Guidance on Recent Trends in Prescribing and Dispensing

Report of the FSMB Workgroup on Trends in Prescribing and Dispensing
Draft, January 2026

Executive Summary

In recent years, a rapid growth of nascent medical practices has been observed that blurs the boundaries between medical practice, wellness promotion, and consumer services. Among these developments are the proliferation of intravenous (IV) hydration and vitamin infusion clinics, psychedelic-assisted therapy for the treatment of mood and pain disorders, and the prescribing of Glucagon-Like Peptide-1 (GLP-1) receptor agonists and other medications for weight management, among other practices. The expansion of these practices has often outpaced existing regulatory frameworks, creating a potential for challenges in ensuring quality of care, appropriate practitioner oversight, and protections necessary for public safety.

Considerations and recommendations offered within this report are intended to provide a foundation for state boards, licensed physicians, PAs, and other health care professionals, policymakers, and the public to better understand these evolving trends and to provide guidance that promotes the importance of protecting the public, respecting patient autonomy, preventing patient harm and exploitation, obtaining informed consent, and appropriately documenting care that is thoughtfully recommended and provided.

The following 11 considerations and recommendations are included in this report:

1. Scope of Practice: Medical diagnosis, treatment, and prescribing must be performed only by appropriately licensed health care professionals acting within their lawful scope of practice.
2. Physician–Patient Relationship: A valid practitioner–patient relationship is required for all medical care, regardless of whether services are delivered in person or via telemedicine.
3. Standard of Care: All services constituting the practice of medicine must meet established standards of care, including individualized assessment, independent medical judgment, and medical necessity.
4. Medical Records: Comprehensive, accurate, and accessible medical records must be created and maintained to support continuity of care, patient safety, and regulatory compliance.
5. Informed Consent: Patients must receive clear, evidence-based information regarding risks, benefits, alternatives, and provider qualifications, supported by comprehensive medical records.
6. Patient Monitoring and Continuity of Care: Appropriate monitoring, follow-up, and emergency planning are essential to ensure patient safety and continuity of care.
7. Advertising: Marketing of medical services must be truthful, evidence-based, and not misleading, including when promoting services as “wellness” offerings.
8. Compounding: Compounding must be patient-specific, medically necessary, and fully compliant with state and federal law and applicable U.S. Pharmacopeia standards.
9. Ownership, Supervision, and Delegation: Business or ownership interests must not interfere with medical judgment, and supervising physicians retain ultimate responsibility for delegated care.
10. Standing Orders/Protocols: Standing orders and clinical protocols must not replace individualized clinical evaluation, diagnosis, or medical decision-making.

DRAFT

11. Regulatory Board Collaboration and Education: State regulatory boards should collaborate across disciplines and educate the public regarding risks associated with retail therapy clinics.

DRAFT

Introduction

In May 2025, George M. Abraham, MD, MPH, Chair of the Federation of State Medical Boards (FSMB), established the Workgroup on Trends in Prescribing and Dispensing in response to recent challenges faced by state medical and osteopathic boards (herein referred to as "state medical boards" or "boards") in addressing the proliferation of certain medical practices that may pose regulatory concerns due to their potential to cause patient harm and exploitation.

The Workgroup was duly charged with developing a report and considering recommendations and/or model guidelines for use by state medical boards in improving the regulatory oversight of certain potentially under-regulated medical practices. In completing its charge, the Workgroup:

- Evaluated the current regulatory landscape related to certain nascent medical practices, such as ketamine therapy, IV hydration therapy, GLP-1 prescribing, dispensing and compounding, and psychedelic-assisted therapies (e.g., psilocybin, LSD, and MDMA);
- Reviewed relevant research regarding clinical safety and efficacy, existing board regulatory approaches, and state and federal rules and regulations;
- Evaluated relevant medical practice/business models, including direct-to-consumer (DTC) telemedicine and medication delivery, prescribing and dispensing of compounded medications, and free-standing clinics;
- Identified regulatory gaps, potential risks to patient safety, risks of off-label medication use, and failure to comply with existing safety standards; and
- Identified best practices including, but not limited to, health practitioner qualifications and licensure, patient assessment, informed consent, documentation, and compliance with federal and state rules, regulations, and statutes.

In recent years, state medical boards have observed the rapid growth of nascent medical practices that blur the boundaries between medical practice, wellness promotion, and consumer services. Among these developments are the proliferation of intravenous (IV) hydration and vitamin infusion clinics, ketamine therapy clinics offering treatment for mood and pain disorders, and the prescribing of GLP-1 receptor agonists and other medications for weight management, among other practices. While many of these developments reflect innovation and respond to patient demand, their expansion has often outpaced existing regulatory frameworks, creating a potential for challenges in ensuring quality of care, appropriate practitioner oversight, and protections necessary for public safety.

This report, and the considerations and recommendations contained within, are intended to provide a foundation for state boards, licensed physicians, PAs, and other health care professionals, policymakers, and the public to better understand these evolving trends and to provide guidance that promotes the importance of protecting the public, respecting patient autonomy, preventing patient exploitation, obtaining informed consent, and appropriately documenting care that is thoughtfully recommended and provided.

Definitions

For the purposes of this report, the following definitions apply:

"Compounding" refers to the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding typically includes the

DRAFT

combining of two or more drugs. Compounded drugs are not formally U.S. Food and Drug Administration (FDA) approved.[1]

"Intravenous Fluids" refers to liquids injected into a person through a vein. This practice includes providing stock intravenous (IV) fluids with or without the addition of vitamins, minerals, amino acids, medications, etc. IV fluids are, as defined by law, drugs that must be prescribed by a licensed independent health care professional for a specific patient with a specific diagnosis for which the intravenous fluids are indicated.[2]

"Medical Practice Act" is the legal statute that determines the structure and function of a state medical or osteopathic board.[3]

"Medical Spa" refers to a facility that provides certain cosmetic medical procedures, such as neuromodulators, dermal fillers, chemical peels, microneedling and laser procedures (which do not remove the skin's epidermis, or outer layer), outside the setting of a physician's office.[4]

The "Practice of Medicine" is generally held to be consistent with the following actions, activities or tasks:

1. Advertising, holding out to the public, or representing in any manner that one is authorized to practice medicine in a particular jurisdiction;
2. Offering or undertaking to prescribe, order, give, or administer any drug or medicine for use by any other person;
3. Offering or undertaking to prevent or to diagnose, correct, and/or treat in any manner or by any means, methods, or devices any disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of any person;
4. Offering or undertaking to perform any surgical operation upon any person;
5. Rendering a written or otherwise documented medical opinion concerning the diagnosis or treatment of a patient, or the actual rendering of treatment to a patient, within a state by a physician located outside the state as a result of transmission of individual patient data by electronic or other means from within a state to such physician or the physician's agent;
6. Rendering a determination of medical necessity or a decision affecting the diagnosis and/or treatment of a patient; and
7. Using the designation Doctor, Doctor of Medicine, Doctor of Osteopathic Medicine/Doctor of Osteopathy, Physician, Surgeon, Physician and Surgeon, Dr., M.D., D.O., or any combination thereof in the conduct of any occupation or profession pertaining to the prevention, diagnosis, or treatment of human disease or condition unless such a designation additionally contains the description of another branch of the healing arts for which one holds a valid license in the jurisdiction where the patient is located.[5]

---

[1] U.S. Food and Drug Administration. *Human Drug Compounding.* Silver Spring, MD: U.S. Food and Drug Administration. Accessed December 1, 2025. https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.

[2] Rhode Island Department of Health. *Guidance Document Regarding the Operation of Medical Spas and Intravenous (IV) Therapy Businesses.* July 2024. https://health.ri.gov/sites/g/files/xkgbur1006/files/publications/guidance/Medical-Spa-and-IV-Therapy-Business.pdf.

[3] FSMB, *Guidelines for the Structure and Function of a State Medical and Osteopathic Board*, April 2024, available at: https://www.fsmb.org/siteassets/advocacy/policies/guidelines-for-structure-function-of-state-medical-and-osteopathic-board-2024.pdf.

[4] American Society for Dermatologic Surgery Association (ASDSA). *Medical Spa Safety Act.* March 2025 https://www.asds.net/Portals/0/PDF/asdsa/asdsa-medical-spa-safety-act.pdf.

[5] FSMB, *Guidelines for the Structure and Function of a State Medical and Osteopathic Board*, April 2024, available at: https://www.fsmb.org/siteassets/advocacy/policies/guidelines-for-structure-function-of-state-medical-and-osteopathic-board-2024.pdf.

The definition of the practice of medicine may also include several exceptions, which exempt certain activities from the categorization of the practice of medicine.

The practice of medicine is determined to occur where the patient is located in order that the full resources of the state are available for the protection of that patient.[6] Licensees licensed in multiple states are responsible for knowing the rules, regulations and statue of each jurisdiction in which they are licensed.

Background

A range of nascent medical practices, including IV hydration clinics, psychedelic-assisted therapy clinics, GLP-1/weight loss clinics, medical spas, and direct-to-consumer (DTC) online clinics, has rapidly emerged across the United States in recent years, reshaping the landscape of elective health and wellness care. These services are often marketed as "wellness treatments," leveraging the public appeal of convenience, lifestyle transformation, and agency, and frequently operate at the intersection of medical and non-medical environments. These clinics, both in-person and online, are often an agglomeration of medical disciplines, and the ownership structure usually varies: some facilities are owned by licensed health care professionals, while others are owned by unlicensed investors employing a designated licensed medical director.

As growth has accelerated with consumer demand and social media influence, medical regulatory oversight of such practices has struggled to keep pace, as these activities often fall into a regulatory gray zone: state medical boards regulate the practice of medicine; state nursing boards regulate the practice of nursing; state pharmacy boards regulate the practice of pharmacy; the Food and Drug Administration (FDA) regulates drugs, devices, biologics, and claims; and the Federal Trade Commission (FTC) regulates advertising, deceptive marketing, and unfair business practices. Collaboration between state and federal entities to mitigate harms is sometimes a challenging endeavor, made more difficult by a wellness industry that is quick to evolve.

At least 21 state regulatory boards (medical, nursing, and pharmacy, among others) have issued specific guidelines or policies addressing these medical practices, reflecting growing and widespread concern about patient safety, the blurring of healthcare and wellness claims, and the need for clearer boundaries in the oversight of such rapidly expanding industries.[7]

IV Hydration Clinics

Retail IV hydration clinics generally operate by offering walk-in patients the administration of IV fluids through drip IV infusion tubing into the patient's vein. The type or composition of the IV fluids is selected from a menu of pre-determined mixtures ("cocktails") of additives to basic IV saline. Some common examples include amino acids, vitamin C and vitamin B complex, Myers' Cocktail (magnesium, calcium, vitamin B complex, and vitamin C), ketorolac, famotidine, and ondansetron. The cocktails are offered to patients for the treatment of conditions as varied as dehydration, migraine relief, hangover recovery, nausea, athletic recovery, appetite regulation, and inflammation support.[8,9]

---

[6] *Ibid*

[7] Sivakumar, Anishaa, Howard P. Forman, Isabel Wang, Peter Lurie, and Joseph S. Ross, "State Policies and Facility Practices of IV Hydration Spas in the U.S.," JAMA Internal Medicine 185, no. 12 (December 1, 2025): 1455–1461, https://pubmed.ncbi.nlm.nih.gov/41051745/.

[8] Mississippi State Board of Medical Licensure. *Guidance Regarding IV Hydration Therapy.* September 2023. https://www.msbml.ms.gov/sites/default/files/news/IV%20Hydration%20Therapy%20Guidance%2009-05-23.pdf.

[9] Ohio State Medical Board, Ohio Board of Pharmacy, and Ohio Board of Nursing. *Joint Regulatory Statement Regarding Retail IV Therapy Clinics*. May 15, 2025. https://www.pharmacy.ohio.gov/documents/pubs/special/ivtherapy/joint%20regulatory%20statement%20on%20the%20operation%20of%20retail%20iv%20therapy%20clinics%20in%20ohio.pdf.

DRAFT

There are nearly 500 IV hydration clinics in the United States at present; however, there are estimates that more than 2,200 medical spas (sometimes abbreviated as medspas or medispas) offer IV hydration services nationwide, and which are the top revenue service for about 40 percent of these establishments. The IV hydration market is estimated to reach about $4.6 billion by 2030.[10] (There may be overlap between revenue figures and the number of clinics for IV hydration, weight loss, and medspas, as the delineation of what is offered and how often is not always known.)

Psychedelic-Assisted Therapy Clinics

Psychedelic-assisted therapy (sometimes abbreviated as PAT) involves the use of a psychoactive substance such as psilocybin, ketamine, ibogaine, lysergic acid diethylamide (LSD), or 3,4-Methylenedioxymethamphetamine (commonly referred to as MDMA or ecstasy) in a controlled, therapeutic setting, where a licensed professional "guides" the patient through a psychedelic experience, immediately followed by "integration," a therapeutic approach where patients process their experience and apply insights to their daily lives.[11]

When utilizing PAT, patients usually undergo a medical and psychological evaluation, including medical history, lab tests, and eligibility screening; this is usually performed by a psychiatrist or other qualified health care professional. Generally, patients meet with a health care professional to discuss symptoms, goals, and risks. This includes preparation sessions to set intentions, review the therapy format, and clarify expectations, often with input from both therapists and medical staff. The treatment usually involves a psychoactive substance administered intravenously or via other methods under direct supervision. During administration, clinicians typically monitor vital signs like heart rate, blood pressure, and consciousness level to keep patients safe; a physician or anesthesiology professional is often available in case of complications. Sessions typically last 40 minutes to two hours, with immediate and post-session monitoring for side effects. After the session, patients are observed until they meet pre-determined recovery criteria and are stable enough to go home, usually accompanied by a caregiver.

Although research into PAT began as early as the mid-20th century, later widespread recreational use led to government concern and strict regulation on possession of psychedelics and (minimal) research. More recent research has shown promising effects for conditions such as post-traumatic stress disorder (PTSD), depression, substance use disorder, and treatment-resistant anxiety.[12] PAT is not without risks, however, as subanesthetic doses of ketamine are associated with dissociative and psychomimetic symptoms, including hallucinatory effects, along with memory impairment. Additionally, ketamine stimulates the sympathetic nervous system, which can lead to rapid heart rate, hypertension, and increased cardiac output.[13] The FDA has also warned about the use of compounded ketamine products, which are being offered for an increasingly wide range of disorders.[14]

---

[10] Mordor Intelligence. *IV Hydration Therapy Market Size.* Accessed December 5, 2025. https://www.mordorintelligence.com/industry-reports/iv-hydration-therapy-market.

[11] Ketamine Clinics Los Angeles. Uncovering the Truth About Psychedelics in Therapy. October 10, 2025. https://ketamineclinics.com/our-blogs/psychedelics-in-therapy.

[12] Johns Hopkins Medicine. *Psychedelics Research and Psilocybin Therapy.* Accessed December 5, 2025. https://www.hopkinsmedicine.org/psychiatry/research/psychedelics-research.

[13] Amol Soin, Yeshwant Reddy, Kris Ferguson, Roland Flores, Yuri Tsirulnikov, Craig Davis, Michael Lewis, and Jennifer Root, "*Ketamine and its Regulatory Implications: A Review*," *Journal of Medical Regulation* 111, no. 3 (December 5, 2025): 41–48, https://meridian.allenpress.com/jmr/article/111/3/41/508288/Ketamine-and-its-Regulatory-Implications-A-Review.

[14] U.S. Food and Drug Administration (FDA), "*FDA Warns Patients and Health Care Providers About Potential Risks Associated With Compounded Ketamine Products, Including Oral Formulations, for the Treatment of Psychiatric Disorders*," October 10, 2023, https://www.fda.gov/drugs/human-drug-compounding/fda-warns-patients-and-health-care-providers-about-potential-risks-associated-compounded-ketamine.

DRAFT

Ketamine therapy was the first to go mainstream and there are now an estimated 500-750 ketamine clinics in the United States. The lightly regulated field's revenues surpassed $3 billion in 2022 and are estimated to grow to nearly $7 billion by 2030, with patients usually paying out-of-pocket as health insurance usually does not cover such treatment.[15] At the state level, Oregon, Colorado, and New Mexico have legalized psilocybin therapy and Texas has established a research program for ibogaine, while other states are setting up pilot programs to research the possibility of legalizing psychedelics in their jurisdiction.

GLP-1s/Weight Loss Clinics

Originally developed to help treat diabetes, glucagon-like peptide-1 (GLP-1) receptor agonists are medications (such as semaglutide, with brand names Ozempic and Wegovy, and tirzepatide, with brand names Mounjaro and Zepbound) that mimic naturally occurring gut hormones and slow gastric emptying, boost insulin secretion, and increase feelings of fullness, helping people lose substantial amounts of weight, regardless of whether or not they have diabetes.[16] GLP-1 clinics, as such, evaluate whether patients would be a good match for the medication, prescribe and adjust dosage, track weight loss, and monitor side effects. Clinics may operate in-person or via telemedicine, as a standalone operation or under the umbrella of a medspa, and may work in tandem with behavioral counseling.

The GLP-1 market was valued at over $10 billion in 2024 and is projected to reach $22.5 billion by 2034. A Kaiser Family Foundation poll conducted in November 2025 found that as many as 18 percent of Americans have tried GLP-1s for weight loss, and 12 percent are currently using them.[17] There are reportedly over 13,000 "weight loss service" businesses across the country, in addition to numerous medspas (with overlap between the two), and hundreds of telemedicine companies that prescribe the medication. Due to the rapid growth of the GLP-1 market, there have been periods of shortages in products. For an extended period of time, branded, finished-dose GLP-1 products were in short supply. To address the shortage, compounding of Active Pharmaceutical Ingredients (API) was allowed by the FDA.[18] The FDA, however, recently warned companies that unapproved, compounded versions of the drugs are being misleadingly advertised.[19]

Medical Spas

Medical spas offer an array of services ranging from traditional esthetic services (e.g., hairdressing, manicures) to traditional medical procedures (e.g., botulinum toxin, fillers, lasers). Medical spas offer or perform esthetic procedures that do not require sedation, are directed at improving the patient's appearance, and do not typically promote the proper functioning of the body or the prevention or treatment of illness or disease. Medical spas are also those entities that offer or perform any other esthetic procedure or treatment requiring the participation of a licensed health care professional.

---

[15] National Public Radio (NPR). "The Ketamine Economy: New Mental Health Clinics Are a 'Wild West' with Few Rules." January 30, 2024. https://www.npr.org/sections/health-shots/2024/01/30/1227630630/ketamine-infusion-clinic-mental-health-depression-anxiety-fda-off-label.

[16] National Library of Medicine. *The Weight-Loss Effect of GLP-1RAs (Glucagon-Like Peptide-1 Receptor Agonists) in Non-Diabetic Individuals with Overweight or Obesity: A Systematic Review with Meta-Analysis and Trial Sequential Analysis of Randomized Controlled Trials.* August 2023. https://pubmed.ncbi.nlm.nih.gov/37661106/.

[17] Kaiser Family Foundation. *Poll: 1 in 8 Adults Say They Are Currently Taking a GLP-1 Drug for Weight Loss, Diabetes, or Another Condition, Even as Half Say the Drugs Are Difficult to Afford.* November 2025. https://www.kff.org/public-opinion/poll-1-in-8-adults-say-they-are-currently-taking-a-glp-1-drug-for-weight-loss-diabetes-or-another-condition-even-as-half-say-the-drugs-are-difficult-to-afford/.

[18] U.S. Food and Drug Administration, "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss," *Postmarket Drug Safety Information for Patients and Providers*, accessed January 14, 2026, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

[19] U.S. Food and Drug Administration. *Hims & Hers Health, Inc. dba Hers.* September 2025. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hims-hers-health-inc-dba-hers-09092025.

DRAFT

Since 2010, the number of medical spas in the United States has increased by nearly 500 percent. Total medical spa revenue was $20 billion in 2023, a 100 percent increase from 2019. Only 37 percent of single-owner spas are reported to be run by licensed physicians. Between 73 percent and 94 percent of medical spa procedures are performed by non-physicians. Physicians are on-site in such instances less than 40 percent of the time.[20]

Direct-to-Consumer Online Clinics

Direct-to-consumer (DTC) prescribing models represent a significant shift in how patients access prescription medications, bypassing traditional pathways that utilize the patient-physician-pharmacy paradigm and frequently leveraging online or telemedicine platforms. These models have rapidly expanded in recent years due to advances in technology, increased consumer demand for convenience, and the rise of emergency preparedness concerns. For example, several companies now offer personalized emergency medical kits containing a curated selection of prescription and over-the-counter medications, available after an online clinical intake form and a remote consultation with a licensed provider. Similarly, DTC online pharmacies allow patients to obtain treatments for common conditions via virtual consultations, with medications shipped directly to the patient's home.

DTC prescribing must still follow the standards of in-person prescribing: the establishment of a patient-physician relationship, the same standard of care (examination, medication history, diagnosis, treatment decision, etc.), receive informed consent, have adequate documentation, and plans for continuity of care and/or emergency situations. However, according to estimates from the National Association of Boards of Pharmacy (NABP), nearly 95 percent of websites offering prescription-only drugs operate illegally, often at steep discounts to patients and without requiring a valid prescription. Internet-based pharmacies often sell unapproved, counterfeit, or otherwise unsafe medicines outside the safeguards followed by licensed pharmacies. Another survey found that 24 percent of online pharmacy patrons have likely been exposed to harmful, counterfeit, or substandard medication.[21, 22]

Other Treatments

There is a plethora of other nascent medical practices that have increased in popularity and prevalence at the same time as other treatments, including ozone therapy, cryolipolysis ("cool" sculpting), thread lifts, oxygen bars, platelet-rich plasma injections, hyperbaric chamber therapy, hormone implants, testosterone replacement therapy, radiofrequency microneedling, and chemical peels.

It is important to differentiate cosmetic procedures (like a superficial chemical peel, which targets the outermost layer of skin, which may be more akin to a facial and thus not constitute the practice of medicine) from actual medical procedures (like a deep peel, which penetrates the deeper layers of the skin, and/or using stronger acids) when determining would qualify as the practice of medicine and if the recommendations of this report are applicable.

Marketing of Services

[20] Presley, C., et al. "Trends in Medical Spa Statistics and Patient Safety." *Dermatologic Surgery,* February 2024. https://www.asds.net/Portals/0/PDF/asdsa/Trends%20in%20Medical%20Spa%20Statistics%20and%20Patient%20Safety%20Article.pdf.

[21] Centers for Disease Control and Prevention. "Potential Public Health Risk Among Individuals Ordering Counterfeit Prescription Medications from Online Pharmacies." October 2, 2024. https://www.cdc.gov/media/releases/2024/s1002-counterfit-prescription-online-pharmacies.html.

[22] Alliance for Safe Online Pharmacies. *Americans' Perception and Use of Online Pharmacies*. September 2023. https://asopfoundation.pharmacy/wp-content/uploads/2023/12/ASOP-Foundation-Consumer-Behavior-Survey-Key-Findings-2023.pdf.

DRAFT

IV hydration, GLP-1s, medspas, and DTC advertising can all constitute the practice of medicine, but are often described as "wellness treatments" as opposed to "medical care," a framing that emphasizes autonomy over one's own health, quick results, service-centric experiences, and aspirational outcomes. Wellness is a lifestyle and it is behavior-based, not evidence-based, as with medicine.[23] Wellness practices usually avoid the strictures of medical regulation, reduce expectations of clinical evidence or medical necessity, and in some cases allow non-health care professionals to provide care without credentials or proper training. Under the guise of "prevention" and "root cause treatment," unsupported and potentially dangerous claims can sometimes be made without evidence.[24, 25]

Many common "wellness treatments" are, in fact, medical care: IV "insertion," for example, is a medical procedure that requires sterile technique and trained staff, as the IV "cocktails" are compounded medications and there are a host of risks attached to the activity, including infection, electrolyte imbalance, inflammation, and vein damage.[26] GLP-1s are prescription medications that require monitoring and may have significant side effects including nausea, vomiting, and diarrhea, and, in rare cases, pancreatitis and acute kidney injury, among other conditions.[27] Medspas offer medical treatments in spa-like environments, touting luxurious or elegant experiences, without the intimidation factor or stigma of a medical facility. Regardless, when such facilities perform medical procedures, a medical risk remains.

The marketing of IV hydration, GLP-1s, medspas, and DTC services usually rely on anecdotes instead of data, placebo effects, and sometimes play on fears of modern medicine, chemicals, or "toxins."[28] Marketing for these treatments frequently uses non-medical terminology, including "hangover cure," "energy boost," "metabolic optimization," and "body transformation," which may circumvent the FDA's regulatory purview over medical claims. Websites promote bold claims, provide few if any scientific studies or mention any potential side effects. Influencers on social media often tout GLP-1s and botulinum toxin, among other services, in a patient's pursuit of wellness, often without acknowledging they are being paid for such promotions. According to one estimate, there were nearly a half million social media posts about GLP-1s across various media platforms in the first three months of 2024, and influencers may make as much as $30,000 per month for promotions.[29] A 2025 survey found that 38 percent of Americans follow influencer advice on healthcare topics.[30] In practice, patients often approach these services as a way to attain an aspirational self-image, while minimally concerned about potential drawbacks.

Regulatory Considerations and Recommendations

The following considerations and recommendations are intended to provide a broad, comprehensive foundation that may also be applicable to future trends in prescribing and dispensing, regardless of the medical service or treatment.

---

[23] Michigan State University. "Understanding Health, Wellness, and Medicine." March 2025. https://cris.msu.edu/news/dietary-supplements/trending-understanding-health-wellness-and-medicine/.
[24] MedPage Today. "Is 'Wellness' Bad News for Healthcare?" September 2024. https://www.medpagetoday.com/opinion/second-opinions/111745.
[25] Matthew A. Crane, Michael J. DiStefano, and Thomas J. Moore, "False or Misleading Claims in Online Direct-to-Consumer Ketamine Advertising in Maryland," *JAMA Network Open* 6, no. 11 (November 7, 2023). https://pmc.ncbi.nlm.nih.gov/articles/PMC10630893/.
[26] National Library of Medicine. "To IV or Not to IV: The Science Behind Intravenous Vitamin Therapy." *Cureus* 17, no. 6 (June 22, 2025): e86527. https://pmc.ncbi.nlm.nih.gov/articles/PMC12182718/.
[27] Cleveland Clinic. "GLP-1 Agonists." July 2023. https://my.clevelandclinic.org/health/treatments/13901-glp-1-agonists.
[28] *Ibid*
[29] Lorenz, Taylor. "Weight-loss Promoters Are Reeling After TikTok Crackdown." *Washington Post*, May 20, 2024. https://www.washingtonpost.com/business/2024/05/20/tiktok-ozempic-weight-loss-body-shaming/.
[30] PartnerCentric. *The Anxiety of Influencers: Top Trends in Influencer Marketing 2025.* September 23, 2025. https://partnercentric.com/blog/influencer-trust-commerce-statistics/.

Recommendation 1: Scope of Practice

Only the following individuals may diagnose, treat, or prescribe medication for wellness treatments that constitute the practice of medicine:

1) A physician licensed pursuant to the state's Medical Practice Act;
2) A physician assistant/associate (PA) licensed pursuant to the state's Medical Practice Act who holds a valid prescriber number and who has been granted prescriptive authority for this purpose; and
3) Any licensed health care professional who has independent prescriptive authority or has been granted physician-delegated prescriptive authority pursuant to the practice act regulating the health care professional.

Licensees must practice within their statutorily defined scope of practice, comply with any clinic licensure requirements, and neither aid nor abet the unlicensed practice by others.

Recommendation 2: Physician-Patient Relationship

A physician or other delegated health care provider must take appropriate steps, whether in-person or through telemedicine, to establish the physician-patient relationship and conduct all appropriate evaluations and history taking of the patient, consistent with established or prevailing evidence-based standards of care for the particular patient presentation. When the standard of care that is ordinarily applied to an in-person encounter cannot be met by virtual means, the use of telemedicine technologies may not be appropriate.[31]

While wellness treatments can increase access, reduce costs, and enhance patient autonomy, they also present new challenges for regulators and health care professionals. Documentation indicates that these models complicate the traditional provider-patient-pharmacist relationship, often resulting in fragmented medical records, reduced oversight of medication history, and increased risk for drug interactions or duplicative therapies. The regulatory environment, especially in online clinics, where the patient may be in one state, the provider in another, and the pharmacy in a third, is complex. However, each prescribing and dispensing sequence must still comply with state and federal laws, requiring valid prescriber-patient relationships, careful tracking of prescriptions, and robust patient education, even in a virtual setting. Active oversight is necessary to ensure patient safety while preserving the promised benefits of convenience and expanded access to care.

Recommendation 3: Standard of Care

If a service constitutes the practice of medicine, the patient requires an assessment by an appropriately licensed healthcare professional, who must follow the standard of care to diagnose, treat, correct, advise, or prescribe, within their scope of practice. A health care professional who delegates treatment must be sure that the delegate is appropriately trained, and that the licensed health care professional retains responsibility for the patient's care, including any reasonable monitoring standards and protocols for possible side effects should they arise.

A physician, PA, or licensed health care professional who has been granted physician-delegated prescriptive authority must personally evaluate the patient, diagnose the patient, and make treatment recommendations. A comprehensive medical record must be created that complies with the prevailing standard of care. It is the obligation of the physician, PA, or licensed healthcare professional to exercise their medical judgment in determining that the treatment will actually

[31] Federation of State Medical Boards (FSMB). *The Appropriate Use of Telemedicine Technologies in the Practice of Medicine: Report of the FSMB Workgroup on Telemedicine.* April 2022. https://www.fsmb.org/siteassets/advocacy/policies/fsmb-workgroup-on-telemedicineapril-2022-final.pdf.

DRAFT

benefit the patient and is for a legitimate medical purpose. Licensees may administer drugs only if administration is within that licensee's scope of practice. It is also critical for the health care professional to educate the patient about the nature of the procedure, any treatment alternatives, potential side effects, and receive informed consent prior to initiation.

Diagnosing, prescribing, or other treatment based solely on static online questionnaires, or those that do not obtain all of the information necessary to meet applicable standards of care, are not acceptable. Physicians and other healthcare professionals practicing telemedicine utilizing adaptive questionnaires must have the ability to ask follow-up questions or obtain further history, especially when doing so is required to collect adequate information to appropriately diagnosis or treat the patient.

When prescribing through telemedicine technologies, measures must be implemented to uphold patient safety in the absence of a traditional physical examination. Measures to assure informed, accurate, and error prevention prescribing practices (e.g. integration with e-Prescription systems) are recommended. To further assure patient safety in the absence of a physical examination, telemedicine technologies should limit medication formularies to ones that are deemed safe.

Prescribing medications via telemedicine, as is the case during in-person care, is at the professional discretion of the physician or other licensed health professional authorized in their jurisdiction to prescribe. The indication, appropriateness, and safety considerations for each prescription issued during a telemedicine encounter must be evaluated by the physician or other health professional in accordance with state and federal laws, as well as current standards of practice, and consequently carry the same professional accountability as prescriptions delivered during an encounter in person. However, where such measures are upheld, and the appropriate clinical consideration is carried out and documented, physicians may exercise their judgment and prescribe medications as part of telemedicine encounters.[32]

Prescribing medications, and treatment of a patient, based solely on a patient-driven selection from a "menu" of options does not meet the standard of care.

Recommendation 4: Medical Records

A comprehensive medical record must be created that complies with the standard of care. In addition to informed consent, the physician, PA, or delegated healthcare professional should keep accurate and complete records to include:

- The patient's medical history and physical examination results;
- Diagnostic, therapeutic and laboratory results;
- Results of evaluations, consultations and referrals;
- Treatment objectives and treatments rendered;
- Documentation of a discussion of risks and benefits;
- Medications (including date, type, dosage and quantity prescribed);
- Instructions and agreements; and
- Periodic reviews.[33]

[32] *Ibid.*

[33] Federation of State Medical Boards (FSMB). *Model Guidelines for the Use of Complementary and Alternative Therapies in Medical Practice.* April 2002. https://www.fsmb.org/siteassets/advocacy/policies/model-guidelines-for-the-use-of-complementary-and-alternative-therapies-in-medical-practice.pdf.

DRAFT

The medical record should remain current, accessible, and consistent with all established laws and regulations governing patient healthcare records, including the length of time they must be retained (policies vary by state but generally span three to ten years).[34]

Recommendation 5: Informed Consent

In-Person:

Evidence documenting appropriate patient-informed consent must be obtained and maintained. Appropriate informed consent should, as a baseline, include the following items:

- Identification of the patient and the physician, including the physician's credentials;
- Types of transmissions permitted using the therapy or treatment (e.g. prescription refills, appointment scheduling, patient education, etc.);
- Agreement from the patient with the physician's determination about whether or not the condition being diagnosed and/or treated is appropriate for the therapy or treatment; and
- An accurate description of the benefits and risks of treatment, based on scientific evidence, as well as an explanation of possible alternatives to treatment, and the right to withdraw from treatment or an intervention without denial of standard of care to the patient.[35]

Via Telemedicine:

For services provided through telemedicine, evidence documenting appropriate patient informed consent for the use of telemedicine technologies must be obtained and maintained. Appropriate informed consent should, as a baseline, include the following items:

- Identification of the patient and the patient's location;
- Identification of the physician, including the physician's credentials, and the physician's state or territory of practice;
- Identification of the patient's primary care physician, if available;
- Types of transmissions permitted using telemedicine technologies (e.g. prescription refills, patient education, etc.);
- The patient agrees that the physician determines, in conjunction with applicable laws, whether or not the condition being diagnosed and/or treated is appropriate for a telemedicine encounter;
- Details on security measures taken with the use of telemedicine technologies, such as encrypting data, enabling password protection of data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy notwithstanding such measures;
- A "hold harmless" clause for information lost due to technical failures; and
- Requirement for express patient consent to forward patient-identifiable information to a third party, if consistent with state and federal law.[36]

Recommendation 6: Patient Monitoring and Continuity of Care

Patient monitoring, particularly during IV therapy or PAT treatments, must be thorough and performed by appropriately trained health care professionals. Depending on the type of care, monitoring vital signs, including measuring cardiovascular and respiratory function, as well as

[34] Health Info Law. *Medical Record Retention Required of Health Care Providers: 50 State Comparison. January 2016.* https://www.healthinfolaw.org/comparative-analysis/medical-record-retention-required-health-care-providers-50-state-comparison.

[35] Federation of State Medical Boards (FSMB). *Regenerative and Stem Cell Therapy Practices. April 2018.* https://www.fsmb.org/siteassets/advocacy/policies/fsmb-stem-cell-workgroup-report.pdf.

[36] Federation of State Medical Boards (FSMB). *The Appropriate Use of Telemedicine Technologies in the Practice of Medicine: Report of the FSMB Workgroup on Telemedicine.* April 2022. https://www.fsmb.org/siteassets/advocacy/policies/fsmb-workgroup-on-telemedicineapril-2022-final.pdf.

DRAFT

side effects, toxic effects, allergic reactions, and unexpected adverse outcomes are required, although the monitoring time period may vary by the type of care.

The patient, or their designee, should be able to seek, with relative ease, follow-up care or information from the health care professional from whom they received care, whether in-person or via telemedicine. Providers have the responsibility to refer patients for follow-up care, such as a physical exam, diagnostic testing, labs, or imaging when medically indicated. For emergencies or complications, the provider should have a standing plan in place and the responsibility to refer the patient to appropriate care (e.g. acute care, emergency room, or another provider) to ensure patient safety; simply referring all patients to the emergency department in the event of an unexpected outcome may be insufficient.

Terminating the medical care of a patient without adequate notice or without making other arrangements for the continued care of the patient, with a qualified caregiver, may be considered patient abandonment and result in discipline from a regulatory board.[37]

Recommendation 7: Advertising

Physicians, PAs, and other healthcare professionals are permitted to advertise themselves, their practice and services offered, provided that the advertisements do not contain any claims that are deceptive or intentionally false or misleading. Physicians, PAs, and other healthcare professionals should be mindful of ways in which patient testimonials, quality ratings, or other evaluative data are presented to prospective patients through advertisements. Such information must be presented in an objective manner and physicians, PAs, and other healthcare professionals must not deliberately misrepresent the expected outcomes or results of treatments offered. This also applies to advertisements about the benefits or efficacy of medical devices sold or rented by physicians, PAs, and other healthcare professionals. Physicians, PAs, and other healthcare professionals should be prepared to support any claims made about the benefits of treatments or devices with documented evidence, for example with studies published in peer reviewed publications.

Physicians, PAs, and other healthcare professionals must be accurate and not intentionally misleading in providing descriptions of their training, skills, or the treatment they are able to competently offer to patients. This includes descriptions of one's specialization and any specialty board certifications. For example, a family physician who chooses to expand his or her area of practice to offer cosmetic procedures cannot describe him or herself as a cosmetic or plastic surgeon in advertisements, unless they have undergone the appropriate postgraduate training to assume the relevant title. As part of the informed consent process, it is essential that patients are fully informed and not misled about any treatment to which they are consenting, as well as the qualifications of the person or people providing it.[38]

Recommendation 8: Compounding

Compounding must occur in strict compliance with federal and state laws, applicable U.S. Pharmacopeia (USP) standards, and conditions designed to prevent contamination and ensure patient safety. By law, the addition of any drug, medication, vitamin, mineral, amino acid, or other substance to an IV solution constitutes compounding. The FDA defines compounding as "the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient." This includes the combining of two or more drugs. Compounded drugs

[37] *Ibid*

[38] Federation of State Medical Boards (FSMB). *Position Statement on Sale of Goods by Physicians and Physician Advertising.* April 2016. https://www.fsmb.org/siteassets/advocacy/policies/position-statement-on-sale-of-goods-by-physicians-and-physician-advertising.pdf.

DRAFT

are not FDA approved. Accordingly, compounding must result from a valid practitioner's order during professional practice based on a specific medical need and may not originate from patient-driven menu selections or requests.

Compounded medications should only be prepared when they are in the best interests of an identifiable patient and should not be compounded in large quantities in anticipation of future demand or for retail sale. Such practices may fall under traditional drug manufacturing, which is limited to FDA-registered entities subject to more stringent oversight. Although Section 503A of the Food, Drug, and Cosmetic (FD&C) Act allows anticipatory compounding in limited quantities before receipt of a prescription, compounding beyond these limited amounts is not permitted.

Compounding must follow the standards outlined in the USP-National Formulary (USP–NF), particularly Chapters <795>, <797>, and <800>, which establish enforceable requirements for non-sterile compounding, sterile compounding, and the handling of hazardous drugs. USP <797> applies to all personnel and settings where compounded sterile preparations are made, including physicians, pharmacists, nurses, and other health care professionals in hospitals, clinics, pharmacies, and office-based practices.

Physicians are encouraged to refrain from compounding when an FDA-approved medication from a licensed and inspected facility is available, except where exempt under USP <797>. When preparing compounds for administration by another provider, physicians should not compound for patients who are not also their own. If a physician compounds sterile medications, they and their staff are responsible for understanding and employing aseptic technique and complying with all applicable federal and state requirements. In general, physicians are encouraged to limit compounding to non-sterile preparations unless sterile compounding is a recognized and routine part of their specialty and appropriate facilities, equipment, and protocols are in place.

Compounding may be delegated to other qualified staff only when performed under direct on-site supervision; remote oversight is not permitted. Clinics that do not prepare their own compounded products must obtain them from a licensed pharmacy or a federally registered 503B outsourcing facility.

Physicians must ensure that each active ingredient in a compounded product is necessary to treat the patient's condition, and the medical rationale — including justification of necessity —should be documented in the patient's record. Physicians should not add ingredients solely to affect reimbursement, nor should they charge unreasonable or exploitative fees. Ultimately, the treating physician is responsible for the safety, legality, and proper preparation of compounded medications, including oversight of any personnel who assist in compounding activities.[39,40]

Recommendation 9: Ownership, Supervision, and Delegation

State laws and regulations vary regarding acceptable ownership and entity restrictions for physicians, PAs, and other licensed healthcare professionals. Regardless of the ownership structure of a medspa or clinic, neither the business nor the business owner is permitted to exercise any control over the way physicians and other health care professionals provide medical, nursing, or pharmacy services. Owners cannot interfere with the licensee's obligation to ensure compliance with applicable state and federal laws, or the medical judgment of prescribers.

[39] Federation of State Medical Boards (FSMB). *White Paper on Compounding of Medications by Physicians. April 2020.* https://www.fsmb.org/siteassets/advocacy/publications/white-paper-on-physician-compounding-2020-for-posting.pdf.

[40] Rhode Island Department of Health. *Guidance Document Regarding the Operation of Medical Spas and Intravenous (IV) Therapy Businesses.* July 2024. https://health.ri.gov/sites/g/files/xkgbur1006/files/publications/guidance/Medical-Spa-and-IV-Therapy-Business.pdf.

Physicians and other prescribers should understand state laws and rules before entering into employment or partnership with these and similar businesses.[41] Maintaining access to and having the ability to produce records is ultimately the responsibility of the licensee.

Additionally, regardless of whether the authority has been delegated to a PA or another licensed healthcare provider, the supervising physician or medical director is ultimately responsible for ensuring the safety of the patient. If the supervising physician or medical director is not physically located at the clinic or facility, they should be easily and readily accessible with a set plan in place should there be an emergency or complications.

Recommendation 10: Standing Orders/Protocols

Physicians, PAs, and other licensed health care professionals with prescriptive authority utilizing "standing orders" as a means of delegating medical diagnosis, prescribing, or treatment decisions to non-physician providers may risk violating a state's medical practice act and such a practice may effectively constitute the unauthorized practice of medicine. This delegation could circumvent legal requirements that a licensed healthcare professional must establish a physician-patient relationship, and have the requisite knowledge, skills, and judgment to perform a direct and individualized assessment, make a diagnosis, and formulate a personalized treatment plan before any prescription medication, including IV fluids, compounded vitamin cocktails, or ketamine infusions, is administered. "Standing orders" issued by clinic medical directors in the absence of a physician-patient relationship are not valid prescriptions nor are they adequate to establish a diagnosis and identify underlying conditions or contraindications to the treatment.[42] Attempting to bypass these core duties through standing orders in retail or online prescribing environments risks regulatory censure and potential criminal penalties for participating in or enabling the unauthorized practice of medicine.

Recommendation 11: Regulatory Board Collaboration and Education

State regulatory boards should collaborate regarding the regulation of those providing services at retail therapy clinics. Since the services overlap many different licensees and practice acts – including state boards of medicine, nursing, pharmacy, dentistry, and other regulatory agencies that license and discipline health care professionals – a collaborative approach will permit the full scope of the services to be covered.

Regulatory boards should also raise awareness among the public of the potential risks associated with retail therapy clinics to ensure public safety and prevent public harm and exploitation from unethical or unprofessional medical practice.

.

DRAFT

[41] Ohio State Medical Board, Ohio Board of Pharmacy, and Ohio Board of Nursing. *Joint Regulatory Statement Regarding Retail IV Therapy Clinics*. May 2025. https://www.pharmacy.ohio.gov/documents/pubs/special/ivtherapy/joint%20regulatory%20statement%20on%20the%20operation%20of%20retail%20iv%20therapy%20clinics%20in%20ohio.pdf.

[42] There are exceptions in which standing orders may be valid prescriptions, such as statewide public-health standing orders for anti-overdose medication; prescribing an epinephrine auto-injector in a school's name and issuing a standing order for its use; and EMS providers administering Schedule II-V controlled substances in the course of providing emergency medical services; among other possible exceptions.

FSMB Workgroup on Trends in Prescribing and Dispensing

Members:

Christine Khandelwal DO, MHPE, Workgroup Chair
FSMB Board of Directors
North Carolina Medical Board

Nicole “Nicki” Chopski, PharmD, ANP
Idaho Division of Occupational and Professional Licenses
President-Elect, National Association of Boards of Pharmacy (NABP)

Kenneth Cleveland, MD
FSMB Board of Directors
Executive Director, Mississippi State Board of Medical Licensure

Kathryn Emmett, Esq.
Chairperson, Connecticut Medical Examining Board

Joy Eckert, MPH (Subject Matter Expert)
Research Manager, The Reagan-Udall Foundation (FDA)

Shami Goyal, MD, MMM
Chief Medical Officer, Illinois State Medical Board

Anjali Gupta, MBBS, MPH
Former Member, Minnesota Board of Medical Practice

Alexander S. Gross, MD
Former Chair, Georgia Composite Medical Board

Kristin Hellquist, MS
Senior Chief Advocacy Officer, American Society for Dermatologic Surgery Association (ASDSA)

Stephanie Loucka, JD
Executive Director, State Medical Board of Ohio

Phyllis Polk Johnson, DNP, APRN, FNP-BC
President, National Council of State Boards of Nursing (NCSBN)
Executive Director, Mississippi Board of Nursing

Susan Winckler, RPh, Esq (Subject Matter Expert)
CEO, The Reagan-Udall Foundation (FDA)

Ex Officio:

George M. Abraham, MD, MPH
Chair, FSMB Board of Directors
Former Chair, Massachusetts Board of Registration in Medicine

DRAFT

Christy L. Valentine Theard, MD, MBA
Chair-elect, FSMB Board of Directors
Former President, Louisiana State Board of Medical Examiners

Humayun J. Chaudhry, DO, MACP
President and CEO, FSMB

Staff Support:

John P. Bremer
Managing Director, Advocacy and Policy, FSMB

Andrew Smith, MPP
Manager, Legislation and Policy, FSMB

DRAFT