



DECLARATORY RULING OF THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

On June 16, 2022, the Alabama State Board of Medical Examiners (“BME”) considered an investigation concerning the operation of certain wellness clinics offering to administer intravenous (“IV”) medications to persons for a fee. The BME issues this declaratory ruling pursuant to Ala. Code § 41-22-11 and Ala. Admin. Code R. 540-X-1-.10 to clarify what practices constitute the practice of medicine or osteopathy under Ala. Code § 34-24-50.

FACTS PRESENTED

On July 21, 2021, the BME began a state-wide investigation into businesses providing IV therapy (“retail IV therapy businesses”). On September 21, 2021, BME investigators visited ten (10) retail IV therapy businesses. These businesses were selected to provide geographic representation of the state. Each business was presented with a standard questionnaire for business personnel to answer in addition to a subpoena requiring the production of documents, to include the identity of any licensed healthcare personnel working for the business and medical records showing the provision of IV therapy to patients.

On June 16, 2022, the BME considered the information gained from this investigation. The retail IV therapy business model is growing in Alabama; however, no rules or regulations directly guide their operation. A business entity can own and operate a retail therapy business and often does. The core business is the offering to walk-in patients of 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. They are sometimes marketed with catchy names and 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. Basic health screening occurs prior to the selection and administration of the IV. While a physician may be associated with the business, he or she is usually not on the premises. Instead, a retail IV therapy business uses a physician's National Practitioner Identification ("NPI") number to acquire the IV supplies and additives, and the physician will issue "standing orders" directing the administration of IVs. The actual patient encounter, evaluation, diagnosis, formulation of the treatment plan, and administration of the IV occurs without the physician's input. In certain instances, a registered nurse ("RN") may be the only licensed health care professional interacting with the patient. In other instances, the BME found that chiropractors were involved with the diagnosis, recommendation, and administration of the IVs. The BME received records for one adverse event involving an individual who had suffered a stroke soon after the individual returned home from receiving an IV.

In a substantial number of cases, the retail therapy business was functioning and treating patients in such a manner wherein unqualified or underqualified individuals were operating the business. Representatives from several of the retail IV therapy businesses that were surveyed requested guidance from the BME to clarify the legality of the operations.

QUESTIONS PRESENTED

- (1) May a person other than a licensed physician diagnose, treat, correct, advise, or prescribe intravenous fluid or medication to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, whether real or imaginary?
- (2) May a person other than a licensed physician maintain an office or place of business for the purpose of diagnosing, treating, correcting, advising, or prescribing intravenous fluid



or medication to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, whether real or imaginary?

ANSWER

Only the following individuals may diagnose, treat, correct, advise, or prescribe intravenous medication to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, whether real or imaginary: (1) a physician licensed under Article 3 of Chapter 24 of Title 34, (2) an assistant to physician (“PA”) licensed under Article 7 of Chapter 24 of Title 34 and practicing pursuant to a registration agreement with a licensed physician, or (3) a certified registered nurse practitioner (“CRNP”) or certified nurse midwife (“CNM”) licensed under Article 2 of Chapter 21 of Title 34 practicing pursuant to a collaboration agreement with a licensed physician. Any person who maintains an office or place of business for the purpose of diagnosing, treating, correcting, advising, or prescribing intravenous medication to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, whether real or imaginary, is engaged in the unlawful practice of medicine unless said person (1) employs a physician or a physician and a PA, CRNP, or CNM working within a registration agreement or collaboration with that physician; and (2) the physician or his or her PA, CRNP, or CNM exercises in fact exclusive authority to diagnose, treat, correct, advise, or prescribe intravenous medication to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, whether real or imaginary.

DISCUSSION

The IV therapy retail business model varies in Alabama. Some models comply with Alabama law, but others do not. The BME has received inquiries from business owners who



operate IV clinics requesting clarification. This ruling is intended to clarify the application of state laws and regulations to the administration of IV therapy within the context of a retail or “on-demand” business setting.

Retail businesses offering IV therapy were typically found to operate by offering patients a menu of pre-selected mixtures (“cocktails”) of additives to basic IV saline, including amino acids, vitamins, minerals, and some prescription drugs like Pepcid, Toradol, and Zofran. These cocktails are sometimes marketed with catchy names and 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. Commonly, a patient enters the business and reviews a menu of treatment options. He or she completes a health questionnaire and is evaluated by an RN.¹ This employee may use diagnostic tools to measure the patient’s pulse oximetry, heart rate, and blood pressure. The RN evaluates the patient’s answers to the health questionnaire, which is designed to elicit the patient’s health history, current medications, and allergies. With this information in hand, the RN will discuss the patient’s current symptoms and treatment goals and recommend an IV cocktail, along with any additives that may be indicated. The RN makes the recommendations with the assistance of standing orders prepared by a physician. The RN then mixes the IV bag according to his or her recommendations and the patient’s selection and administers the IV therapy. The RN remains with the patient to assess the patient’s treatment and observe any complications. Once the IV therapy is complete, the RN removes the IV catheter and applies a dressing. The patient is then discharged.

¹ In some locations, a chiropractor was present and interacted with the patient. However, chiropractors are forbidden by state law from prescribing or administering medicine to patients. Ala. Code § 34-24-122.



Under Ala. Code § 34-24-50, the “practice of medicine or osteopathy means (1) to diagnose, treat, correct, advise, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, physical or mental, real or imaginary, by any means or instrumentality;” and (2) “to maintain an office or place of business for the purpose of doing acts described in subdivision (1), whether for compensation or not.” It is a Class C felony for a person to practice medicine or osteopathy without a certificate of qualification issued by the BME and without a license and certificate of registration issued by the Medical Licensure Commission of Alabama. *See* Ala. Code § 34-24-51. It is also violation of state law for a physician to aid or abet the unlicensed practice of medicine. *See* Ala. Code § 34-24-360(13). Each of these prohibitions is implicated by some of the practices observed by the BME’s investigators.

First, 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. *See* Ala. St. Bd. of Med. Examiners Opinion 1-0399 March 23, 1999 (“only the physician has the authority to make the decision to provide medication, by injection or otherwise, to a patient”). The discussion with the patient and recommendation of an IV and the additives to the IV, including the “cocktails” and prescription drugs, are also outside the scope of practice of an RN. Only a licensed physician, or a PA, CRNP or CNM legally practicing with a physician, may diagnose a patient, assess his or her symptoms, and recommend an IV for the treatment of the patient’s condition.

While some retail IV therapy businesses have a physician owner, co-owner, investor, or associate, the physician in most instances does not actually evaluate the patient. Instead, a physician or CRNP may be on staff or “available,” but absent some affirmative action by the patient, the RN will treat the patient. The issuance of “standing orders” by the physician for the



RN to follow does not satisfy the physician’s legal duties to the patient. Instead, this “standing order” model creates a situation in which the physician is aiding and abetting the practice of medicine by the RN, in violation of Ala. Code § 34-24-360(13).²

Indeed, the “standing order” model not only violates Alabama law relating to the unauthorized practice of medicine, but it also implicates the Alabama Pharmacy Act. Physicians are generally authorized to dispense prescription medications. *See* Declaratory Ruling of the Ala. St. Bd. of Med. Examiners for the Jefferson County Department of Health (October 2020). Under Ala. Code § 34-23-11, nothing in the Alabama Pharmacy Practice Act “shall prevent any licensed practitioner of the healing arts from personally compounding, dispensing, administering, or supplying to his or her patients drugs and medicines for their use.” (Emphasis added). This section “clearly exempts duly licensed physicians from the coverage of Chapter 23 . . . and furthermore expressly permits” the activities of dispensing, administering, or supplying drugs and medicines for the use of a physician’s patients. *See* Ala. Op. Att’y. Gen. No. 83-00393 (July 18, 1983) (emphasis added). A “licensed practitioner of the healing arts” includes a physician licensed to practice medicine or osteopathy in Alabama. *See* Ala. Op. Att’y. Gen. No. 96-00263 (July 12, 1996) (concluding that “a licensed physician” is a “practitioner” exempted from the requirements of the Alabama Pharmacy Practice Act under Ala Code § 34-23-11). In the cases surveyed by the BME, the physician’s NPI was typically used to order the medical supplies, medications, and additives. The retail IV therapy businesses are exploiting the exception to the Alabama Pharmacy

² The participation of the patient in the selection of the IV cocktail and additives does not change the analysis. A patient is not licensed to practice medicine. A patient cannot enter a hospital and demand an IV or direct his or her own appendectomy. Even physicians are prohibited from treating themselves except in emergency situations. AMA Code of Medical Ethics Opinion 1.2.1.; Ala. Admin. Code R. 545-X-4-.06(12). A retail IV therapy business cannot obviate the need for physician involvement by letting the patient solely direct his or her own care.



Act by using the physician's NPI to obtain medical supplies from a pharmacy. In these instances, the physician is representing to the pharmacy that he or she is legally permitted to possess the supplies, and that he or she will dispense them to his or her patients. However, a physician's acquisition and dispensing authority is limited to medical supplies obtained and personally compounded and dispensed by the physician for the use of his or her patients. *See* Ala. Code § 34-23-11.

Nonetheless, this personal compounding, administering, or dispensing of medical supplies obtained by the physician to his or her patients is rarely happening. Instead, in instances where the RN alone sees the patient, there is no physician-patient relationship. BME rules generally require the examination of the patient by the physician prior to prescribing a drug or medication. *See* Ala. Admin. Code R. 540-X-9-.11(1). Without an evaluation by the physician to create a physician-patient relationship, the RN is dispensing medical supplies and medications to a person who is not the physician's patient. This violates both the physician's and the RN's legal authority to dispense or administer medications. *See* Ala. Code § 34-23-13.

To comply with Alabama law, retail IV therapy businesses must create a physician-patient relationship through the performance of an individualized evaluation by a physician or a PA, CRNP, or CNM working in a legal registration or collaboration with a physician. The physician, PA, CRNP, or CNM must personally evaluate the patient, diagnose the patient, and make the treatment recommendations. The evaluation and treatment of the patient may occur in person or utilizing telemedicine. *See* Ala. Code § 34-24-703(b). The physician, PA, CRNP, or CNM must further create a medical record that complies with the BME's regulations. If the physician, PA, CRNP, or CNM decides to prescribe IV therapy, he or she must issue a prescription, and only then



may the IV therapy be administered. A licensed person other than the physician, PA, CRNP, or CNM may administer the IV if administration of IVs is within that licensee's scope of practice.

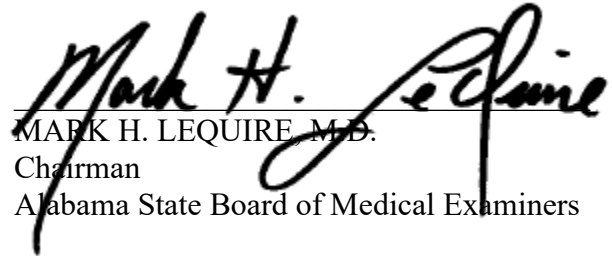
The BME notes that the involvement of business owners in the operation of retail IV therapy businesses may implicate the prohibition against unlicensed persons maintaining an office or place of business for the purpose of practicing medicine. *See Ala. Code § 34-24-50.* A business may employ a physician to provide medical services so long as the physician independently exercises his or her medical judgment when providing medical services to his or her patients. *See Declaratory Ruling of the Medical Licensure Commission 2-1195 (October 28, 1992).* Neither the business nor the business owner is permitted to exercise "any control over the manner in which the physicians provide medical services or the independent exercise of the physicians' medical judgment." *Id.* Whether or not a business is illegally practicing medicine, or whether a physician is illegally aiding and abetting the unlicensed practice of medicine by the business, is a fact-intensive inquiry. However, due to the presence of business owners, franchisors and franchisees, and investors in the corporate makeup of retail IV therapy, physicians are cautioned to understand the BME's regulations and Alabama law before entering employment or partnership with these and similar businesses.

This ruling is based upon the precise facts presented and upon statutes and rules currently in existence. The BME offers no opinion or evaluation of the efficacy of IV therapy as offered by retail IV therapy businesses. This ruling assumes that when a physician, PA, CRNP, or CNM diagnoses a patient and prescribes, orders, or administers an IV, he or she has determined that the treatment will benefit the patient. Should any relevant statutes or rules be amended or repealed,



this ruling may no longer be valid. This ruling is not meant to modify, supplement, or overrule existing protocols and practices in licensed healthcare facilities.

DONE this 21st day of July, 2022.


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Chairman
Alabama State Board of Medical Examiners