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House Committee on Public Health
Indiana Statehouse
200 W Washington St.
Indianapolis, IN 46204

Re: SB 282

Members of the House Committee on Public Health,

On behalf of the American Med Spa Association (AmSpa), I would like to submit the following in relation to SB 282. We applaud the efforts to address the issues surrounding unlicensed providers operating medical spas, an increasingly troublesome issue that our industry is grappling with not only in Indiana, but across the country.

Ultimately, we can't support this bill, not because we don't support sensible legislation that makes the industry safer, but because we don't believe this bill achieves that purpose. While undoubtedly well-intentioned, this bill makes medical spas *less* safe by forcing compliant and safe medical practices – i.e. the good actors – into burdensome and expensive administrative compliance while failing to address the actual problem this industry faces. In short, this bill creates a compliance trap for safe medical spas (in addition to many other clinics swept up in its broad language), while allowing the bad actors to continue unabated.

There are three primary concerns that this Committee should be aware of:

- 1. The bill does not address the primary problem facing the medical spa industry – lack of enforcement against bad actors violating existing law.***

The central issue facing medical spas is individuals and businesses who are ***already violating existing law***. These bad actors will not be stopped by new paperwork requirements — only clarity and enforcement of existing law will solve the problem at hand.

As discussed in more detail below, medical spas are medical practices. Therefore, medical spas and their providers are already subject to the laws contained in Title 25 and their supporting regulations, including oversight by the Medical Board. In fact, the requirements created by this bill *are already required by Title 25 and the standards of care in physician and nursing practice*. What's more, the Medical Board already has both the authority and the jurisdiction to create and enforce rules to enforce existing law.

The issue we all want to solve is not the absence of law or regulation — ***it is the absence of clarity and enforcement of existing regulation.*** Unfortunately, for a variety of reasons, enforcement of existing law against bad actors has been virtually non-existent for years, leading to the emergence of an unchecked, unregulated “black-market” segment of the industry. It is this segment that is primarily responsible for violating compounding pharmacy rules, unauthorized practice of medicine violations, and patient complaints. The overwhelming majority of medical spas are operated by compliant, licensed providers motivated by safety and patient care. The laws already exist – we need consistent oversight to weed out the bad actors, not an entirely new regulatory system that the bad actors will ignore anyway.

2. SB 282’s registration and reporting requirements are burdensome, will make patient care more difficult for compliant actors, and will not improve patient safety in a meaningful way.

The registration requirement of SB 282 requires medical spas to list all medications, all procedures, and all practitioners at each location. In real medical practice, this creates a constant compliance trap — any staffing change, medication alteration, or new treatment requires administrative updates before care can even be offered. Under this bill, any physician who treats “wellness” or “longevity” – which in practice could be *any* physician in *any* practice – would be subject to reporting requirements *before* a new treatment was provided, a new medication was prescribed, or a new provider was contracted. Not only does this not improve patient safety in any meaningful way, but it is also inimical and antithetical to the physician-patient relationship.

Compliant physicians in wellness, lifestyle and aesthetics treat patients’ overall well-being, and that necessarily requires judgement based on experience, the standard of care, and the patient’s wants and needs. Forcing any licensed provider to submit to this level of administrative burden prior to adding any treatment, any change in medication, or any staffing change does not help Indiana patients; it simply creates ongoing burdens for compliant medical practices and interferes with their ability to treat patients.

3. The bill’s definition of “medical spa” is so broad that it would sweep a massive swath of physicians under its purview.

The bill’s definition of “med spa” is that provides treatments related to lifestyle, weight loss, wellness, hair loss, hormone therapy, or prenatal nutrient therapy. In practice, this definition would include virtually any physician in the state looking to improve a patient’s health and well-being. The definition could easily include OB/GYNs, cardiologists, sports medicine physicians, primary care doctors, general practitioners, dermatologists, and plastic surgeons — all of whom routinely prove these types of “lifestyle” treatments. SB 282 effectively subjects the entire Indiana medical practice to new registration and reporting requirements.

Given that lack of enforcement of current law has contributed to the current situation, it is unreasonable to think that the Medical Board has the capability to administer or enforce this type of administrative program. Moreover, it is highly doubtful the medical community in Indiana wants their medical decision-making to be subject to this level of oversight.

AmSpa and the Medical Spa Industry

The American Med Spa Association (AmSpa) is the largest trade group in the medical spa industry. Consisting of close to 4,000 members. We estimate that there are close to 1,500 medical aesthetic practices in Indiana employing up to 10,000 Hoosiers 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. It is in our best interests to rid the industry of unqualified practitioners and unsupervised medical spas.

Partnered with ByrdAdatto, the leading aesthetic health care law firm in the United States (headquartered in Dallas), as well as some of the top clinical providers in the industry, AmSpa has developed a database and corresponding legal analysis of the medical spa laws in all 50 states. We have also created comprehensive practice guidelines that will not only address the circumstances contemplated in the current bill but also ensure that *all* med spas commit to and comply with minimum standards and requirements widely accepted as safe.

How Safe (and Most) Medical Spas Work:

Medical spas are considered medical practices, and therefore the medical laws and regulations of each state govern medical spas in that state. In Indiana, med spas must adhere to the medical framework of a traditional medical practice, which make compliant med spas very safe. Reports of complications and side effects are rare, despite an explosion in treatments in recent years. Evidence of this exists in the cost of professional insurance policies for medical spas, which remain far below national averages. The numbers of lawsuits and malpractice claims is also far lower than other areas of medicine.

While medical spas are designed to have a more patient-centered experience (i.e. not as clinical and sterile as a typical doctor's office), the patient treatment process is the same:

- All patients are examined by qualified and experienced physicians, or, with proper documentation and training in place, qualified and experienced Physician Assistants or Nurse Practitioners.
- Informed consent must be obtained, including the patient being informed that they are being seen and treated by a non-physician, if that is the case.

- Following this initial examination, treatments can only be delegated to providers that the delegating physician confirms are trained and qualified in the procedures being offered, and only if properly supervised.
- Proper protocols and procedures for addressing side effects, complications and emergency situations must be in place.
- Practicing within HIPAA and OSHA standards.
- Implement up-to-date and thorough standard operating procedures (SOPs).
- Ensure that physicians are well-trained in every procedure offered; and
- Nurse practitioners, physician assistants, and registered nurses are licensed in good standing, and well-trained in every procedure offered.

The Path Forward: Working Together

AmSpa welcomes the opportunity to work with all stakeholders on this issue. We have been researching, training, and educating the industry for over twelve years, and we have access to advisors and professionals that have been in the space for over 20 years.

AmSpa has already developed detailed practice guidelines defining safe and compliant operations, and this year we are launching a national compliance certification program so patients can identify responsible providers. We welcome the opportunity to work with Indiana legislators and regulators to strengthen patient safety in a way that is practical, enforceable, and effective.

Respectfully,



Alex R. Thiersch
Chairman, American Med Spa Association (AmSpa)

Appendix A: Specific Concerns with the SB 282 Language

1. Overbroad Definition of “Medical Spa”

The bill defines a “medical spa” as any facility that holds itself out as focused on “cosmetic or lifestyle treatments,” including weight loss, wellness, longevity, hormone therapy, hair loss, aesthetic services, and IV therapies.

Under this definition, the bill would reasonably apply to practices focusing in, among others:

- OB/GYN
- Primary Care
- Family Practice
- Sports Medicine
- Cardiology
- Internal Medicine
- Dermatology
- Plastic surgery

In effect, the bill does not regulate a niche industry — it reclassifies a massive portion of modern medical practice as “medical spas.”

2. Creates Regulatory Burdens for Mainstream Medicine

Because of this definition, thousands of physician practices that have nothing to do with the typical concept of a “med spa” would be required to register as medical spas, disclose all medications and procedures, continuously update staffing and treatment offerings, and maintain ongoing administrative compliance unrelated to patient safety.

3. Turns Ordinary Medical Operations into Compliance Traps

In real-world medicine, providers regularly update services, adopt new treatments, and experience staffing changes. Under this bill, each of those routine events becomes a regulatory risk — requiring updated filings before care can even be delivered.

4. Section 9: Prohibition on Off-Site Care

Section 9 prohibits medical spas from providing services anywhere other than a medical office, physician’s office, or licensed health care facility. This would unintentionally block education and training and eliminate legitimate home-based and mobile care models.

5. Section 6: Adverse Event Reporting Requirements

The adverse event definitions are misaligned with outpatient aesthetic care and would create overwhelming reporting burdens given the bill’s broad scope.