Regulatory Considerations for IV Hydration Clinics and Med Spas in Virginia

Introduction

IV hydration clinics and med spas offering injectable vitamin and amino acid infusions, IV fluids (including normal saline and Lactated Ringer's) with antinausea, anti-inflammatory, or analgesic medications, weight loss drugs such GLP-1, GIP, or other peptides, compounded drug products, medical aesthetic services, and similar therapies are expanding across Virginia. While the terms "IV hydration clinic" and "med spa" are not used in Virginia law, the services rendered and personnel performing them may be regulated by one or more professional licensing boards. For the purpose of this document, the terms "IV hydration clinic" and "med spa" mean a fixed or mobile clinic in which medical procedures and services may be delivered, albeit in a more casual or consumer-focused setting than a traditional clinic and potentially alongside nonmedical services. These entities may operate without recognizing that selecting, preparing, compounding, and administering prescription drugs, including IV fluids or injectable substances, constitutes the practice of medicine, nursing, or pharmacy under Virginia law. IV hydration clinics and med spas that allow patients to select treatments from a menu, complete a brief questionnaire, and undergo a basic screening by a nurse or unlicensed staff member may be operating in an illegal and unsafe manner. Practice models in which there is no prescriber physically present and that rely on "protocols" or "standing orders" to guide treatment may be conducting their practice in a manner that constitutes the unlicensed practice of medicine, may exceed applicable scopes of practice, may constitute the improper delegation of tasks, illegal compounding, mixing, diluting, or reconstituting of drugs, may constitute unsafe sterile practices, or constitute a lack of appropriate prescriber-patient relationship.

This document summarizes key requirements and regulatory concerns based on existing statutes and regulations enforced by the following:

- Virginia Board of Medicine;
- Virginia Board of Nursing; and
- Virginia Board of Pharmacy.

These Boards emphasize that all clinical activities performed in IV hydration clinics and med spas should comply with Virginia's laws regarding the prescribing, obtaining and storing of drugs, administration, dispensing, scope of practice, compounding, and patient-care requirements.

Key Compliance Expectations

IV hydration clinics and med spas should ensure:

- A licensed prescriber evaluates each patient and issues patient-specific orders in accordance with prescribing requirements found in Virginia Code § 54.1-3303;
- Drugs are not administered or dispensed pursuant to protocols or standing orders;
- Compounded drugs obtained from a pharmacy are compounded in compliance with United States Pharmacopeia (USP) compounding requirements or, as a standard of care, are mixed, diluted, and reconstituted by the physician, advanced practice registered nurse, or physician assistant or under their supervision in compliance with USP compounding requirements and Virginia Code § 54.1-3410.2;
- Only licensed personnel administer prescription drugs, including IVs or injections, within their scope of practice and Virginia Code § 54.1-3408;
- Proper documentation, informed consent, and medical records are maintained;
- Drugs are purchased only from licensed wholesale distributors, pharmacies, or outsourcing facilities whose verification of Virginia licensure may be found online via License Lookup;
- Proper licensure is obtained from the Board of Pharmacy for dispensing drugs, if applicable; and
- The business entity does not interfere with clinical judgment of licensed professionals.

Medical Director and Clinic Involvement

"Medical director" is not a defined term in Title 54.1 of the Code of Virginia and applicable laws are silent on the requirement to designate a medical director. Other sections of the Code restrict use of the term to a physician. While it is unclear if a medical director of an IV hydration clinic and med spa must be a physician, applicable laws do require a prescriber to be responsible for ordering and prescribing drugs and delegation of activities to other licensed health professionals. Within this context, and for the purposes of this document, a medical director may be considered anyone who has the legal authority to prescribe, order drugs, and supervise or delegate medical or nursing activities. A person serving as the medical director of an IV hydration clinic or med spa providing services that require professional licensure takes on the responsibility of ensuring that any delegation is appropriate under state law and within the medical director's own scope of practice. This includes ensuring the appropriateness of any licensing, training, and education of persons to whom they are delegating. In contrast, a registered nurse, licensed practical nurse, chiropractor, dentist, physical therapist, massage therapist, emergency medical technician (EMT), paramedic, or other licensed health care provider may not evaluate, diagnose, determine, or

delegate treatment for a patient in a general medical spa or IV hydration clinic setting. Refer to the individual scopes of practice for these licenses and certifications.

Healthcare practitioners employed by or treating patients of a clinic or med spa should insist on a contract from the IV hydration clinic or med spa that defines the company's expectations of practice and that such expectations are compliant with the authority and limitations of the practitioner's Virginia license. When working with other licensed healthcare practitioners, and possibly with individuals who are unlicensed, each practitioner should understand the role of their co-workers and whether that role complies with coworkers' status as licensed or unlicensed individuals. Physicians working with physician assistants and advanced practice registered nurses should ensure that practice agreements are in place. It is recommended that the health practitioner delegating tasks ensure all individuals delegated tasks are trained and meet the requirements of Virginia Code §§ 54.1-2901(A)(6) and 54.1-3408(V).

The medical director must remain readily available for consultation by the person to whom the duty is delegated, either in person or by telecommunication. To stock drugs, a prescriber must practice on-site at least part of the time. During medical procedures, a person with the appropriate level of licensure to perform the procedure and manage emergencies according to established facility protocols should always be onsite. The medical director should be immediately available (by phone or text) in case of complications.

The risk assumed by a medical director in IV hydration clinics and med spas is the same as it would be for any practitioner within any other medical practice. If a licensee delegates authority to another person, the licensee also assumes the risk associated with actions taken by the individual with delegated authority. If the medical director is also the owner of the facility, additional risks regarding the workplace or public access may apply, which this document does not address.

Any facility where medical services are provided should have written protocols, both to address general medical emergencies and those specific to the potential risk of the procedures being performed. Providers should be trained in monitoring patients for adverse outcomes and how to respond in case of an emergency. The medical director should always be available onsite or by telecommunication.

Pursuant to Virginia Code § 54.1-3303, a bona fide practitioner-patient relationship must be established to issue an order for administration or dispensing of a drug to a patient. Prescribers should develop and maintain a record of a treatment plan that includes the reason or diagnosis that justifies the use of therapeutics, identifies injection sites, documents dosage of medications, fluids, supplements, minerals, and vitamins to be administered. It is recommended that the prescriber obtain the patient's informed consent using the form provided by the clinic or spa. It is also recommended that healthcare providers ensure that the ordering of drugs is done in accordance with Board of Pharmacy law.

Practice of Medicine in Virginia

Under Virginia Code § 54.1-2900, the practice of medicine includes the prevention, diagnosis, and treatment of human physical or mental ailments, conditions, diseases, pain, or infirmities by any means or methods. This may include:

- Examining, diagnosing, and evaluating patients;
- Prescribing or administering drugs; and
- Providing treatment for any condition or symptom, including the performing of certain aesthetic procedures.

Only the following may diagnose and prescribe prescription drugs, including IV or injectable therapy:

1. Physicians (MD/DO);
2. Physician assistants (PA), practicing under a written practice agreement;
3. Advanced Practice Registered Nurses (APRN), practicing under a collaborative agreement or autonomous practice authorization

Pursuant to Virginia Code § 54.1- 3303, a valid practitioner-patient relationship must be established before any drug, including injectable or IV therapy, is ordered or prescribed.

Patient Evaluations, Diagnosis, and Treatment Recommendations

A physician, an APRN practicing under autonomous practice authority, a PA practicing under a written practice agreement, or an APRN practicing under a collaborative agreement may evaluate patients, perform diagnosis, and make recommendations for treatment which may include prescribing a drug for administration or the performance of a medical aesthetic procedure. Physicians, PAs, or APRNs may delegate certain functions relating to patient intake, such as performing an interview regarding symptoms and medical history and taking vital signs, to registered nurses, licensed practical nurses, medical assistants, and other persons with appropriate training. Nurses or unlicensed staff may not, however, diagnose the patient or recommend treatment. Information gathered by nurses or unlicensed staff helps inform the physician, PA, or APRN in performing the physician's patient evaluation. It is important to note that a patient may not self-diagnose or select a prescription drug, including an IV fluid, for administration.

Telehealth Considerations

Virginia law permits a valid practitioner–patient relationship to be established through telemedicine. (*See* Va. Code § 38.2-3418.16.) The Board of Medicine states in its Guidance Document on Telemedicine (Guidance Document 85-12) that telehealth is held to the same

professional, ethical, and clinical standards as in-person care. When providing telemedicine services, physicians, APRNs, and PAs must:

- Hold a current active license to practice in Virginia.
- Meet the same standard of care required for an in-person encounter, including the ability to gather sufficient clinical information to make safe treatment decisions.
- Conduct an appropriate medical evaluation, using real time interactive technology that allows adequate assessment of the patient's condition.
- Verify the patient's identity and location, and disclose the provider's name, credentials, and licensure status, as required by Board guidance.
- Obtain and document informed consent for telemedicine services.
- Document the encounter thoroughly, including history, assessment, diagnosis, treatment plan, and any prescriptions issued.
- Determine whether in-person care is necessary and arrange timely referral or in person evaluation if the patient's condition cannot be safely managed via telehealth.
- Use technology that meets privacy and security requirements, consistent with state and federal law.

Sole use of questionnaires is insufficient in establishing a valid practitioner-patient relationship. If the patient has not interacted in real-time with the prescriber, then a valid practitioner-patient relationship has not been established.

Use of Protocols and Standing Orders

Virginia law does not permit nurses or unlicensed staff to select or recommend drugs, including IV therapies or injections, or medical aesthetic procedures based solely on protocols. *See, e.g.,* Va. Code § 54.1-3408. Protocols may only be used in limited, legally defined circumstances (e.g., public health vaccination programs). Protocols cannot replace individualized medical evaluation for elective med spa or IV hydration services.

Compounding, Mixing, Diluting, and Reconstituting

All IV fluids, including plain IV saline, are prescription drugs. Drugs may only be mixed or compounded pursuant to a valid patient-specific prescription or order. The Boards note that compounded drugs are not FDA-approved, and improper sterile technique can pose significant risks, including infection, contamination, and dosing errors. When a drug is mixed with additives, such as vitamins or minerals, the result is a compounded drug. Virginia Code § 54.1-3401 defines compounding as the combining of two or more ingredients to fabricate such ingredients into a

single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device. This definition encompasses:

- Adding medications, vitamins, or minerals to IV fluids; and
- Preparing sterile injectable products or customized drug formulations such as peptides for weight loss or skin care.

Compounding is considered the practice of pharmacy, and activities that meet the statutory definition of compounding are regulated by the Virginia Board of Pharmacy. Pursuant to Virginia Code § 54.1-3410.2, all non-sterile and sterile compounding must be performed in compliance with United States Pharmacopeia (USP) compounding standards. The law further indicates when a pharmacist may not perform regular compounding of inordinate amounts of drugs that are essentially copies of manufactured drugs.

Virginia Code § 54.1-3401 authorizes physicians, advanced practice registered nurses, and physician assistants to mix, dilute, and reconstitute drugs. If mixing, diluting or reconstituting of drugs is delegated, ensure that the individuals are trained to follow aseptic techniques and supervised in their work. As a matter of standard of care, the mixing, diluting, and reconstituting of drugs should be performed in compliance with USP compounding standards.

Simply reconstituting a drug in accordance with the manufacturer's directions does not constitute compounding. USP allows drugs to be mixed or compounded for immediate use if administered within four hours of beginning the compounding.

Administration of IV Therapy and Injections

Registered Nurses (RNs)

RNs may administer IV fluids and injections only pursuant to a valid order from a licensed prescriber. They may not:

- Diagnose conditions;
- Recommend specific IV "cocktails," other compounded drugs, or medical aesthetic procedures; or
- Determine dosage, route, or frequency.

Licensed Practical Nurses (LPNs)

LPNs have **limited IV authority** and may not initiate or administer many types of injectable or IV medications or vitamin containing solutions unless specifically permitted under 18VAC 90-19-260 and supervised by an RN or prescriber. They, too, may not diagnose, recommend drugs or medical aesthetic procedures, or determine dosage, route, or frequency of drug administration.

Emergency Medical Service (EMS) Personnel or Paramedics

EMS personnel and paramedics should not practice advanced procedures outside of advanced life support (ALS) activities authorized within their certification while employed at a medical spa. Doing so may constitute a breach of the Office of Emergency Medical Services regulations, placing an ALS EMS clinician at professional risk.

Unlicensed Individuals

Notwithstanding Virginia Code § 54-1-3408(V), unlicensed staff may not:

- Administer IV fluids or injections;
- Prepare or compound drugs;
- Perform medical assessments; or
- Provide treatment recommendations.

Doing so constitutes the unlicensed practice of medicine or pharmacy, which is prohibited under Virginia law. *See, e.g.,* Va. Code §§ 54.1-3320 and 54.1-2900.

Dispensing and Storage of Prescription Drugs

When a patient is provided a prescription-only drug to consume or administer at a later time, the drug is generally considered to have been dispensed to the patient.

Any medication indicating "for research purposes only" or other similar statement is unlawful to possess by IV hydration clinics and med spas and is both a violation of state and federal law regardless of patient "consent."

Pharmacy

A pharmacy may hand-deliver a dispensed drug that is labeled for a specific patient directly to the patient or the patient's agent, or the pharmacy may deliver the drug to the patient's residence. Alternatively, a pharmacy may deliver a dispensed drug to an alternate location in accordance with Virginia Code § 54.1-3420.2 and 18VAC110-20-275. Patient-specific drugs that have been dispensed by the pharmacy are the property of the patient and cannot be administered to other persons. This is a violation of both federal and state law.

Physician, APRN, or PA

A physician may dispense drugs to his or her own patients after obtaining a license and a facility permit from the Board of Pharmacy for such purpose. APRNs and PAs may only obtain a limited-use license to dispense certain Schedule VI drugs when practicing at a non-profit facility. While a trained nurse or pharmacy technician may assist with preparing the drug for dispensing, the act of

verifying the dispensed drug for accuracy may not be delegated by the licensed physician, APRN, or PA. Refer to Board of Pharmacy Guidance Document 110-19 for additional information.

Reconstituted Neurotoxins & Beyond-Use Dates

The reconstitution of neurotoxins (e.g., Botox®, Dysport®, XEOMIN®, etc.) is not considered prescriber compounding if done in accordance with the manufacturer's labeling. The beyond-use date for all neurotoxins is determined by the manufacturer's labeling. If the label states, "use within 24 hours," then the product should be used within that timeframe. If no such beyond use date or timeframe exists on the label, the drug may only be used for up to six hours following preparation.

As a reminder, all neurotoxins should:

1. Be prepared using aseptic technique and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids.

2. Unless administered immediately, the drug product described in this paragraph should bear a label listing the name of the drug (if not legible), date, and time prepared.

References:

FDA Compounding Risk Alerts
FDA: Insanitary Conditions in Medical Offices/Clinics
FDA: Concerns with Unapproved GLP-1 Drugs Used for Weight Loss
Virginia Board of Medicine Telemedicine Guidance (Guidance Document 85-12)
Virginia Board of Pharmacy Guidance Document (Guidance Document 110-19)
Virginia Board of Pharmacy USP Compounding Guidance (Guidance Document110-36)
Va. Code § 38.2-3418.16
Va. Code § 54.1-2900
Va. Code § 54.1-2901
Va. Code § 54.1-3303
Va. Code § 54.1-3401
Va. Code § 54.1-3408
Va. Code § 54.1-3410.2
Va. Code § 54.1-3420.2
18VAC 90-19-260
18VAC110-20-275