for each of the devices the individual will be operating.

There are a number of courses currently available which cover the above and award a certificate upon completion.

In closing, I would like to thank the Board for their consideration. I am happy to answer any questions or to provide additional information.

Sincerely,

Henry Wilson, MD, FACS
President, Virginia Society of Plastic Surgeons

Yeatts, Elaine J. (DHP)

From: Henry Wilson <hbwilson1@gmail.com>
Sent: Friday, November 17, 2017 2:23 PM
To: Harp, William L. (DHP); Yeatts, Elaine J. (DHP)
Subject: HB 2119 Comments--Clarification of Supervision

Dr. William Harp

Executive Director, Board of Medicine

9960 Mayland Drive

Suite 300

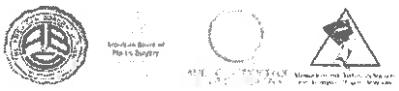
Henrico, Virginia 23233

Dr. Harp,

I will not be able to attend the regulatory advisory panel on Monday. My apologies. I would like to clarify our request for having supervision defined as "....immediately available to include by electronic or telephonic means but shall not be construed to mean physically present." There are times when the physician may not be able to be physically present due to offsite patient commitments such as surgery. As you are aware, prior to the passage of HB 2119 there were no requirement for supervision by a physician. The intent of the bill was to prevent improperly trained individuals from performing laser hair removal procedures. We welcome the provisions requiring supervision and proper training. However, we do not want to disrupt the established and safe practice of laser hair removal as performed in physicians' offices currently. We feel that properly trained individuals performing laser hair removal in a physician's office, with a physician available remotely when that physician is out of the office, is an appropriate standard of supervision.

Thank you for your further consideration. Please let me know if you have any questions.

Henry Wilson, MD, FACS
President, Virginia Society of Plastic Surgeons



Project 5269 - NOIRA

BOARD OF MEDICINE

Supervision and direction for laser hair removal

18VAC85-20-91. Practice and supervision of laser hair removal.

A. A doctor of medicine or osteopathic medicine may perform or supervise the performance of laser hair removal upon completion of training in the following:

1. Skin physiology and histology;

2. Skin type and appropriate patient selection;

3. Laser safety;

4. Operation of laser device or devices to be used;

5. Recognition of potential complications and response to any actual complication resulting from a laser hair removal treatment; and

6. A minimum number of 10 proctored patient cases with demonstrated competency in treating various skin types.

B. Doctors of medicine or osteopathic medicine who have been performing laser hair removal prior to (the effective date of this regulation) are not required to complete training specified in subsection A.

C. A doctor who delegates the practice of laser hair removal and provides supervision to a person other than a licensed physician assistant or licensed nurse practitioner, shall assure that such person has completed the training required in subsection A.

D. A doctor who performs laser hair removal or who supervise others in the practice shall receive ongoing training as necessary to maintain competency in new techniques and laser

devices. The doctor shall assure that persons he supervises also receive ongoing training to maintain competency.

E. A doctor may delegate laser hair removal to a properly trained person under his direction and supervision. Direction and supervision shall mean that the doctor is readily available at the time laser hair removal is being performed. The supervising doctor is not required to be physically present, but is required to see and evaluate a patient for whom the treatment has resulted in complications prior to the continuance of laser hair removal treatment.

F. Prescribing of medication shall be in accordance with provision of § 54.1-3303 of the Code of Virginia for the establishment of a practitioner/patient relationship.

18VAC85-50-191. Practice and supervision of laser hair removal.

A. A physician assistant, as authorized pursuant to § 54.1-2952, may perform or supervise the performance of laser hair removal upon completion of training in the following:

1. Skin physiology and histology;

2. Skin type and appropriate patient selection;

3. Laser safety;

4. Operation of laser device or devices to be used;

5. Recognition of potential complications and response to any actual complication resulting from a laser hair removal treatment; and

6. A minimum number of 10 proctored patient cases with demonstrated competency in treating various skin types.

B. Physician assistants who have been performing laser hair removal prior to (the effective date of this regulation) are not required to complete training specified in subsection A.

C. A physician assistant who delegates the practice of laser hair removal and provides supervision for such practice shall assure the supervised person has completed the training required in subsection A.

D. A physician assistant who performs laser hair removal or who supervise others in the practice shall receive ongoing training as necessary to maintain competency in new techniques and laser devices. The physician assistant shall assure that persons he supervises also receive ongoing training to maintain competency.

E. A physician assistant may delegate laser hair removal to a properly trained person under his direction and supervision. Direction and supervision shall mean that the physician assistant is readily available at the time laser hair removal is being performed. The supervising physician assistant is not required to be physically present, but is required to see and evaluate a patient for whom the treatment has resulted in complications prior to the continuance of laser hair removal treatment.

F. Prescribing of medication shall be in accordance with provision of § 54.1-3303 of the Code of Virginia for the establishment of a practitioner/patient relationship.

VIRGINIA BOARD OF MEDICINE

GUIDANCE DOCUMENT FOR LIGHT-BASED HAIR REMOVAL IN PHYSICIAN PRACTICES

INTRODUCTION

Light-based hair removal is and has been available in Virginia in physicians' practices and, as in other states, in nonmedical settings as well. The Board of Medicine receives a number of inquiries about the modality, usually in the realm of, "Does the Board of Medicine have laws or regulations governing light-based hair removal?" and "Is light-based hair removal considered the practice of medicine?"

There have been no Board of Medicine laws or regulations that specifically address light-based hair removal to inform the public, physicians and Board staff about this modality. Given the level of interest and lack of clarity in Virginia and across the nation on this matter, the Board determined that a review of the practice of laser hair removal should be undertaken. To accomplish this, an Ad Hoc Committee on Laser Hair Removal comprised of Board members and stakeholders was appointed to study light-based hair removal as it relates to the practice of medicine, public safety and the Board's role.

CURRENT VIRGINIA LAW

There is nothing in Virginia law specific to laser hair removal, the use of lasers or the delegation of authority to use lasers. However, in Section 54.1-2400.01 of the *Code of Virginia,* there is a definition of laser surgery as follows:

As used in this subtitle, "laser surgery" means treatment through revision, destruction, incision or other structural alteration of human tissue using laser technology. Under this definition, the continued use of laser technology solely for nonsurgical purposes of examination and diagnosis shall be permitted for those professions whose licenses permit such use.

Additionally, Chapter 29 in Title 54.1 (the Medical Practice Act) has general law about delegation. Found in Section 54.1-2901, there are exceptions to the requirement for a license to practice medicine in (4) and (6) for:

...4. Any registered professional nurse, licensed nurse practitioner, graduate laboratory technician or other technical personnel who have been properly trained from rendering care or services within the scope of their usual professional activities which shall include the taking of blood, the giving of intravenous infusions and intravenous injections, and the insertion of tubes when performed under the orders of a person licensed to practice medicine;

6. Any practitioner licensed or certified by the Board from delegating to personnel supervised by him, such activities or functions as are nondiscretionary and do not require the exercise of professional judgment for their performance and which are usually or customarily delegated to such persons by practitioners of the healing arts, if such activities or functions are authorized by and performed for such practitioners of the healing arts and responsibility for such activities or functions is assumed by such practitioners of the healing arts;...

CURRENT VIRGINIA REGULATIONS

Again, there are no Board regulations on the practice of laser hair removal in physician practices, but 18VAC85-20-29 on practitioner responsibility specifies that:

A. A practitioner shall not:
1. Knowingly allow subordinates to jeopardize patient safety or provide patient care outside of the subordinate's scope of practice or area of responsibility. Practitioners shall delegate patient care only to subordinates who are properly trained and supervised;

The foregoing laws and regulations make it quite clear that a licensee of the Board can delegate certain tasks and will be held accountable for the performance by subordinates.

What is not clear from the above laws and regulations is whether light-based hair removal is the practice of medicine.

MEDICAL OR AESTHETIC?

The statutory argument made for light-based hair removal not being considered the practice of medicine is the definition of the practice of medicine in the Code of Virginia. Section 54.1-2900 defines the practice of medicine as:

"Practice of medicine or osteopathic medicine" means the prevention, diagnosis and treatment of human physical or mental ailments, conditions, diseases, pain or infirmities by any means or method."

Given that normal hair follicles and normal hairs are the target of services, there appears to be no prevention or diagnosis of pathological conditions involved that would make light-based hair removal the practice of medicine. Misdiagnosis is often used as the argument that these services should be provided by physicians. The most worrisome missed diagnosis would be a malignancy. There are no malignant hairs, but there are some rare follicular tumors.

If the practice of medicine involves diagnosis and pathology, and if it is true that pathology requiring diagnosis is rarely encountered in those individuals seeking light-based hair removal services, then the larger issue for patient safety becomes the use of the machine and its potential for patient harm. The energy from the light-based devices

penetrates into the dermis and usually temporarily disables the hair follicle. In the hands of inadequately trained personnel, the machine becomes a greater risk factor, so proper training was seen by the committee as the most significant element in ensuring the public's safety. Just behind training in its impact on patient safety was supervision, and supervision will always be an issue when these services are provided in a physician's practice.

BOARD ACCEPTANCE OF COMMITTEE RECOMMENDATIONS

Based on the Committee's recommendations and further review by the Legislative Committee, the Board adopts the following principles:

1. That the use of intense pulsed light devices solely for the removal of hair does not appear to be the practice of medicine.

2. That the use of light-based devices that involve revision, destruction, incision or other structural alteration of human tissue constitutes laser surgery in accordance with § 54.1-2400.01 of the Code of Virginia.

Given these two principles, coupled with the laws and regulations governing physician delegation and responsibility, the Board provides the following guidance.

GUIDANCE

Physicians who perform or delegate any aspect of light-based hair removal are fully responsible for the provision of such services and should maintain written policies and procedures to include:

1) Training and/or certification for staff involved in hair removal services
2) Initial assessment of patient
3) Informed consent
4) Energy or fluence setting
5) Management of complications
6) Emergency preparedness and procedures
7) Procedure if treatment results in an adverse reaction
8) Post-treatment follow-up.

The written policies and procedures should indicate the level of discretion granted to staff, as well as criteria that necessitated physician involvement.

Adopted by the Board of Medicine on February 21, 2008

Agenda Item: Guidance document

Staff Note:

The Board has discussed the issues some applicants face with completion of Form B as required for licensure. The draft guidance should address questions and issues raised by applicants.

Enclosed is:

A copy of a draft guidance document on completion of Form B

Action: Motion to adopt Guidance Document 85-3.

Board of Medicine

Guidance on Completing Form B Employment Verifications

A completed Form B Activity Questionnaire or a letter of recommendation must be received from all locations of service, places of practice or professional employment, observerships, professional research positions or professional volunteer service listed for the 2 years immediately preceding application.

Complete the "Employment Activity" section of the application beginning with your professional school graduation. Leave no date gaps in the chronology. You should list all employers and locations of service. For example, if you work for a locums tenens or you are a traveler, name the employer and list all of the locations and dates where you provided service. It is helpful to request your placement company to send a list of all locations of service to the Board of Medicine for a minimum of the 2 years previous to the date of application.

A Form B Employment verification MUST be received for each location where professional services were provided for the 2 years previous to the date of the application. Form B's should be completed by a supervisor or colleague who is a medical professional. Form B's not completed by a medical professional may not be accepted. If the location where you provided service is closed or no longer in business, a Form B is still required. Applicants may need to make use of social media to contact former supervisors or colleagues. Applicants who allow their applications to stagnate may be required to provide Form B's for dates subsequent to the original date of application.

In lieu of Form B's the Board may accept a letter from the hospital credentials office that includes the dates privileges were active, their standing and whether there has been any disciplinary action. For travelers, the Board may accept evaluations completed by the location of service and provided to the placement company. These evaluations must be provided to the Board by the placement company.

Internships, residencies and fellowships must have a Form B if the training occurred within the last 2 years. If the training occurred more than 2 years prior to the date the application is submitted, you may provide a copy of the certificate of completion in lieu of a Form B. All post-graduate training received in the United States or Canada must be accounted for regardless of when it occurred.

For Medicine and Surgery and Osteopathy and Surgery applicants, verification of all post-graduate training is required regardless of when it was completed. If your post-graduate training was completed more than 2 years ago, the Board will accept a copy of the certificate of completion you were provided at the conclusion of the internship, residency or fellowship. If the post-graduate training was completed less than 2 years ago or you are still in a residency or fellowship program, a Form B must be received and it must be signed by the program director.

If engaged in private practice, without hospital affiliation, have another physician who is not related submit a Form B or letter of recommendation attesting to your practice.

For applicants practicing telemedicine, a Form B is only required from the chief medical officer of the company to which you are employed. To be accepted, the Form B must be signed by the CMO or medical director with a complete professional evaluation along with all locations of service.

Completed Form B's may be attached as a PDF and sent to medbd@dhp.virginia.gov, faxed to (804) 527-4426 or mailed by the person completing the document.