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Healthcare Alert

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## Rhode Island issues guidance for medical spas and IV therapy businesses

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Rhode Island joins a growing number of states issuing ownership and scope of practice regulations in response to a drastic increase in medical spas and intravenous (IV) therapy businesses



### What's the impact?

- Medical spas and IV therapy businesses in Rhode Island must comply with new guidance from RIDOH with respect to licensure, ownership, standard of care, and standard of practice
- Failure to comply could result in disciplinary action and/or penalties

The Rhode Island Department of Health (RIDOH) [released guidance](#) with respect to licensure, ownership, standard of care, and standard of practice in medical spas and IV therapy businesses. Failure to abide by the guidance may be deemed unprofessional conduct and result in disciplinary action by applicable licensing boards, fines, and/or civil or criminal penalties.

## **Applicability of guidance**

RIDOH's expansive authority includes overseeing healthcare facilities and healthcare professionals in Rhode Island. In recent years, RIDOH has seen a steep rise in the popularity of two new healthcare industries—medical spas and IV therapy businesses.

Medical spas offer a broad range of services, from traditional esthetic services (e.g., hairdressing and manicures) to medical procedures (e.g., Botox, fillers, and laser hair removal). IV therapy services may be provided at a medical spa but are more commonly emerging as standalone businesses.

Both types of businesses advertise their panel of services as minimal risk, which typically results in their designation as spa treatments rather than medical procedures. RIDOH notes that this can lead to confusion among healthcare professionals and the public regarding each specialty's responsibilities in providing these services.

Further, RIDOH uncovered that many businesses in the medical spa and IV therapy space have been operating without proper healthcare facility licensure and/or have providers performing procedures that are not within their scope of practice or aligned with the proper standard of care. As such, patients' medical treatments in medical spas or IV therapy businesses have a higher risk for complications, including insufficient results (requiring additional procedures), infections, burns, and, in extreme cases, death.

Consequently, RIDOH's Division of Healthcare Quality and Safety (DHQS), after consultation with the professional boards of licensure and discipline, issued guidance to clarify the licensure, ownership, standard of care, and standard of practice for healthcare professionals staffing medical spas and IV therapy businesses.

## **Business ownership and licensure**

According to RIDOH's guidance, a medical spa and IV therapy business's need for a healthcare facility license is determined by several factors, including ownership structure, scope of services, and professional licenses obtained by the owners, if any. When the owner and/or operator is not licensed by a professional board in Rhode Island or does not otherwise meet an exemption through a professional service corporation (PSC), the medical spa or IV therapy business must obtain an organized ambulatory care facility (OACF) license. An OACF license requires prior initial licensure review and recommendation by the Health Services Council before the license is issued by the Center for Health Facilities Regulation (CHFR).

Rhode Island law allows certain professions, such as physicians, dentists, registered nurses (RNs), and physician assistants (PAs), to form PSCs. Through this formation, licensed professionals are exempt from obtaining an OACF license (unless providing services within a mobile unit) so long as licensed professionals own and operate the business and, importantly, provide services within

their scope of practice. Rhode Island law also permits a combination of professional licensees to form a PSC (e.g., physician and dentist) to qualify for exemption from the OACF license, as long as at least one of the professionals performs the services the business is offering, and such services are within the licensed professional's scope of practice. Further, if a medical spa provides, arranges to provide, offers to provide, or in any other way provides for the delivery of direct nursing services in a workplace, poolside, event space, etc., outside of their normal physical location, the medical spa must obtain a home nursing care provider (HNCP) license regardless of the professional license the medical spa has. The medical spa must submit a certificate of need (CON) to obtain the HNCP license. If the medical spa utilizes a mobile unit or wants to provide services in a van, trailer, or other mobile method, the medical space must obtain an OACF license.

The guidance also highlights instances where a provider or group of providers form a PSC to meet the exemption requirement but then utilize a management company to provide significant influence over the business operations while the providers have little to no involvement. If a management company exhibits significant influence over the business, the guidance states that the business must obtain an OACF license. Further, if a business chooses to engage a management company, the business will be responsible for the limited services provided by the management company.

## **Standard of care in medical spas and IV therapy businesses**

Before a patient receives services in a medical spa or from an IV therapy business, the patient must first be assessed by practitioner licensed in Rhode Island<sup>1</sup>. Rhode Island laws only allow the following professionals to diagnose, treat, correct, advise, or prescribe medication (including IV fluids) to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other medical condition:

- / Rhode Island licensed allopathic or osteopathic physician;
- / Licensed physician assistant (PA) with sufficient academic and practical training to provide medical and surgical services in collaboration with physicians;
- / A certificated nurse practitioner (CNP);
  - Only CNPs specializing in family practice and adult gerontology may participate in medical spas and IV therapy businesses. The remaining CNP specialties are prohibited from performing services as the procedures are outside the scope of practice and training.
- / Licensed dentists.<sup>2</sup>

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<sup>1</sup> For purposes of this alert, "practitioner" means physician, PA, or CNP.

<sup>2</sup> "Dentistry" means the evaluation, diagnosis, prevention, and/or treatment (nonsurgical, surgical, or related procedures) of diseases, disorders, and/or conditions of the oral cavity, cranio-maxillofacial area, and/or the adjacent

Physicians, PAs, CNPs, and dentists must create comprehensive medical records that comply with the standard of care. Additionally, a practitioner must obtain informed consent prior to the patient receiving services and document the consent in the patient's medical record. Along with informed consent, the patient's medical record must include:

- / Patient history;
- / Examination results;
- / Records of drugs (including intravenous fluids) prescribed, dispensed, and/or administered;
- / Diagnosis;
- / Nature and purpose of recommended interventions;
- / Burden, risks, and expected benefits of all options, including foregoing treatment; and
- / Patient's decision.

Rhode Island retention laws mandate that medical records be stored for at least seven (7) years. Medical spas are prohibited from circumventing the physical assessment requirement through the use of standing orders.

## **Scope of practice and standard of care requirements specific to IV therapy businesses**

Services offered at an IV therapy business are considered the practice of medicine<sup>3</sup> and require an evaluation, diagnosis, and treatment of the patient. The guidance states that professionals, such as emergency medical service practitioners (EMTs),<sup>4</sup> phlebotomists, licensed practical nurses, nursing assistants, medical assistants, dentists, podiatrists, chiropractors, veterinarians, naturopaths, and midwives are prohibited from providing services at these businesses because the procedures fall outside the scope of practice of such professionals.

RIDOH notes that when RNs are the only licensed healthcare providers onsite at an IV therapy business, the RN is exceeding their scope of practice if they engage in diagnosing, prescribing, compounding, and/or treating the patient with IV hydration or therapy a patient. IV therapy businesses that have a physician, PA, and/or CNP owner, co-owner, investor, or associate must have a practitioner evaluate the patient to make a diagnosis and prescribe a specific therapy to treat that diagnosis; otherwise, the valid practitioner-patient relationship necessary to prescribe

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and associated structures and their impact on the human body.

<sup>3</sup> "Practice of medicine" as it is used in this document does not mirror the term as it is used under R.I. Gen. Laws § 5-37-1 or the rules and regulations for *Licensure and Discipline of Physicians* (216-RICR-40-05-1).

<sup>4</sup> The guidance notes that even for those procedures that would typically fall within the EMT scope, EMTs cannot provide these services for a medical spa or IV therapy business since EMT licensure is solely in affiliation with their ambulance service licensed by RIDOH unless the EMT is providing care as a Good Samaritan (Emergency Medical Services, 216-RICR-20-10-2).

and administer drugs, including IV therapies, is not established. Further, practitioners deemed “medical director,” “consultant,” “collaborator,” “on staff,” or “available,” but having an RN assess and treat the patient will not suffice to establish that relationship. Per the guidance, an in-person medical assessment is preferred and cannot be satisfied through use of a simple questionnaire, which is strictly prohibited and may be deemed professional misconduct.

Instead, a practitioner must create a comprehensive medical record that complies with the standard of care in the manner detailed above. Even if an IV therapy business has a practitioner available via telemedicine, they must still follow medical records and standard of care requirements. Utilizing the NPI number of a physician, PA, or CNP via telemedicine to acquire necessary supplies and then using standing orders directing the administration of IVs does not satisfy the standard of care by such practitioner, and the use of standing orders for this is considered unprofessional conduct that could lead to disciplinary action.

IV treatments should be individualized to patients and prescribed in the same manner as an urgent care center, emergency department, or hospital. An IV therapy business cannot remove the practitioner involvement requirement and allow a patient to direct their own care, which includes a practitioner (or nurse) allowing a patient to select their own medications and/or IVs from a menu. If such an act occurs, it will be considered unprofessional conduct.

## Compounding

The IV therapy business model typically involves providing walk-in patients with a variety of pre-selected mixtures of additives to basic IV fluids (e.g., saline), including amino acids, vitamins, minerals, nutrients, and some medications, like famotidine, omeprazole, ibuprofen, or ondansetron. These mixtures offer several remedies to patients, including treating dehydration, migraines, hangovers, nausea, athletic or postoperative recovery, appetite regulation, and/or inflammation support. When an IV therapy customizes an IV mix based on the patient’s selection or examination results and adds any drug(s)/medication(s), vitamin(s), mineral(s), amino acid(s), or other substance to an IV bag, it is considered compounding.<sup>5,6</sup>

Because of this, compounding must originate from a valid practitioner’s order during professional practice and not from a patient-driven menu. The United States Pharmacopeia (USP) publishes standardized requirements for compounding, including sterile compounding found in USP <797>, and has been adopted by the FDA and RIDOH as the enforceable standard.

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<sup>5</sup> “Compounding” means “[t]he act of combining two or more ingredients as a result of a practitioner’s prescription or medication order occurring in the course of professional practice based upon the individual needs of a patient and a relationship between the practitioner, patient, and pharmacists.” (*Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors* (216-RICR-40-15-1)).

<sup>6</sup> “Compounding” means “[t]he process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs.” (Rules and Regulations for The Food and Drug Administration (FDA)).

Further, all compounding must also meet the requirements promulgated within *Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors* (216-RICR-40-15-1).

Rhode Island law allows pharmacists to compound drugs and oversee trained personnel compounding drugs. Physicians may also compound, in addition to delegating compounding to other healthcare professionals under a physician's supervision. When compounding, physicians must follow USP <797> and the rules and regulations for *Pharmacists, Pharmacies, and Manufacturers, Wholesalers and Distributors* (216-RICR-40-15-1). The regular storage, preparation, and compounding of drugs by anyone other than these licensed professions is prohibited unless otherwise licensed by RIDOH.

Compounding IV therapy businesses must have a physician on-site for supervised compounding or have a licensed pharmacy on-site to prepare compounds under pharmacist supervision. Remote supervision of compounding is not allowed. IV therapy businesses that do not compound may outsource from a licensed pharmacy or a federally registered outsourcing facility (i.e., 503B Outsourcing Facility). USP <797>'s "immediate use" provision governs the emergency preparation of a sterile drug product and, in defined scenarios, allows a sterile product to be prepared outside of full USP compliance. This is not permissible in scenarios where an IV therapy business uses the "immediate use" concept to avoid USP requirements, especially for sterility and training. The provision is not a workaround for the quality and safety standards governing sterile product preparation. Walk-in or concierge IV therapy services do not meet USP <797>'s "immediate use" definition.

## Scope of practice chart

The guidance provides a [scope of practice chart](#) for those professions regulated by RIDOH. The scope of practice chart examines procedures commonly performed in medical spas and IV therapy businesses and identifies those that fall within each licensee's scope of practice as long as the licensee has obtained the required training and experience. Recognizing that the list is not exhaustive, RIDOH advises business owners to reach out to licensing boards and/or RIDOH with any questions.

RIDOH further advises that those license types not included within the scope of practice chart, such as nursing assistants, EMTs, optometrists, veterinarians, or hairdressers, are prohibited from performing any of the medical procedures since they do not fall within these practitioners' scope of practice.

## Enforcement

Individuals lacking professional licensing may not perform any medical procedure. The guidance specifies that course certificates of completion for procedures do not count as being licensed. Performance of a medical procedure without a license puts an individual at risk of fines and/or civil or criminal penalties.

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