Division of Professional Regulation

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# IDFPR, IDPH Issue Memo Regarding Medical Spa Services

In recent years, numerous medical spas ("medspas") have opened in Illinois. A variety of nonsurgical cosmetic procedures are performed in this setting, including injections of botulinum toxin (Botox), injections of weight loss medications, dermal fillers, laser hair removal, platelet rich plasma, and vitamins.

This memo from Illinois Department of Financial and Professional Regulation (IDFPR) and Illinois Department of Public Health (IDPH) outlines key responsibilities of medspas and includes information for compliance with IDFPR and IDPH regulations and the need to make infection prevention a priority.

# I. Regulatory Requirements:

# 1. IDFPR topics:

Physicians licensed to practice medicine in all of its branches have, within their scope of practice, the ability to operate a medspa, including performing cosmetic procedures which affect the living layers of skin, and to prescribe and administer drugs, including Botox and weight loss medication injections. A licensed physician may also supervise and delegate these procedures. A licensed physician may also perform microblading without a body art license from IDPH. Nothing shall be construed to limit the delegation of patient care tasks or duties by a physician, to a licensed practical nurse, a registered professional nurse, or other licensed person practicing within the scope of his or her individual licensing Act. No physician may delegate any patient care task or duty that is statutorily or by rule mandated to be performed by a physician. In an office or practice setting and within a physician-patient relationship, a physician may delegate patient care tasks or duties to an unlicensed person who possesses appropriate training and experience provided a health care professional, who is practicing within the scope of such licensed professional's individual licensing Act, is on site to provide assistance. Any such patient care task or duty delegated to a licensed or unlicensed person must be within the scope of practice, education, training, or experience of the delegating physician and within the context of a physician-patient relationship. 225 ILCS 60/54.2

Advanced Practice Registered Nurses (APRNs), pursuant to 225 ILCS 65/65-43, who possess full practice authority have, within their scope of practice, the following abilities: (1) all matters included in subsection (c) of Section 65-30 of the Act; (2) to practice without a written collaborative agreement in all practice settings consistent with national certification; (3) the authority to prescribe both legend drugs and Schedule II through V controlled substances; this

authority includes prescription of, selection of, orders for, administration of, storage of, acceptance of samples of, and dispensing over the counter medications, legend drugs, and controlled substances categorized as Schedule II through V controlled substances, as defined in Article II of the Illinois Controlled Substances Act, and other preparations, including, but not limited to botanical and herbal remedies; (4) to prescribe benzodiazepines or Schedule II narcotic drugs, such as opioids, only in a consultation relationship with a physician this consultation relationship shall be recorded in the Prescription Monitoring Program website, pursuant to Section 316 of the Illinois Controlled Substances Act, by the physician and advanced practice registered nurse with full practice authority and is not required to be filed with the Department; the specific schedule II narcotic drug must be identified by brand or generic name and may be administered by oral dosage, topical, or transdermal application; injection or other route of administration is not permitted; at least monthly, the physician must discuss the condition of the patients for whom a benzodiazepine or opioid is prescribed with the advanced practice registered nurse; (5) the authority to obtain an Illinois controlled substance license and a federal Drug Enforcement Administration number; (6) use local anesthetic only; and (7) delegate selected nursing interventions to a licensed practical nurse, a registered professional nurse, or other personnel. Their authority does not include operative surgery.

Delegation of authority by registered professional nurses: 225 ILCS 65/50-75 indicates that a Registered Professional Nurse may: (1) delegate nursing interventions to other registered professional nurses, licensed practical nurses, and other unlicensed personnel based on a comprehensive nursing assessment including (a) the stability and condition of the patient; (b) the potential for harm; (c) the complexity of the nursing intervention to be delegated; (d) the predictability of outcomes; and (e) competency of the individual to whom the nursing intervention was delegated; (2) delegate medication administration to other nurses; (3) in community based or in home care settings, delegate the administration of medication (limited to oral or subcutaneous dosage and topical or transdermal application) to unlicensed personnel, if all the conditions for delegation are met; (4) refuse to delegate, stop, or rescind a previously authorized delegation; or (5) in community based or in home care settings, delegate, guide, and evaluate the implementation of nursing interventions as a component or patient care coordination after completion of the comprehensive assessment based on analysis of the comprehensive assessment data; care coordination in home care and school settings may occur in person, by telecommunication, or by electronic communication.

Medical esthetics and other professions: cosmetologists and estheticians are prohibited from using any technique, product, or practice intended to affect the living layers of the skin. (Barber, Cosmetology, Esthetics, Hair Braiding and Nail Technology Act of 1985; 225 ILCS 410/3-1 and 410/3A-1.) Cosmetologists, estheticians, and nail technologists are not permitted to provide services that are "for the treatment of medical disorders" and they are prohibited from "render[ing] advice on what is appropriate medical treatment for diseases of the skin and nails" 225 ILCS 410/3-1, 3A-1 and 2, and 3C-1.

Cosmetologists, estheticians, and nail technologists may only provide services that are within their respective scopes of practice as set forth in the Barber, Cosmetology, Esthetics, Hair Braiding, and Nail Technology Act of 1985. Further, that a salon registration issued by IDFPR cannot be used

to operate a medspa and any such salon may only provide services authorized by the Barber, Cosmetology, Esthetics, Hair Braiding, and Nail Technology Act of 1985 under its registration.

**Prohibited Practices:** IDFPR issued a statement that the following procedures constitute the practice of medicine and are not within the scope of practice of a cosmetologist or an esthetician (see <u>IDFPR Statement on Prohibited Practices</u>): botox (botulinum toxin); chemical peels; collagen injections; colonics; liposuction; microdermabrasion, (except superficial or light microdermabrasion intended to only remove dead skin cells, oil, and other debris from the surface of the skin); dermaplaning; microblading; microneedling; Radio Frequency; and Hydrafacial machine treatment.

Lasers: IDFPR also issued a statement regarding lasers, which discusses that the Rules for the Administration of the Medical Practice Act includes Section 1285.336 Use of Lasers, specifies that the use of lasers is the practice of medicine, and excludes the use of lasers from the practice of cosmetology and esthetics (see IDFPR Statement Regarding Lasers). This statement states that procedures involving a laser classified by the FDA as a medical device must be performed by a licensed physician. The physician must examine the patient and determine an appropriate course of treatment before laser procedures are performed. The physician may delegate the performance of laser procedures to a person who is functioning as an assistant to the licensed physician; and that an individual may not hold himself or herself out as a cosmetologist or esthetician while performing a service delegated by a licensed physician. An individual may not indicate in any manner that a service delegated by a licensed physician is part of the practice of cosmetology or esthetics.

The use of a light emitting device, including, but not limited to, intense pulsed-light, red light therapy, low-level laser; cold and soft laser therapy; and non-thermal LED light, radiofrequency and medical microwave devices used for the treatment of dermatologic conditions or cosmetic procedures that disrupt the epidermal surface of the skin, whether ablative or non-ablative, is considered to be the practice of medicine, and shall only be performed by a physician licensed to practice medicine. A physician licensed to practice medicine in all of its branches may delegate the performance of ablative procedures to a licensed practical nurse, a registered professional nurse, full practice authority APRN, or other persons, with on-site supervision by the physician. A physician licensed to practice medicine in all of its branches may delegate the performance of nonablative procedures to a licensed practical nurse, a registered professional nurse, full practice authority APRN, or other persons, with on-site supervision by the physician or the physician must be available by telephone or other electronic means to respond promptly to any question or complication that may occur. A licensed practical nurse, registered professional nurse, full practice authority APRN, or other person delegated the authority to perform any ablative or non-ablative procedures must have received appropriate, documented training and education in the safe and effective use of each system utilized in accordance with 68 Illinois Administrative Code 1285.336.

**Ownership and Entity Restrictions:** The Medical Practice Act and the Nurse Practice Act require that medspas be owned and operated by physicians and for some services can be owned and operated by an APRN, since services provided are medical services. Medspas can choose the type of corporate entity under which they operate. Only physicians may organize under the Medical Corporation Act, 805 ILCS 15/et seq., but physicians may also organize under the Professional

Service Corporation Act, 805 ILCS 10/ et seq., or the Professional Limited Liability Company Act, 805 ILCS 185/et seq. APRNs may only organize under the Professional Service Corporation Act or the Professional Limited Liability Company Act. A corporate entity operated by a physician may only have physicians as shareholders or members, officers, directors, or managers with some limited exceptions. A corporate entity operated by an APRN must likewise only have APRNs as shareholders or members, officers, directors, or managers. A person who is not a physician or an APRN cannot be a shareholder or member, officer, director, or manager. A medspa that does not organize as a corporate entity (such as a sole proprietorship or a partnership) must be owned and operated by a physician(s) or APRN(s). Medspas organized as a professional limited liability company, a professional service corporation, or a medical corporation are required to register with and are regulated by the IDFPR. Also required is that these medspas file appropriate articles with the Illinois Secretary of State, in addition to applying for registration as a PSC, PLLC, or medical corporation with the IDFPR.

All medspas are subject to the restrictions of the Medical Practice Act, including those regarding advertising in accordance with 225 ILCS 60/26.

All professional entities regulated by the IDFPR under the PLLC and PSC Acts are limited to performing one type of professional service and certain types of "related professional services" as set forth in the Professional Limited Liability Company Act at 805 ILCS 185/13 and the Professional Service Corporation Act at 805 ILCS 10/3.6. None of the "related professional services" listed in the Acts would permit the practice of cosmetology or esthetics by the same entity that is also practicing medicine, or vice versa. Entities organized under the Medical Corporation Act may only provide medical services.

When medical procedures are performed at a medspa, they must be performed by a licensed physician within their scope of practice or by the delegation of a licensed physician within their scope of practice to a person appropriately trained and supervised by the physician. The medspa may employ persons who have other licenses, such as nurses, advance practice nurses with or without full practice authority, physician assistants, and other laypersons, as long as they are properly trained and supervised by the physician, and there exists a physician-patient relationship with the person receiving the services. A medspa may employ a cosmetologist or an esthetician as an employee but said employee may not hold themselves out as practicing under the scope of their cosmetology or esthetics license while performing delegated medical procedures from a physician.

Facilities providing cosmetology and/or esthetics services are required to obtain a shop or salon registration with the IDFPR pursuant to 225 ILCS 410/3D-5, and are not permitted to use a business name that includes "medical" terminology, as the Rules regarding that Act also provide in Section 1175.1305(b), regarding salon and barber shop registrations, that "the use of "medical" or similar term in a business name is deemed to imply a service that cannot be legally offered by the salon or shop and to be misleading to consumers and is therefore prohibited."

# 2. IDPH topics

IDPH Communicable Disease Rules (77 Illinois Administrative Code 690) require reporting to the Local Health Department of (1) any unusual case of a disease or condition caused by an infectious agent that is of urgent public health significance, and (2) any outbreak of public health significance. Any unusual infection, outbreak, or suspected case or outbreak should be reported to the local health department. All staff at medspas are designated as reporters. In addition, Section 690.30 of the Rules establishes routine measures for the control of communicable diseases (CDs) by IDPH, LHDs and health care providers and establishes progressive initiatives to ensure that disease-appropriate measures are implemented to control the spread of CDs. IDPH Communicable Disease (CD) Rules require reporting to the Local Health Department (LHD) of (1) any unusual case of a disease or condition caused by an infectious agent that is of urgent public health significance, and (2) any outbreak of public health significance. This may include onsite investigations, collection and testing of samples, lists of patients and their contact information, review of medical records, and performing interviews of patients to collect pertinent and relevant information. A directory of local health departments is available at: <a href="https://dph.illinois.gov/contact-us/regional-health-departments.html">https://dph.illinois.gov/contact-us/regional-health-departments.html</a>.

### **II. Infection Prevention**

Although most medspa procedures are associated with minimal adverse events, an increase in the number of procedures performed in this setting may lead to a concurrent increase in the number of complications. Among these complications is the rare, yet potentially serious, incidence of severe skin and soft tissue infections. <sup>1,2</sup> Infections related to injections and other procedures that disrupt skin integrity can be due to a variety of factors, and can result in skin and soft tissue infection, as well as blood borne pathogen (e.g. hepatitis B virus, hepatitis C virus, and HIV) transmission.

All medspas, regardless of the level of care provided, must make infection prevention a priority per CDC's and OSHA's guidance below, as they are considered health care facilities. Key aspects of infection control include establishing and maintaining infection control policies and procedures; proper use and handling of needles, cannulae, and syringes; proper handling of medication and solutions; adherence to aseptic technique; and proper reprocessing of equipment.

The Centers for Disease Control and Prevention (CDC) has developed numerous resources to support infection control in outpatient settings, including the following:

 CDC. <u>Safe Injection Practices to Prevent Transmission of Infections to Patients</u>. 2011. (Excerpt from the <u>2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings</u>)

<sup>&</sup>lt;sup>1</sup> Beshearse, E., Perz, J. and Perkins, K.M., 2022, December. 1222. <u>Summary of CDC consultations related to non-traditional medical therapies</u>, 2016—2021. In *Open Forum Infectious Diseases* (Vol. 9, No. Supplement\_2, pp. ofac492-1054).

<sup>&</sup>lt;sup>2</sup> Ferneini EM, Beauvais D, Aronin SI. <u>An overview of infections associated with soft tissue facial fillers:</u> identification, prevention, and treatment. Journal of Oral and Maxillofacial Surgery. 2017 Jan 1;75(1):160-6.

Safe injection practices are intended to prevent transmission of infectious diseases between one patient and another, or between a patient and health care personnel during preparation and injection of medications.

2. CDC. <u>Guide to Infection Prevention for Outpatient Settings (Complete Guide and Checklist)</u>. 2016.

This summary guide represents the <u>minimum</u> infection prevention expectations for safe care in outpatient settings. Medspas are urged to use the Infection Prevention Checklist for Outpatient Settings (Appendix A), a companion to this and to consult additional CDC guidelines (available at <a href="http://www.cdc.gov/HAI/prevent/prevent\_pubs.html">http://www.cdc.gov/HAI/prevent/prevent\_pubs.html</a> for additional background, rationale, and evidence behind each recommendation.

Infection prevention programs must extend beyond Occupational Safety and Health Administration (OSHA) bloodborne pathogens training to address patient protection. Facilities should ensure that at least one individual with training in infection prevention is employed by or regularly available (e.g., by contract) to manage the facility's infection prevention program. This individual should be involved in the development of written infection prevention policies and have regular communication with heath care personnel to address specific issues or concerns related to infection prevention. The development and ongoing refinement of infection prevention policies and procedures should be based on evidence-based guidelines, regulations, or standards. These policies and procedures should be tailored to the facility and re-assessed on a regular basis (e.g., annually), taking into consideration the types of services provided by the facility and the patient population that is served. This process (referred to as risk assessment by the Infection Prevention profession) will allow facilities to better prioritize resources and focus extra attention on that are determined to pose greater risk to their

3. CDC. <u>Guidelines for Environmental Infection Control in Health-Care Facilities</u>. 2003 (Updated July 2019).

Throughout healthcare, the physical environment represents an important source of pathogens that can cause infections, e.g., fungi can be present on wet or damp surfaces or materials, and bacteria can be present in plumbing fixtures including sink drains or ice machines. Lack of adherence to established standards and guidance can result in adverse patient outcomes in health-care facilities.

In addition, industry groups such as the National MedSpa Association have also developed <u>infection control resources</u> relevant to medspas to assist with development and implementation of infection prevention programs.

For any questions related to infectious disease reporting requirements, please contact your local health department. To make a complaint about a professional licensed through the IDFPR, please visit <a href="http://idfpr.illinois.gov">http://idfpr.illinois.gov</a> or call the Department complaint line: (312) 814-6910.