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JOINT COMMITTEE ON AGENCY RULE REVIEW
THE OHIO GENERAL ASSEMBLY
via email JCARR1@JCARR.STATE.OH.US

Re: Proposed Rules 4731-18-01 and 4731-18-03

Dear Committee Members,

On behalf of the American Med Spa Association (AmSpa), allow me to submit the following comments in relation to the current proposed rules for Light Based Procedures under Ohio Administrative Code Chapter 4731-18. We applaud the efforts to address the concerns surrounding unsupervised laser and light-based procedures in medical spas, an increasingly troublesome issue with which our industry is grappling across the country. While the proposal is well-intentioned and has some favorable components, we feel that because of the complexity and breadth of issues involved, the current proposal will ultimately not provide an adequate solution to the problem at hand and will unduly burden compliant practitioners. Therefore, we must oppose the proposed changes in their current form. AmSpa has been working on comprehensive medical spa standards and certification that we believe will fully address the underlying issues, and we request that we work together on creating a more focused solution.

AmSpa is the largest trade group in the medical spa industry. Consisting of more than 3,000 members, with close to 500 in Ohio alone, AmSpa is dedicated to ensuring the non-invasive aesthetic industry is safe and that its practitioners are trained, qualified and compliant. AmSpa's goal since its founding in 2013 is to ensure the aesthetic industry understands and complies with the myriad health care regulations put in place to ensure the public is protected and, ultimately, rid the industry of unqualified practitioners and unsupervised medical spas. AmSpa has endeavored to develop and disseminate comprehensive practice standards that will not only address the circumstances contemplated in your current proposed rules, but also ensure that medical spas commit to and comply with minimum standards and requirements widely accepted as safe practices.

Your current efforts fall squarely in AmSpa's purview and address issues that AmSpa has been tackling for more than six years. No one knows more about the underlying concerns in your proposal than AmSpa. With a database and corresponding legal analysis of medical spa laws in all 50 states, connections with nearly every medical spa in the country, and relationships with industry

executives and key opinion leaders throughout aesthetics, we are well positioned to assist you in leading the country in keeping this fast-growing, exciting industry safe for the public.

The Underlying Issue

Before we address the specific proposals, it is important to understand the underlying problem that this industry faces. The fact is that the overwhelming number of medical spas and aesthetic clinics offer services with very few incidents, side effects or bad outcomes. This is an overwhelmingly safe industry that offers incredibly popular and manifestly safe procedures. But as the industry has grown and become lucrative, we have seen a number of unsupervised medical aesthetic centers, often run by entrepreneurs as opposed to physicians, enter the industry. Often, these businesses try to follow the rules but find it difficult to find the relevant regulations to follow. And because many of the procedures offered in aesthetics are “non-invasive” and require little downtime, some of these businesses operate with limited medical oversight, if any at all. We refer to these businesses as “rogue medical spas,” and they are, unfortunately, the root of most of the problems this industry faces.

In your proposed rules, you accurately identify that laser treatments are often the primary culprit in terms of injury. Many of the problems occur because businesses do not treat laser and energy-based treatments as medical treatments. Instead, because they are easy to operate and, if performed properly, have little risk of complication, they are treated like spa services and offered without medical supervision. This is often done out of ignorance, not malice, but regardless, it is 100% the wrong approach. These are medical facilities offering medical treatment using medical devices. Accordingly, laser, light and energy-based treatments must be treated as medical procedures.

The real problem here is that rogue medical spas don’t treat their services as medical treatments, but rather as a commodity to be sold in order to make a profit. These businesses therefore do not have proper delegation and supervision protocols in place. But the solution here is much more simple than many in this industry assume: We need to explicitly define, through legislation or rulemaking, that these treatments are medical in nature and must be overseen by physicians, not laypeople. Once physicians (or formally delegated mid-levels such as nurse practitioners or physician assistants) take over responsibility for these treatments, they assume responsibility for ensuring they are performed safely by trained and qualified practitioners. This is the same standard as any medical treatment—while treatments may be delegated, it is the duty of the physician to ensure all treatments meet the applicable standard of care.

Comments on Proposed Rules

The proposed rules seek to provide training and supervision requirements for laser and light-based medical procedures. This is a laudable goal overall and one that we support. As written, though, the current proposal will likely not prevent the activity it seeks to stop, and will unduly burden many trained physicians and licensed professionals who are currently operating in a safe and compliant manner.

Definitions

The definitions used for many of the specific light-based procedures are too specific and leave out many common laser and light based treatments. Additionally, the specific definitions will have the effect of preventing the development and innovation of new laser or light-based treatments by Ohio physicians. As an example, section 4731-18-01 (B) defines phototherapy as one of two specific treatments, but it does not allow for the common red and blue LED light treatments often used to treat acne or reduce redness. Additionally, section 4731-18-01 (C) defines “ablative” as excising below the dermo-epidermal junction, and section (D) defines “non-ablative” as not excising below the epidermal surface of the skin. This leaves an undefined gap in the definitions for an intra-epidermal ablative procedure, which may excise a portion of the epidermis but is not expected to excise to the dermo-epidermal junction.

Further 4731-18-01 (I) “*Off-site Supervision*” includes a reference to a “cosmetic therapist” which is not a currently issued license in Ohio. This definition should be updated to either remove the specific reference or to make it generally applicable to situations where the physician’s physical presence is not required when delegating services under these sections.

Supervision and Delegation

The supervision and delegation requirements found in 4731-18-03 are unduly restrictive and do not follow practices common in the majority of states. An appropriate patient examination is critical to ensuring the high standards necessary to the practice of medicine. However, requiring that the physician personally perform this examination greatly underutilizes Ohio’s highly trained and skilled advanced practitioners, such as physician assistants (PAs) and nurse practitioners (NPs). In most states, these advanced licensees are permitted to perform patient examinations and prescribe treatments when working in a supervisory or collaborative relationship with a physician. If the medical board were to adopt a rule allowing these types of delegations, it would free the physician to focus on more complex and taxing cases and permit the advanced licensees the ability to practice to the level of their training, education and skill, as their counterparts in other states are able to.

Similarly, the requirement for physicians to be on site to supervise is unduly restrictive to their practice and excessive in light of many of the more common low-risk laser and light procedures. For these types of procedures, it is common for the physician to provide supervision while being readily available to respond to complications, but not necessarily on the physical premises. Further, many states permit the physician to delegate the supervision of the procedure to appropriately trained PAs and NPs who are physically on site. The current proposed rule will unnecessarily use up the physician’s time and reduce the total availability of medical care in Ohio.

Additionally section 4731-18-03 (C) appears to provide for substantially more leeway in the supervision of unlicensed persons performing laser hair removal than it does for licensed practical nurses (LPN) and registered nurses (RN). The physician is able to provide off site supervision the

the unlicensed persons but is required to be on site for RNs and LPNs when performing laser hair removal. Ideally, licensed healthcare professionals would be able to work under the same or better conditions as unlicensed persons.

Ablative and Non-Ablative Procedures

4731-18-03 as filed in general excludes unlicensed medical assistants from receiving any type of delegation. In excluding trained medical assistants from performing any non-ablative light or energy-based procedures, you have identified a pressing issue that must be addressed, but unfortunately we don't believe the solution proposed targets the real problem facing the industry. The problem here is not that medical assistants or other unlicensed professionals are unable to safely administer these procedures, but rather that physicians and business owners allow these procedures without proper training, delegation and supervision procedures in place. In other words, the problems herein are not caused by treatments being performed by trained individuals under proper supervision—they are caused by treatments being performed without any supervision at all.

Indeed, nationally we have seen many of these procedures offered safely and effectively when provided by trained health professionals under the supervision of a physician trained in the procedures. Like all other medical procedures, physicians should be able to delegate these procedures to individuals who are skilled, trained and experienced in the procedure. But like other procedures, before this happens the physician must perform a sufficient exam, implement proper protocols and engage in appropriate supervision.

The solution here is to clearly state that all non-ablative laser, light and energy-based aesthetic procedures are *medical procedures*, and that the physician (or mid-level practitioner, as appropriate) must utilize the same standard of care as they would for any medical procedure. By disseminating and implementing this rule, we will place the onus on the physician to prevent these procedures from taking place in unsupervised settings by individuals not trained or qualified to perform them in the first place.

Furthermore, restricting ablative procedures only to physicians does not comport with the practice environment elsewhere in the country. In most states, physicians are permitted to exercise their professional judgment and may delegate these types of procedures to appropriately prepared PAs and NPs, provided there is onsite physician supervision.

With all dermatologic procedures, our recommendation is to adopt a tiered approach where procedures are grouped by risk and chance of complication or injury. Under this approach, only higher level and advanced licensees would be permitted to perform the riskiest procedures, and licensed practical nurses (LPNs) and unlicensed persons would only be permitted to perform the least risky.

Training and Education

Proper training and education in light and other energy-based procedures is critical to maintaining high levels of patient care. However, the proposed rules currently are unduly onerous and would make it exceedingly difficult for non-physicians to meet the requirements on an ongoing basis. Many devices are multi-mode and able to provide a number of different non-ablative treatments. Additionally, it is extremely common for practices to own multiple types of laser and light devices from multiple manufacturers. Skills and knowledge in a certain procedure can translate across multiple similar devices, and knowledge and skill in one device can translate to its use in a number of differing procedures.

As stated above, the problem, here is not the lack of training, but rather that these procedures are sometimes performed without any physician supervision whatsoever. By requiring that a physician be involved in the process, it becomes the physician's responsibility to ensure delegates are properly trained and supervised in the procedures they are performing.

Accordingly, our recommendation is to require that the supervising physician review the prospective delegate's pertinent training, education and skill, and assess their competency. This assessment may include observing the person perform a procedure, but the frequency and requirement should be left to the physician's judgment. Training can take many forms—including classroom, hands-on and proctored demonstrations—but the specific form and sufficiency of a particular person's acquired skills should remain for the supervising physician to judge.

Conclusion

AmSpa welcomes the opportunity to work all stakeholders in this process. We are glad that the State of Ohio has recognized that laser and light procedures need to be further regulated. However, we cannot support your proposed rules in their current form. We have been researching, training and educating the industry for more than six years, and we have access to advisors and professionals who have been in the space for more than 20 years. We have the respect and confidence of over half of the existing medical spas in the U.S. We believe that by working together, Ohio will be the leader on this unique, but fast-growing industry, and other states will quickly follow Ohio's guidance. We look forward to hearing from you on how we can help shape the regulations to structure a complaint medical spa industry.

Very truly yours,



Alex R. Thiersch, CEO, AmSpa