JOINT REGULATORY STATEMENT OF THE STATE MEDICAL BOARD OF OHIO, OHIO BOARD OF PHARMACY, AND OHIO BOARD OF NURSING REGARDING RETAIL IV THERAPY CLINICS

Date Issued: 5/15/2025

This statement highlights existing law and is intended for the benefit of practitioners and the public to promote better understanding of the laws governing the practice of medicine, nursing, and pharmacy.

Introduction

As with the rest of the country, the number of retail IV therapy clinics is increasing in Ohio. Many of the clinics are adopting business and/or practice models without realizing the selection, prescribing, preparation, and administration of IV therapy constitutes the practice of medicine, nursing, and pharmacy. Because of the concern over the proliferation of retail IV therapy clinics, the lack of any industry-specific guidelines, and the potential harm to the citizens of this state, the State Medical Board of Ohio, the Ohio Board of Pharmacy, and the Ohio Board of Nursing (collectively the "Boards") have issued this joint regulatory statement. This regulatory statement is based upon existing Ohio laws and rules governing the scope and standards of care and compounding of drugs that are performed by individuals within these clinics.

Description of Current Practices at Retail IV Therapy Clinics

A retail IV therapy clinic offers the administration of IV fluids through drip IV infusion tubing into a patient's vein. The type or composition of the IV fluids is selected from a menu of preselected mixtures ("cocktails") or additives to basic saline. Some common examples include amino acids, vitamin C and vitamin B complex, Myers' Cocktail (magnesium, calcium, vitamin B complex, and vitamin C), Toradol (ketorolac), famotidine, and ondansetron. The cocktails are often offered to patients for the treatment of conditions such as dehydration, migraine relief, hangover recovery, nausea, athletic recovery, appetite regulation, and inflammation support.



Generally, a patient will walk into the business, review the menu of treatment options, complete a health screening questionnaire, and undergo a precursory evaluation (including pulse oximetry, heart rate, blood pressure, review of medications, and allergies) with an employee who is not a prescriber, usually a registered nurse or a paramedic. The employee will then recommend an IV cocktail, with or without additives, based on the "protocol" established by a licensed prescriber, which could be a physician (MD/DO), APRN, or PA. The employee prepares the IV cocktail and administers the IV therapy to the patient. The employee assesses the patient's treatment and observes any complications. Once the IV therapy is complete, the patient is then discharged.

In many instances, a registered nurse or paramedic may be the only licensed health care professional interacting with the patient or present at the facility. The Boards are concerned about whether qualified individuals are making appropriate diagnoses and preparing and administering these IVs in a sterile manner consistent with state law based upon their statutorily defined scopes of practice and are complying with all the laws governing the practice of medicine, nursing, and pharmacy.

Application of Pharmacist, Physician, PA, and APRN Scope of Practice to IV Therapy Practice of Pharmacy - Compounding

Ohio law defines compounding as the preparation, mixing, assembling, packaging, and labeling of one or more drugs pursuant to a prescription issued by a licensed health

¹ The State Board of Emergency Medical, Fire, and Transportation Services (EMFTS) determines the scope of practice for all certified Ohio EMS providers. The Board also authorizes the services respective for each level of Ohio EMS certification within the Ohio EMS scope of practice. Please note that the administration of IV fluids has not been authorized by the EMFTS Board for certified Ohio emergency medical technicians (formerly EMT-Basics). The administration of medicated IV fluids has been authorized solely for certified Ohio paramedics and is not permitted for advanced emergency medical technicians (formerly EMT-Intermediates). For additional questions regarding permitted activities by paramedics within retail IV therapy clinics, please contact the EMFTS Board

² Licensed practical nurses have limited and dependent authority to administer only certain types of IV fluids, and in retail IV therapy clinics the authority is predicated on the RN or physician's presence on site (See ORC 4723.18).

³ "APRN" is used throughout to refer to CNPs, CNSs, and CNMs, but not CRNAs, as CRNAs do not have prescriptive authority outside of a hospital setting. In an IV clinic, a CRNA can only function as an RN and must follow those rules applicable to RNs.

professional authorized to prescribe drugs.⁴ Compounding may only be performed by a licensed pharmacist or licensed health professional authorized to prescribe drugs.⁵ ⁶ The preparation of IV cocktails as previously described is considered compounding under Ohio law and the clinic is required to obtain a license as a terminal distributor of dangerous drugs (TDDD) from the Ohio Board of Pharmacy.

While compounded drugs can serve an important medical need for certain patients, they may also present a risk to patients. Compounded drugs are not FDA approved. In other words, the FDA has not reviewed these drugs to evaluate their safety, effectiveness, or quality. Further, there have been instances when compounded medications - primarily those injectable/IV medications that are intended to be sterile - have endangered public health due to unsanitary conditions or improper storage.

Practice of Medicine - Examination, Evaluation, Diagnosis, and/or Assessment of Patients, as well as Prescribing/Ordering Drugs

The operation of a retail IV therapy clinic involves the practice of medicine, nursing, and pharmacy. The practice of these professions requires a license and adherence to a scope of practice established by Ohio law. A license to practice these professions is specific to the licensee and does not generally permit the delegation of their scope of practice to any other unlicensed person except under specific laws and rules. Only licensed prescribers may diagnose a patient, assess their symptoms, and prescribe/order the administration of sterile compounded medications.

The services provided by retail IV therapy clinics constitute the practice of medicine or osteopathic medicine. The practice of medicine includes examining or diagnosing patients as well as prescribing, advising, recommending, administering, or dispensing a drug or medicine, application, operation, or treatment, of whatever nature, "for the cure or relief of a wound, fracture or bodily injury, infirmity, or disease." Physicians and other prescribers

⁴ See ORC 4729.01 (C)

⁵ See ORC 4729.01, OAC 4729:7-2, OAC 4729:7-3

⁶ The compounding of certain types of drugs in a clinic setting may be delegated to a nurse or nurses. However, a prescriber is required to verify the final product before it is administered to the patient or is required to be physically on-site if verified by a nurse (See OAC 4729:7-3-04)

⁷ See ORC 4731.34 (A)

(APRN/PA) must follow the standard of care for their health care profession and are each responsible and accountable for their clinical decisions.

Only the following individuals may diagnose, treat, or prescribe IV medication:

- (1) A physician licensed pursuant to Chapter 4731. of the Ohio Revised Code;
- (2) A physician assistant, licensed under Chapter 4730. of the Ohio Revised Code, who holds a valid prescriber number issued by the State Medical Board of Ohio and who has been granted physician-delegated prescriptive authority for this purpose; or
- (3) A certified nurse practitioner, certified nurse midwife, or clinical nurse specialist licensed pursuant to Chapter 4723. of the Ohio Revised Code.

Licensees of the State Medical Board of Ohio, the Ohio Board of Pharmacy, and the Ohio Board of Nursing are cautioned to practice within their statutorily defined scope of practice, comply with the clinic licensure requirements of the Ohio Board of Pharmacy, and to neither aid nor abet the unlicensed practice of others.

<u>Legal Restrictions and Prohibitions on Protocols, Nurses, Paramedics, and Unlicensed</u> Individuals

Use of Protocols for Administration of IV Therapy is Prohibited

The use of protocols (sometimes referred to as standing orders) for the recommendation, compounding, and administration of IV medications is not authorized under Ohio law. The Boards have observed clinics where a nurse or paramedic is making recommendations with the assistance of a protocol.

To address the appropriate use of protocols for drug administration, the Boards collaborated to develop OAC 4729:5-3-12. This rule was developed based upon an earlier joint regulatory statement issued by the Boards and authorizes the use of protocols in the following scenarios:

(1) The provision of medical services to individuals in an emergency situation when the services of a prescriber authorized by the revised code to prescribe dangerous drugs as part of their professional practice are not immediately available. An emergency situation may manifest itself by acute symptoms of sufficient severity that an authorized individual providing medical services under this paragraph could reasonably expect the absence of immediate medical attention to result in placing the health of the individual

or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Examples of emergency situations include cases such as heart attacks, severe burns, extravasation, overdoses, cyanide poisonings, electrocutions, or severe asthmatic attacks;

- (2) The administration of biologicals or vaccines to individuals for the purpose of preventing diseases;
- (3) The administration of vitamin K for prevention of vitamin K deficient bleeding in newborns;
- (4) The administration of erythromycin for prevention of ophthalmia neonatorum; and
- (5) The administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel at an institutional facility, as defined in agency 4729. of the Administrative Code, according to current guidance issued by the United States center for disease control and prevention.

None of the scenarios listed above apply to the administration of IV therapies provided by retail IV therapy clinics. Therefore, the use of protocols by a retail IV therapy clinic for this purpose would be considered a violation of Ohio law.

Diagnosis of Patient and Recommendation of IV Therapy by Nurse or Paramedic is Prohibited

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 a nurse or paramedic. Only a physician, PA, or APRN has the statutory authority to diagnose a patient's condition and 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 additives thereto, including "cocktails" and prescription drugs, are also outside the scope of practice of a registered nurse or paramedic. Only a licensed physician, PA, or APRN may diagnose a patient's condition and recommend IV treatment for the patient's condition.⁸

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⁸ See ORC 4731.34 (A), ORC 4730.20, and ORC 4723.43

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 prescriber may not be the individual who actually evaluates the patient. Instead, a physician, PA, or APRN may be identified as "a medical director," "on staff," or "available," but it is only the nurse or paramedic who interacts with and 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.

Use of Unlicensed Individuals is Prohibited

Ohio laws prohibit a physician, PA, or APRN from delegating the administration of intravenous drugs or controlled substances to an unlicensed individual. Further, ORC 4729.01 defines "drug" broadly to include any article or supplement to an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals. Cumulatively, these laws prohibit unlicensed persons from administering IV drugs at an IV clinic.

Standard of Care for Physicians, PAs, and APRNs

A 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, that prescriber must issue a prescription or medication order, 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 and is for a legitimate medical purpose. 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.

In addition to creating a comprehensive medical record that complies with the standard of care, the prescriber must obtain informed consent and document it in the medical record prior to the delivery of care. It is important to recognize that obtaining informed consent is an educational process involving the patient in shared decision-making. In obtaining informed consent, the health care provider should assess the patient's ability to understand relevant

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⁹ See ORC 4731.053, ORC 4730.203, and ORC 4723.489

medical information and the implications of treatment alternatives and to make an independent, voluntary decision and present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. Information should include: (1) the diagnosis; (2) the nature and purpose of recommended interventions; (3) the burdens, risks, and expected benefits of all options, including forgoing treatment; (4) document the informed consent conversation, or written consent; and (5) the patient's decision in the medical record in some manner.

Use of Telehealth

The relationship between health care professionals, such as physicians, PAs, and APRNs, and a patient may be established via telehealth in accordance with ORC 4743.09 and telehealth rules implementing this section. ¹⁰ The Medical Board's telehealth rule in OAC 4731-37-01 is applicable to physicians as well as PAs and APRNs.

Pursuant to these telehealth laws and rules, a physician, PA, or APRN who establishes a prescriber-patient relationship via telehealth shall adhere to the same standard of care for telehealth visits as the standard of care for an in-person visit.

If a health care professional (physician, PA, or APRN) determines at any time during the provision of telehealth services that a telehealth visit will not meet the standard of care for the medical condition of the patient or if additional in-person care is necessary, the health care professional shall see the patient in a reasonable timeframe or make the appropriate referral to another health care professional to meet the standard of care.¹¹

When a telehealth visit is conducted by a health care professional, pursuant to OAC 4731-37-01, the health care professional shall comply with all standard of care requirements to provide telehealth services to a patient including, but not limited to:

- (1) Verify the patient's identity and physical location in Ohio, communicate the health care professional's name and type of active Ohio license, and document this in the patient's medical records;
- (2) Document the consent for telehealth treatment of the patient;

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¹⁰ See ORC 4723.94, ORC 4730.60, ORC 4731.741, OAC 4731-37-01, OAC 4731-11-09, OAC 4730-1-07 (B), and OAC 4723-8-02 (D)

¹¹ See OAC 4731-37-01 (B)(4)

- (3) Comply with patient privacy and security requirements for the patient and their protected health information required by Ohio and federal law;
- (4) Through interaction with the patient, the health care professional shall complete a medical evaluation that is appropriate for the patient and the condition with which the patient presents and that meets the minimal standards of care for an in-person visit;
- (5) Establish or confirm a diagnosis and treatment plan including documentation of the necessity for the utilization of a prescription drug;
- (6) Document in the patient's medical record the consent for treatment, pertinent history, evaluation, diagnosis, treatment plan, underlying conditions, any contraindications, and any referrals to appropriate health care providers, including primary care providers or health care facilities. The complete medical record shall be available to the patient and other treating health care professionals.

Further, physicians and PAs who hold a valid prescriber number issued by the State Medical Board of Ohio and who have been granted physician-delegated prescriptive authority may prescribe non-controlled drugs through telehealth provided that they comply with the requirements of OAC 4731-37-01 which include an appropriate medical evaluation through interaction with the patient. If the telehealth prescribing involves controlled substances, the physician or PA must also comply with state and federal laws and rules regarding the prescription of controlled substances, including the requirements in OAC 4731-11-09.

The prescriptive authority of PAs and APRNs shall not exceed the prescriptive authority of the supervising or collaborating physician respectively and shall comply with all applicable state and federal laws and regulations.

Additional Legal and Scope of Practice Requirements

Compliance with Prescriber Compounding Rules

As previously stated, the addition of drugs or vitamins to an IV solution is considered compounding under Ohio law and requires the clinic to obtain a license as a terminal distributor of dangerous drugs (TDDD) from the Ohio Board of Pharmacy. While there are some exceptions to Ohio Board of Pharmacy licensure for clinics that possess prescription medications (referred to in law as dangerous drugs), those exceptions do not apply if the clinic is engaged in sterile drug compounding. This means that retail IV therapy clinics are

required to be licensed and comply with Ohio's prescriber compounding rules established by the Ohio Board of Pharmacy.

Generally, the compounding of IVs can be done under the Ohio Board of Pharmacy's immediate-use rule¹² if the sterile compounding involves not more than two entries into any one package (e.g., bag, vial) of sterile infusion solution or administration container/device using commercially manufactured sterile, non-hazardous drugs from the manufacturer's original container. Additionally, any IV prepared under this rule must be administered no later than six hours following preparation of the drug. Other compounding activities may require compliance with more advanced compounding standards, including USP 797 (see table 1).

Table 1. Ohio Prescriber Compounding Requirements 13

Type of Drug Preparation	Compounding	Requirements
Admixing or compounding	Immediate Use	Comply with OAC 4729:7-3-04
NO MORE than three		
commercial products and <u>NO</u>		Beyond-Use Date: 6 hours following
MORE than two entries into		preparation
any one container.		
		Compounding must be prepared in
		a designated clean medication area.
		Prohibits anticipatory compounding
		(compounding in advance)
		Prohibits personally furnishing of
		compounded products
		A licensed prescriber is on-site and
		immediately available
Admixing or compounding	Compounding	Comply with OAC 4729:7-3-03 and
more than three commercial	(Medium Risk/	USP 797 Compliance
products or more than two	Category 2 CSP)	

¹² See OAC 4729:7-3-04

¹³ For more information on prescriber compounding requirements, visit: <u>www.pharmacy.ohio.gov/prescribercomp</u>.

entries into any one		A licensed prescriber is on-site and
container.		immediately available
Repackaging and relabeling	Compounding	Comply with OAC 4729:7-3-03 and
sterile products to individual	(Medium Risk/	USP 797 Compliance
doses.	Category 2 CSP)	
		A licensed prescriber is on-site and
		immediately available
Admixing or compounding a	Compounding	Comply with OAC 4729:7-3-03 and
nonsterile powder to use as	(High Risk/	USP 797 Compliance
sterile injection.	Category 3 CSP)	
		A licensed prescriber is on-site and
		immediately available
Reconstitution <u>NOT</u>	Compounding	Comply with OAC 4729:7-3-04 or
according to manufacturer's	(Immediate Use or	USP 797 Compliance
labeling (i.e. using other	Low Risk/	
diluents or amounts of	Category 1 CSP)	A licensed prescriber is on-site and
diluents).		immediately available
Reconstitution according to	This is not	Use aseptic technique
the manufacturer's labeling.	considered	
	compounding	
	under Ohio law	

The compounding of drugs in a prescriber setting may be delegated to a nurse or nurses. However, a prescriber is required to verify the final product before it is administered to the patient or is required to be physically on-site if verified by a nurse. Unlike a nurse, a paramedic is not permitted to independently verify a compounded medication prior to administration under any circumstances. Failure to adhere to these standards is considered a violation of Ohio law and could subject the clinic to administrative discipline.

Please be advised that a full list of the requirements for prescriber compounding can be found in the Ohio Board of Pharmacy's prescriber compounding inspection guide that can be accessed by visiting: www.pharmacy.ohio.gov/prescribercomp.

As part of the Ohio Board of Pharmacy's TDDD licensing process, each license is required to have a responsible person at all times. By rule, the responsible person on the TDDD license is responsible for compliance with all state and federal laws, regulations, and rules governing

the distribution of dangerous drugs. The Board of Pharmacy is growing concerned that those who agree to serve as the responsible person on a TDDD license are not exercising an appropriate level of supervision of the activities of the clinic. The rules require the responsible person to be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site. ¹⁴ For example, some licensees have responsible persons listed who are not physically located in the state. Having a responsible person "in name only" puts the clinic, staff, and patients at risk and may subject the clinic and the responsible person to administrative discipline.

Regardless of the ownership structure of the retail IV therapy 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 responsible person's obligation to ensure compliance with the law, nor the medical judgment of prescribers employed by the clinic. Physicians and other prescribers are cautioned to understand Ohio laws and rules before entering employment or partnership with these and similar businesses, especially if they agree to serve as the responsible person on the clinic's TDDD license.

Lastly, a retail IV therapy clinic is only permitted to purchase drugs from Ohio Board of Pharmacy license holders. To ensure that a clinic is purchasing from a licensed drug distributor (e.g., wholesaler, manufacturer, outsourcing facility, etc.), each TDDD is required, per OAC 4729:5-3-04, to verify the seller is appropriately licensed with the Ohio Board of Pharmacy. This verification, which can be performed using Ohio's eLicense system, must be done prior to an initial purchase and then annually if the clinic continues to purchase from that drug distributor. By verifying a supplier is legally authorized to sell drugs in Ohio, licensees can avoid the purchase of counterfeit medications. For more information about avoiding counterfeit medications, visit: www.pharmacy.ohio.gov/counterfeit.

Ohio Board of Nursing and the Nurse Practice Act

The Ohio Board of Nursing joins with the State Medical Board of Ohio and the Ohio Board of Pharmacy in their concern about the rise of retail IV therapy clinics and the possibility that nurses are working outside the confines of the laws and rules of the Boards. Specifically, the

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¹⁴ See OAC 4729:5-2-01

Board of Nursing is concerned that nursing licensees participating in retail IV therapy may be practicing beyond their scope and without the proper steps in place to ensure safe and legal administration.

IV therapy is a complex, learned skill. Registered nurses (RNs) and APRNs choosing to provide this therapy must ensure they are properly educated and fully compliant with all the requirements under the law.

LPNs

A licensed practical nurse (LPN) is not authorized to administer IV solutions at a retail IV therapy clinic. While an LPN may administer some IV solutions ¹⁵ for individuals aged eighteen or older and only when directed to do so by a licensed physician, physician assistant, dentist, optometrist, podiatrist, or registered nurse in accordance with ORC 4723.18, they are not permitted to initiate the administration of IV solutions containing vitamins or electrolytes. ¹⁶ Therefore, utilizing an LPN to initiate an IV therapy containing the additives is not permissible.

RNs

A registered nurse (RN) can only administer intravenous fluids, nutrient therapies, vitamin infusions, and medications after obtaining a valid prescription or order that was issued by a physician, PA, or APRN. The prescription or order must be part of a medically prescribed plan of care that includes a personal examination and a bona fide patient relationship. "Protocols," as discussed previously in this document, are not permitted under Ohio law. An RN cannot order IV hydration fluids and cannot determine the dosage, route, or frequency.¹⁷

An RN may engage in the preparation of a compounded IV therapy. ¹⁸ However, a prescriber is required to verify the final product prior to administration or is required to be physically

¹⁵ Five per cent dextrose and water; five per cent dextrose and lactated ringers; five per cent dextrose and normal saline; normal saline; lactated ringers; 0.45 per cent sodium chloride and water; 0.2 per cent sodium chloride and water; or 0.3 per cent sodium chloride and water.

¹⁶ An LPN is not permitted to administer IV solutions containing vitamins or electrolytes unless a registered nurse initiates the first infusion of the solution containing vitamins or electrolytes.

¹⁷ See ORC 4723.151(A)

¹⁸ See OAC 4729:7-3

present on site to answer any questions the nurse may have regarding the compounding process.¹⁹

An RN administering IV therapy must have the knowledge, skill, and competency necessary to carry out the administration procedures and monitor the client in a safe manner. An RN should perform a nursing assessment of the patient to include vital signs. An RN should monitor the patient while the patient undergoes the IV administration. The RN should monitor the patient for such things as side effects, toxic effects, allergic reactions, unusual and unexpected effects, changes in a client's condition that contraindicate continued administration of the pharmaceutical or treatment regimen, those effects that may rapidly endanger a client's life or well-being, and must be prepared to make judgments and decisions concerning actions to take in the event such effects occur.

An RN is expected to document all nursing acts performed by the RN in carrying out the IV administration and noted during the monitoring of the patient during administration.

APRNs

APRNs are held to the same standard as a physician or PA working in a retail IV hydration clinic. An APRN must have the appropriate prescriptive authority to prescribe medications under Ohio law and in accordance with the standards set forth in this statement.

APRNs should carefully review the portion of this statement applicable to prescribers to understand their obligations while working in a retail IV therapy clinic. An APRN must also include a retail IV therapy clinic as part of their collaborative agreement prior to undertaking this role.

Physician Agreements with PAs and APRNs

A PA must have a signed supervision agreement with a physician licensed in Ohio to provide services to patients located in Ohio including in a retail IV therapy clinic.²⁰ The physician shall supervise the services provided by the PA and only allow the PA to perform services that are within the physician's normal course of practice and expertise.²¹

¹⁹ See OAC 4729:7-3-04

²⁰ See ORC 4730.19

²¹ See ORC 4730.02

The physician shall be continuously available for direct communication with the PA by either being physically present at the location where the PA is practicing or being readily available through telecommunication and being in a location that is a distance from the location where the PA is practicing "that reasonably allows the physician to assure proper care of patients." A physician may not supervise more than five (5) PAs at any one time. ²²

The physician shall personally and actively review the PA's activities, and also establish a quality assurance system which, among other activities, requires the physician to routinely review patient records and PA orders regarding selected patients.²³ The physician and PA are required to have a copy of the supervision agreement and records of the required quality assurance activities.²⁴

Similarly, an APRN must have a written standard care arrangement with a physician licensed in Ohio to provide services anywhere, including in a retail IV therapy clinic. ²⁵ The physician that the APRN is collaborating with must be licensed in Ohio and must be practicing in a specialty that is the same as or similar to the APRN's specialty. ²⁶

Likewise, the physician with whom the APRN has entered into a standard care arrangement must be continuously available to communicate either in person or by electronic means.²⁷ A physician may not collaborate with more than five (5) APRNs in the prescribing component of their practices.²⁸ A physician and APRN in a standard care arrangement must participate in a quality assurance process that includes periodic random chart review, which includes review of prescribing patterns.²⁹

CONCLUSION

The diagnosis of a condition that results in the ordering of IV-delivered drugs, amino acids, or vitamins is the practice of medicine and the preparation of these drugs is considered drug compounding. Failure to obtain licensure as a terminal distributor of dangerous drugs is a

²² See ORC 4730.21

²³ See ORC 4730.21

²⁴ See ORC 4730.19 and ORC 4730.21

²⁵ See ORC 4731.27 and ORC 4723.431

²⁶ See ORC 4723.431

²⁷ See ORC 4723.01

²⁸ See ORC 4723.431

²⁹ See OAC 4723-8-05

violation of Ohio law and may subject a retail IV therapy clinic to administrative and/or criminal penalties. Meanwhile, the failure of licensees to follow the laws and rules 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.

Most important, however, is the safety of Ohio patients who seek IV treatment through these clinics. Patients must be evaluated by an appropriate practitioner. The IV medications must be compounded in a safe and sterile environment. Administration of the IV must be done by those with the education, training, and skills to do so. Each of these roles in the process requires that the individual be licensed and requires them to carry out their obligations in the same manner that is required of them for any other task within their scope of practice. Each of the Boards is dedicated to ensuring the law in these areas of practice is followed, as that is how the public is best protected.