JOINT STATEMENT OF THE KENTUCKY BOARDS OF MEDICAL LICENSURE, NURSING AND PHARMACY REGARDING RETAIL IV THERAPY

The retail IV therapy business model is rapidly expanding across the country. Many clinics engaging in this therapy are adopting business and/or practice models without realizing IV therapy constitutes the practice of medicine, nursing and/or pharmacy. Many of these establishments do not have appropriately licensed and qualified staff to perform the necessary tasks and satisfy minimum statutory and regulatory requirements of practice. The Kentucky Board of Medical Licensure, Kentucky Board of Nursing, and Kentucky Board of Pharmacy acknowledge and appreciate the work of their colleagues at the South Carolina Boards of Medical Examiners, Pharmacy and Nursing, the Alabama Board of Medical Examiners, and the Mississippi State Board of Medical Licensure for rendering thoughtful and well-reasoned guidance on the issues presented herein. Kentucky licensees are encouraged to review the guidance offered in those states and to consider its application within the Commonwealth of Kentucky.

Typical Retail IV Therapy Business Model

The typical retail IV therapy business model offers to walk-in patients a menu of pre-selected mixtures ("cocktails") of additives to basic IV saline. The cocktails include amino acids, vitamins, minerals, and some prescription drugs like Pepcid, Toradol, and Zofran. The cocktails are offered to patients for the treatment of conditions such as dehydration, migraine relief, hangover recovery, nausea relief, athletic recovery, appetite regulation, and inflammation support.

Although a physician (MD/DO) may be associated with the business, the physician is usually not on the premises. Instead, the business uses the physician's National Practitioner Identification ("NPI") number to acquire the IV supplies and additives, and the physician issues "standing orders" directing the administration of IVs.

Commonly, a patient walks into the business, reviews a menu of treatment options, completes a health questionnaire, and undergoes a precursory evaluation (including pulse oximetry, heart rate, blood pressure, review of medications and allergies) with an employee, usually an employee nurse. The employee will discuss the patient's symptoms and treatment goals. The employee recommends an IV cocktail, with or without additives, based on "standing orders" prepared by a physician. The employee mixes the IV bag and

administers the IV therapy. The employee assesses the patient's treatment and observes any complications. Once the IV therapy is complete, the employee removes the IV catheter and applies a dressing. The patient is then discharged.

The signatory Boards are concerned whether qualified individuals are making appropriate diagnoses and administering these IVs in a legal manner based upon their statutorily defined scopes of practice. Notably, operation of retail IV therapy clinics implicates multiple areas of the Kentucky Pharmacy Practice Act, including compounding, dispensing, storage, safeguarding and administration of sterile products.

Licensees Scope of Practice

The FDA defines compounding as the combining, mixing or alteration of ingredients of a drug pursuant to a prescription to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients, they also present a risk to patients because of instances when in which medications, primarily injectable medications that are intended to be sterile have endangered public health. Compounded drugs are not FDA-approved. The FDA has not reviewed these drugs to evaluate their safety, effectiveness, or quality before they reach patients.

Pursuant to federal law, compounding may be performed by a licensed pharmacist in a state-licensed pharmacy, or federal facility, or by a physician. Regardless of where compounding occurs, in a pharmacy or physician's office, federal and state law apply.

The retail IV therapy business model implicates the practice of medicine, nursing and/or pharmacy. The practice of these professions requires a license, and the scope of practice is defined by statutory schemes specific to each profession. A license to practice these professions is specific to the licensee and is not a "plus one" – i.e., the licensee may not "train and delegate" their professional scope of practice to any other unlicensed person. Only licensed professionals may diagnose a patient, assess his or her symptoms, recommend and administer an IV for the treatment of the patient's condition and compound medications.

Licensees of the Kentucky Board of Medical Licensure, Kentucky Board of Nursing, and the Kentucky Board of Pharmacy are cautioned to practice within their statutorily defined scope of practice and to neither aid nor abet the unlicensed practice of others.

Medical Practice Act

There is no question that the services being provided by IV retail clinics constitutes the practice of medicine or osteopathy. The practice of medicine or osteopathy in Kentucky is defined as "the diagnosis, treatment, or correction of any and all human conditions, ailments, diseases, injuries, or infirmities by any and all means, methods, devices, or instrumentalities." *See* KRS 311.550(10). Physicians must practice within acceptable and

prevailing medical practices and are individually responsible and accountable for their clinical decisions. The Kentucky Board of Medical Licensure adopts by reference herein its "Board Opinion Regarding 'Practice Drift'" (published December 20, 2023) and encourages its licensees to review that opinion. Physicians may prescribe and administer medications, including compounded medications, but they may not delegate the prescribing, compounding or administration of such medications to other unlicensed persons.

If the IV therapy treatment is pursuant to a lawful prescription, it may be prepared for immediate use, i.e., administration within four hours. However, the preparation cannot include more than three different sterile products. Otherwise, under the Food, Drug and Cosmetic Act, the preparation of the IV therapy treatment would need to comply with the USP 797, including the facility and engineering controls that include the use of isolators, air exchange requirements, precise pressure differentials, humidity control and cleanroom suites with access doors and seals. Despite USP 797 not applying entirely to the compounding of three or fewer sterile products that will be administered in fewer than four hours, there are provisions of USP 797 that under federal law still govern. Those standards are found on pages 5-7 of this document but include specific training requirements and the use of aseptic techniques.

Nurse Practice Act

A nurse's practice should be consistent with the Kentucky Revised Statutes Chapter 314, evidence based, and within established standards of practice. Nurses are responsible and accountable for their decisions regarding the implementation of patient care orders based upon the individuals' educational preparation and clinical competence in nursing. See KRS 314.021(2). The Kentucky Board of Nursing adopts by reference its Advisory Opinion Statement 15- "Role of Nurses in the Supervision and Delegation of Nursing Tasks to Unlicensed Personnel" and encourages its licensees to review that opinion.

IV therapy is a treatment. An Advanced Practice Registered Nurse (APRN) may be authorized to prescribe and administer certain medications. See KRS 314.011(8) and 314.042(6)(c). Prior to determining and ordering a course of treatment, the APRN should establish a practitioner-patient relationship, see KRS 218A.010(41), and conduct a good-faith prior examination, see KRS 218A.010(18), to assess a patient's medical history. Such assessments may be conducted by a Registered Nurse (RN) using a standardized review document as noted within protocols or standing orders that have been created by the facility/agency/office providing IV hydration services. The standardized review must be approved by the prescribing practitioner. An APRN may order and stock nonscheduled legend drugs for the specific purpose of prescribing them for the direct administration.

It is within the scope of an RN or a licensed practical nurse to administer medication and treatment if it has been lawfully prescribed by a physician, physician assistant, dentist, or APRN. See KRS 314.011(6)(c) and (10)(c).

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Pharmacy Practice Act

The Board of Pharmacy has received numerous inquiries regarding IV hydration therapy by non-practitioners and is troubled about the safety of this practice. By adding drugs or vitamins to the IV bag, these individuals at IV therapy clinics are compounding. "Compound" or "compounding" is defined by the Kentucky Pharmacy Practice Act as the preparation or labeling of a drug pursuant to or in anticipation of a valid prescription drug order, including but not limited to packaging, intravenous admixture, or manual combination of drug ingredients. At the federal level, the Food and Drug Administration (FDA) defines compounding as "the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient." Compounding is the responsibility of a licensed pharmacist. Because of this requirement, a Board of Pharmacy permit is required for any place where prescription drug orders are compounded under the supervision of the pharmacist. The only exception to this is when a physician is compounding in their practice or a physician, pharmacist or APRN is compounding for immediate use.

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Non-practitioners, including but not limited to RNs, EMTs, and LPNs, may not possess and/or store legend medications of any type. This prohibition includes overnight storage in any non-permitted location, including but not limited to a home or vehicle.

USP 797 Standards[1]—the FDA Enforceable Standard for all Practitioners

In relation to pharmaceutical compounding, USP (United States Pharmacopeia) is the FDA recognized standard of care in relation to all things compounding, to include sterile compounding found in USP 797, and has been adopted by the FDA as the enforceable standard. Furthermore, all sterile compounding performed by pharmacists is subject to the requirements outlined in 201 KAR 2:076. For purposes of USP 797, sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile medication. This chapter applies to all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared for human and animal patients. This includes, but is not limited to, pharmacists, technicians, nurses, physicians, veterinarians, dentists, naturopaths, and chiropractors in all places including, but not limited to, hospitals and other healthcare institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physicians' or veterinarian practice sites. The compounding facility must designate one or more individuals as a designated person(s). This individual is responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions as described in USP 797.

"Immediate Use" does not negate following USP 797. Certain provisions still apply.
The concept of "immediate use" is being interpreted to allow the compounding of IVs to circumvent USP requirements, especially for sterility and training. USP <797>'s "immediate use" provision governs the emergency preparation of a sterile drug product, and in certain circumstances, this provision allows for the preparation of a sterile product to be made outside of full USP compliance. This provision is not a workaround for the quality and safety standards that govern sterile product preparation.

Standards for Immediate-Use of Compounded Sterile Preparations

All the following conditions shall be met before a compounded sterile preparation may be prepared for immediate use:

Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of

[1] "United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—sterile preparations (2023).

particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.

- Aseptic processing: A method by which separate, sterile components (e.g. drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (e.g. by membrane filtration or by autoclave).
- Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
- Facilities that prepare CSPs must develop SOPs for the compounding process and other support activities. SOPs must include the types of CSPs that are prepared. A designated person(s) must ensure that SOPs are appropriate and are implemented, which includes ensuring that personnel demonstrate competency in performing every procedure that relates to their job function. All personnel who perform or oversee compounding or support activities must be trained in SOPs.
- SOPs must be reviewed initially and at least every 12 months by the designated person(s) to ensure that they reflect current practices, and the review must be documented. Any changes or alterations to an SOP must be made only by a designated person(s) and must be documented. Revisions to SOPs must be communicated to all personnel involved in these processes and procedures, and personnel should document acknowledgement of the communication.

- Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.
  - Personnel compounding only immediate-use CSPs must complete training as required by the facility's SOPs.
  - Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel must complete training and be able to demonstrate knowledge of principles and competency of skill for performing sterile manipulations and achieving and maintaining appropriate environmental conditions ***as applicable*** to their assigned job functions. This must be completed initially and at least every 12 months in at least the following:
    - Hand hygiene
    - Cleaning and disinfection
    - Calculations, measuring, and mixing
    - Aseptic technique
  - All compounding personnel must be trained to:
    - Recognize potential problems, deviations, failures, or errors associated with preparing a CSP (e.g. those related to equipment, facilities, materials, personnel, the compounding process, or

testing) that could potentially result in contamination or other adverse impact on CSP quality
        - Report any problems, deviations, failures, or errors to the designated person(s)
    - If the facility has only one person in the compounding operation, that person must document that they have obtained training and demonstrated competency, and they must comply with the other requirements of this chapter.
- The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g. approved labeling, stability, and compatibility studies).
- The preparation involves not more than 3 different sterile products.
- Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.
    - A conventionally manufactured single-dose container is a container closure system that holds a sterile product for parenteral administration (injection or infusion) that is not required to meet the antimicrobial effectiveness testing requirements.
    - Single-dose containers: A container of sterile product for parenteral administration (e.g. injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative. See <659>, *Injection Packaging Systems, Single-dose container.*
- Administration begins within 4 hours following the start of the preparation. If administration has not begun within 4 hours following the start of preparation, it must be promptly, appropriately, and safely discarded.
    - Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form.
- Unless directly administered by the person who prepared it or administration witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 4-hour time period within which administration must begin.

Acceptable and Prevailing Practices

Delegation

Neither a business nor business owner can lawfully exercise control over the independent professional clinical judgment of a licensed healthcare professional. Licensees are responsible for practicing within their scope of practice and exercising their professional

judgment within the standards of acceptable and prevailing practice of their individual profession.

Delegation of one's professional clinical judgment and responsibilities to unqualified and unlicensed persons is prohibited. In that vein, licensees are cautioned against the use of "standing orders" that may allow unqualified and unlicensed employees to exercise discretion, make diagnoses, and prescribe and compound IV medications under guise of a licensee's authority. The Food, Drug and Cosmetic Act only authorizes pharmacists and physicians to compound drugs. Compounding for immediate use is the only exception and this practice is authorized to be performed by an APRN. Utilizing a standing order to bypass this federal requirement is unlawful. The issuance of standing orders by a practitioner to the RN to follow does not satisfy the physician's legal duties to the patient. Nor does it satisfy a PA's or APRN's duty to the patient. The use of standing orders in what is supposed to be an individualized assessment, diagnosis and treatment of patients at a retail IV therapy business creates a situation in which the physician is aiding and abetting the unlawful practice of medicine by the RN.

The diagnosis of the patient's condition and the recommendation of IV therapy constitutes the practice of medicine. This act is outside the scope of practice for an RN. Only a physician, PA or APRN has the statutory authority to diagnose a patient and make the decision to provide medication, by injection or otherwise.

The discussion with the patient and recommendation of an IV and additives thereto, including "cocktails" and prescription drugs, are also outside the scope of practice of an RN. Only a licensed physician, PA or APRN may diagnose a patient, assess his or her symptoms, and recommend IV treatment for the patient's condition.

While some retail IV therapy businesses have a physician owner, co-owner, investor, or associate, it has been reported that the physician or another licensed practitioner may not actually evaluate the patient. Instead, a physician, PA, or APRN may be a "medical director," "on staff," or "available," but only the RN treats the patient, aside from the patient's specific request for medications. This is insufficient to establish a valid practitioner-patient relationship which is required before the administration of prescribed drugs.

Purchasing Legend Drugs

IV therapy fluids are legend drugs and must be purchased under a qualified practitioner's authority. As with other legend drugs, to satisfy legal requirements, a qualified licensed practitioner must establish a valid practitioner-patient relationship, make an *individualized differential diagnosis necessitating IV therapy*, develop a treatment plan, and prescribe IV fluids for a specific patient. The adding of drugs or vitamins to a prescription IV bag is a compounding practice and must be performed in accordance with Kentucky Board of Pharmacy laws.

Legend drugs should only be purchased from wholesalers licensed with the Kentucky Board of Pharmacy, and compounded drug products should only be purchased from 503B outsourcing facilities licensed by the Kentucky Board of Pharmacy. 503B outsourcing facilities sell compounded drug product directly to licensed healthcare facilities or practitioners where it is used as office stock for an APRN or physician to administer directly to a patient or for a pharmacy to dispense pursuant to a prescription. No compounded drug product may be resold, transferred, or redistributed unless authorized under state and federal law. The Kentucky Board of Pharmacy issued an opinion-declaratory ruling specifically for pharmacies acquiring 503B compounded drug products. This guidance also applies to physicians and APRNs purchasing compounded drug products from 503B outsourcing facilities. If a compounded drug product from a 503B outsourcing facility is obtained, no further manipulation may occur except for products being administered in an acute care facility by a healthcare provider or if the product is labeled with a patient specific label. Adding additional compounded drug product or legend drugs to the compounded drug product procured from the 503B outsourcing facility in any other setting is considered adulteration and is prohibited.

Patient Choice of Drugs

The participation of the patient in the selection of the IV additives is problematic because the patient is not a practitioner. A patient is not licensed to practice medicine. A patient cannot enter a doctor's office or hospital and demand an IV any more than a patient can direct his or her own appendectomy. Even physicians are prohibited from treating themselves except in emergency situations.

Comprehensive Medical Record

The physician, PA, or APRN must personally evaluate the patient, diagnose the patient, and make the treatment recommendations. The physician, PA, or APRN must further create a comprehensive medical record that complies with the standard of care. If the physician, PA, or APRN decides to prescribe IV therapy, he or she must issue a prescription, and only then may the IV therapy be administered. It is the obligation of the physician, PA, or APRN to exercise their medical judgment in determining that the treatment will actually benefit the patient. A licensed person other than the physician, PA, or APRN may administer the IV only if administration of IVs is within that licensee's scope of practice.

Conclusion

Licensees must protect themselves and the public by ensuring that their participation in any business venture constituting the practice of medicine, nursing, or pharmacy complies with legal requirements and satisfies all applicable professional standards. Public health and safety require no less.

Despite the proliferation of IV hydration clinics around the state, the diagnosis of a condition that results in the ordering of IV-delivered drugs, amino acids, or vitamins is unambiguously the practice of medicine. Likewise, the storage and administration of these medications constitutes both the practice of pharmacy and the practice of nursing. Failure to be licensed by the Boards as required is a violation of Kentucky law and can be punished. Meanwhile, failures by licensees to follow the laws governing their practice(s) could result in disciplinary proceedings and sanctions by their respective boards; by law, sanctions may include monetary fines, probation of a license, suspension of a license, or even revocation of a license, as set forth in each of the practice acts.

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