

JOINT STATEMENT REGARDING IV THERAPY CLINICS AND MEDICAL SPAS
From the Vermont Office of Professional Regulation and
Boards of Medical Practice, Nursing, Osteopathic Medicine, and Pharmacy

The Office of Professional Regulation (OPR) and Board of Medical Practice (BMP) have received complaints and reports about inappropriate activities occurring at IV (intravenous) therapy clinics and medical spas. These activities may include out-of-scope practice, delegation of tasks to unqualified individuals, and unlicensed practice of medicine.

Nationally and in Vermont it is becoming increasingly common to see retail IV therapy clinics or “medical spas” that offer IV “cocktails” of additives to saline that may include vitamins, minerals, or prescription drugs. They are marketed to consumers as treatments for conditions such as dehydration, fatigue, and hangovers, or to aid individuals with athletic recovery or weight loss.

Vermont does not have laws and regulations that specifically govern IV therapy clinics and medical spas. Rather, these businesses are subject to the same laws and regulations that govern all spas and medical practices.

We believe this advisory statement will benefit licensed professionals who provide such services at these businesses by providing clarity about the legal and regulatory requirements that apply.

IV Therapy Services Constitute the Practice of Medicine

In Vermont, the practice of medicine includes but is not limited to (1) prescribing, ordering, or administering drugs, or offering to do so; (2) preventing, diagnosing, or treating any disease, illness, pain, or abnormal physical or mental condition, or offering to do so; and (3) determining medical necessity or making a decision that affects diagnosis or treatment.¹

Offering and providing IV therapy indisputably constitutes the practice of medicine. The unlicensed practice of medicine is illegal and punishable by imprisonment for not more than two years and/or a fine of not more than \$10,000.²

Only Licensed Prescribers May Prescribe IV Products

Only allopathic physicians (MDs), osteopathic physicians (DOs), physician assistants (PAs), advanced practice registered nurses (APRNs or nurse practitioners), and

¹ 26 V.S.A. §§ 1311(1)(C)-(D), (G).

² 26 V.S.A. § 1314(a).

naturopathic physicians (NDs) with a prescribing endorsement, may prescribe saline IV products.³ A patient may not self-prescribe IV products by choosing an IV “cocktail” from a menu.

Registered nurses (RNs), licensed practical nurses (LPNs), licensed nurse assistants (LNAs), cosmetologists, and estheticians are not authorized under the law to prescribe any drugs, including IV saline. It would be illegal for them to do so even if the clinic has a medical director or if the patient requests the drug.

“Standing Orders” Are Not Valid Prescriptions

It is illegal for anyone to administer a prescription drug without a valid prescription. To issue a valid prescription, a practitioner must:

- Have legal authority to prescribe,
- Establish a valid practitioner-patient relationship,
- Conduct an appropriate patient evaluation,
- Make a diagnosis necessitating IV therapy,
- Develop a treatment plan,
- Prescribe IV fluids for the patient, and
- Document the patient evaluation, diagnosis, treatment plan, and prescription.

“Standing orders” issued by IV clinic medical directors are not valid prescriptions because they do not arise from a prescriber-patient relationship adequate to establish diagnoses and identify underlying conditions or contraindications to the treatment.⁴ Drug

³ Certain other licensees, such as dentists and optometrists, also have limited prescribing authority not relevant to IV hydration clinics.

⁴ There are a few situations in which standing orders may be valid prescriptions. For example, public-health standing orders issued by the Commissioner of Health, such as for anti-overdose medication, are valid because of statutes overriding Pharmacy Rule 10.2. 18 V.S.A. § 4240(c)(1). MDs, PAs, and APRNs may prescribe an epinephrine auto-injector in a school’s name and issue a standing order for its use. 16 V.S.A. § 1388. Emergency medical services providers may administer Schedule II, III, IV, and V controlled substances in the course of providing emergency medical services pursuant to standing orders in certain circumstances. 21 U.S.C. § 823. Hospitals receiving federal funding under Medicare and Medicaid may use standing orders in limited situations only if those orders are approved and regularly reviewed by medical staff, nursing, and pharmacy leadership and follow nationally recognized, evidence-based guidelines. 42 C.F.R. § 482.23(c)(3). None of these exceptions apply to IV therapy clinics, however.

compounding can never take place under a standing order because valid compounding prescriptions may only be issued to an individual, identified patient.⁵

Only Authorized Individuals May Compound Drugs

All IV fluids, including plain IV saline, are prescription drugs.⁶ When a drug is mixed with additives, such as vitamins or minerals, the result is a *compounded drug*. It is illegal for anyone to administer a prescription drug, including a compounded drug, without a valid prescription.

Improper compounding of IV products endangers patients by risking serious infection or death.⁷ Mixing saline with additives is compounding.⁸

Only individuals whose legal scope of practice includes compounding may compound drugs.⁹ PAs, APRNs and RNs may compound only in specific clinical circumstances, which do not include IV hydration clinics or medical spas. LPNs, LNAS, cosmetologists, and estheticians may never compound drugs and are not authorized to mix additives with IV saline. Doing so is considered unprofessional conduct and subject to prosecution. This is true even if an authorized prescriber has appropriately prescribed the compounded IV medication.

LNAs, Cosmetologists, and Estheticians May Not Administer IV Products

Even with a valid prescription, IV products, including IV saline, are permitted to be administered only by someone licensed to do so. This includes MDs, DOs, PAs, APRNs, NDs with the prescribing endorsement, RNs, and certain LPNs.¹⁰

LNAs, cosmetologists, and estheticians are prohibited from administering IV products and may not do so even with a medical director on-site. Doing so is considered unprofessional conduct and subject to prosecution.

⁵ 21 U.S.C. § 353a(a)(1). There are exceptions, such as wholesale compounding by 503B outsourcers, but they do not apply to IV hydration clinics.

⁶ Food and Drug Administration, *Approved Drug Products with Therapeutic Equivalence Evaluations*, 43d Ed. 2023, at 3-415 to 3-416.

⁷ FDA, “The Special Risks of Pharmacy Compounding,” Dec. 2012.

⁸ Administrative Rules of the Board of Pharmacy (“Pharm. R.”) at 1.10(9).

⁹ 21 U.S.C. § 353a(a)(2), “Pharmacy Compounding.”

¹⁰ To administer IV fluids, and LPN must have specific, validated documented competency and must be under the direct supervision of a provider with authority to prescribe or an RN.

Prescribers May Not Instruct Unlicensed Individuals to Administer IVs

A professional may not authorize someone to perform an activity outside his or her scope of practice.¹¹ While MDs and DOs may delegate medical activities to appropriately trained, educated, and/or experienced individuals, the activity must be within the individual's scope of licensed practice, and must remain under the MD or DO's control.¹²

It is unprofessional conduct for an MD or DO to delegate professional responsibilities to a person whom the MD or DO knows or has reason to know is not qualified by training, experience, education, or licensing credentials to perform them.¹³ For example, it is unprofessional conduct for an MD or DO to instruct an RN to prescribe IV products on the MD or DO's behalf, or to instruct an LNA, cosmetologist, or esthetician to administer IV products.

Approved by the Board of Medical Practice on June 5, 2024.

Approved by the Board of Osteopathic Medicine on March 11, 2024.

Approved by the Board of Pharmacy on March 27, 2024.

Approved by the Board of Nursing on May 13, 2024.

This statement constitutes the joint position of OPR and the Boards of Medical Practice, Nursing, Osteopathic Medicine, and Pharmacy. If you have any questions, feel free to contact Nursing Executive Shiela Boni (shiela.boni@vermont.gov), Pharmacy Executive Carrie Phillips (carrie.phillips@vermont.gov), OPR Staff Attorney Emily Tredeau (emily.b.tredeau@vermont.gov), or the Executive Director of the Board of Medical Practice, David Herlihy (david.herlihy@vermont.gov).

¹¹ 3 V.S.A. § 129a(a)(6); 26 V.S.A. § 1354(a)(26) & (29).

¹² *Id.*; 26 V.S.A. § 1444(a).

¹³ *Id.*; 26 V.S.A. § 1444(a).