



# IV Spa Hydration, Should I Be Doing This?

The Board of Nursing has received inquiries about practice settings that market wellness promotion services, such as intravenous (IV) spa hydration, also sometimes referred to as “IV vitamin therapy” or “hydration therapy”. For the purpose of this article, we will use the term “IV hydration” to refer to these spa treatments. In keeping with the Board’s mission of public protection, this article aims to offer regulatory considerations nurses should be mindful of when deciding whether to practice in such a setting.

## Introduction

IV spa hydration treatments are provided to individuals without medical necessity and are offered for “wellness” on a cash basis and they are becoming increasingly popular and sought-after solutions for improved wellness or recovery. The facilities offering these practices are not individually licensed or regulated in Arkansas at this time. The practices performed in these facilities if required should be performed by licensed health care providers practicing within their scope of practice based on their licensure. The purpose of this article is to provide a guidance document with references for the various elements of practice that are often the source of questions about IV hydration.

IV therapy is a complex, learned skill and there are many considerations necessary to ensure the safe performance of this skill outside of a traditional facility setting.

## Complex Interventions

IV therapy typically takes place in a healthcare clinic environment that is clear/sterile, and is a medically necessary intervention with medication ordered by a licensed provider for IV delivery. The healthcare professional will clean the area where the IV will go, place the IV catheter in your vein, secure the access site and begin running the medication either by pump or drip rate. You are then monitored for reactions to the medication or the fluid infusion. That’s a routine description of the procedure.<sup>1</sup>

IV spa hydration is the practice of inserting an IV catheter into the client’s vein to infuse fluid that has been compounded with vitamins or medications. Only licensed nurses should be inserting the IV and administering the fluids. Providers with active prescriptive authority should be prescribing the fluid plus any additives or IV push medication for individual patients.

All nurses licensed to practice nursing in Arkansas must adhere to the *Arkansas Nurse Practice Act (NPA)* and *Board Rules*, as well as other regulations pertinent to the setting. Therefore, the performance of IV spa hydration in a non-traditional setting, such as a mobile unit or wellness spa, should be consistent with prevailing standards of care, and current national nursing guidelines specific to IV therapy. When

initiating IV therapy services, including the administration of medications, such as isotonic IV fluids, a valid provider order is required.<sup>2</sup>

IV spa hydration and vitamin infusion therapy are not medically necessary because this service is a client driven, on demand service. The “treatments” are done in a “spa” setting or may be done in a home, office, hotel room or another location. These settings are subject to the same standards as conventional practice settings for client assessment, medical necessity for treatment, record keeping, informed consent, and sterility.

Before the IV spa infusion, the client is assessed by some type of exam, called a “good faith exam.” There are several large companies offering franchises and each seems to have their own way of “assessing” the client, protocols for the service itself, etc. Further, it is unclear if these businesses have record keeping standards that are HIPPA compliant. They may have, it’s just not easy to find out. The healthcare worker (nurses or in some cases, an EMT) is relying on the client to provide accurate and true information without any validation from medical records. Lab values may or may not be performed. There is typically an informed consent for the client to read and sign. It can be quite lengthy and comprehensive, however may not be easy to understand which may be problematic for informed consent.<sup>3,4</sup>

For IV spa services, these are medical in nature and will require an order or prescription from a licensed provider. This includes the establishment of a provider-patient relationship, determination of need, proper documentation, and record keeping.

## Decision-Making Framework

When evaluating whether you as a nurse or advanced practice registered nurse should be doing this, a resource called the Decision-Making Model is a powerful tool to help when trying to determine those answers. However, nurses, no matter their licensure, are responsible for their own practice and license protection. Nurses are encouraged to independently review the Decision-Making Model and apply it based on his/her individual educational background, knowledge, experience and licensure. The Scope of Practice Decision-Making Models for LPN/RNs and APRNs are located on the ASBN website.

## Evidence

Currently, the practice of IV spa hydration is not evidence based. There is research regarding the components of the IV drip (vitamins, minerals) but not for this type of delivery. It is unknown if these short-term effects are lasting. The one research study that looked at treatment for fibromyalgia was

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inconclusive at best. The subjects reported improvement in both the treatment and placebo groups. So really what is meant by “evidence-based practice”?

Research studies show that evidence-based practice (EBP) leads to higher quality care, improved patient outcomes, reduced costs, and greater nurse satisfaction than traditional approaches to care.<sup>1-4</sup> Despite these favorable findings, many nurses remain inconsistent in their implementation of evidence-based care. Moreover, some nurses, whose education predates the inclusion of EBP in the nursing curriculum, still lack the computer and Internet search skills necessary to implement these practices. As a result, misconceptions about EBP—that it’s too difficult or too time-consuming—continue to flourish.

Research evidence alone is not sufficient to justify a change in practice. Clinical expertise, based on patient assessments, laboratory data, and data from outcomes management programs, as well as patients’ preferences and values are important components of EBP. There is no magic formula for how to weigh each of these elements; implementation of EBP is highly influenced by institutional and clinical variables.<sup>5</sup>

### Public Safety

These products are not FDA approved. Once the components of an IV spa treatment are mixed in a way that does not guarantee the products are sterile and without contamination, they are listed as (503b) due to the sterility and safety of the components cannot be confirmed. The transport of these items for the mobile version of the IV spa has problems as well. It is uncertain if the meds are transported in a refrigerator or kept at a certain temperature. The mobile aspect of the clinic may also interfere with the components becoming unstable or de-natured.<sup>6, 7, 8</sup>

In 2018, the Federal Trade Commission (FTC) filed charges against a marketer and seller of IV therapy products in Texas for making false and unsupported health claims (FTC, 2018). These claims advertised IV therapy products to treat serious diseases such as cancer, multiple sclerosis, diabetes, and congestive heart failure (FTC, 2018). The final FTC order prohibits the company from making such claims, unless they can be supported by competent and reliable scientific evidence (FTC, 2018). Joe Simmons, chairman of the FTC (2018), emphasized that, “This enforcement action should send a clear message to the burgeoning IV therapy industry and sellers of all healthcare products.” Nurses should be mindful of practicing in a setting that makes false and unsupported health claims such as these.<sup>9</sup>

IV spa hydration procedures performed by nurses are subject to the same standards for nursing practice as those driven by medical necessity. IV spa hydration treatments and procedures are elective, and patients self-refer to a practitioner of their choice for services. The lack of consistent standards for education and training in this service coupled with the rapid proliferation and ready availability of products and services that may or may not be regulated (Jones, et. al, 2018)<sup>10</sup> has resulted in confusion regarding nursing scope of practice and competency.

### Compounding

What is compounding? Are nurses able to perform this activity within their scope of practice in Arkansas?

The combining of different products into a saline bag may be considered compounding which has to be done according to statute. The mixing of two or more drug products is considered compounding.

38-2811. Compounding, defined: Compounding means the preparation of components into a drug product.

38-2867.01. Authority to compound; standards; labeling; prohibited acts.

- (1) Any person authorized to compound shall compound in compliance with the standards of chapters 795 and 797 of The United States Pharmacopeia and The National Formulary, as such chapters existed on January 1, 2015, and shall compound (a) as the result of a practitioner’s medical order or initiative occurring in the course of practice based upon the relationship between the practitioner, patient, and pharmacist, (b) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing, or (c) for office use only and not for resale.
- (2) Compounding in a hospital pharmacy may occur for any hospital which is part of the same health care system under common ownership, or which is a member of or an affiliated member of a formal network or partnership agreement.
- (3)
  - (a) Any authorized person may reconstitute a commercially available drug product in accordance with directions contained in approved labeling provided by the product’s manufacturer and other manufacturer directions consistent with labeling.
  - (b) Any authorized person using beyond-use dating must follow the approved product manufacturer’s labeling or the standards of The United States Pharmacopeia and The National Formulary if the product manufacturer’s labeling does not specify beyond-use dating.
  - (c) Any authorized person engaged in activities listed in this subsection is not engaged in compounding, except that any variance from the approved product manufacturer’s labeling will result in the person being engaged in compounding.
- (4) Any authorized person splitting a scored tablet along scored lines or adding flavoring to a commercially available drug product is not engaged in compounding.
- (5) No person shall compound:
  - (a) A drug that has been identified by the federal Food and Drug Administration as withdrawn or removed from the market because the drug was found to be unsafe or ineffective;
  - (b) A drug that is essentially a copy of an approved drug unless there is a drug shortage as determined by the board or unless a patient has an allergic reaction to the approved drug; or
  - (c) A drug that has been identified by the federal Food and Drug Administration or the board as a product which may not be compounded.

When a client enters into an agreement with the healthcare

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provider to have an IV spa treatment, there are generally a menu of mixtures that can be purchased. Items like vitamins or medications are injected into the bag of normal saline and mixed. Then the bag is hung, a drip rate is set, and the client relaxes while the fluid infuses. Introducing items into the bag of saline is compounding and that is not in nursing scope of practice. To do the mixing properly, you need to have at least a pharmacy certificate. The mixing itself is required to be done under a hood with very specific readings all while in full protective gear. This all to ensure a clean and sterile environment and reduce the chance of contaminants being introduced into the mixture.

Once products are mixed, they cannot be advertised as FDA compliant or approved due to the risk of contamination. The safe selection of products must be done by a licensed provider. The client or RN does not have the knowledge or scope to perform this activity.

### Are APRNs authorized to compound?

Any authorized person may reconstitute a commercially available drug product in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with labeling. Mixing two drug products is compounding and is a pharmacy activity and is outside the scope of an APRN.

#### United States Pharmacopeia (USP)

##### Chapter 797 on compounding (<https://www.uspnf.com>)

To qualify for the immediate use criteria listed under USP Chapter 797, these compounded mixes need to be used for an emergency use and for immediate patient administration. The 503B products need to meet the requirements of the FDA; and the facilities they are compounded in need to be properly registered. The 503B products need to meet the requirements of the FDA; and the facilities they are compounded in need to be properly registered.

#### From USP Chapter 797:

The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a Compounded Sterile Product (CSP). Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for Low-Risk Level CSPs subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs are not intended for storage for anticipated needs or batch compounding. Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs. Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met:

1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs.
2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.

3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.
4. Administration begins not later than 1 hour following the start of the preparation of the CSP.
5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time.
6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. Compounding in worse than ISO Class 5 (see Table 1) conditions increases the likelihood of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization and thus for patient harm, especially in critically ill or immunocompromised patients.

### Nursing Practice

#### Nursing Code of Ethics

There are 4 main principles that are part of the nursing code of ethics. They are:

1. Autonomy
2. Beneficence
3. Justice
4. Non-maleficence

These principles are ideally what every nurse should be aware of in their daily nursing practice. While ethical principles are sometimes confusing and often taught briefly during undergraduate nursing -- they should be constants in nursing practice to provide the best, safest, and most humane care to all patients.

**Autonomy** is recognizing each individual patient's right to self-determination and decision-making. As patient advocates, it is imperative that nurses ensure that patients receive all medical information, education, and options to choose the option that is best for them. This includes all potential risks, benefits, and complications to make well-informed decisions.

**Beneficence** is acting for the good and welfare of others and including such attributes as kindness and charity. The American Nurses Association defines this as "actions guided by compassion."

**Justice** is that there should be an element of fairness in all medical and nursing decisions and care. Nurses must care for all patients with the same level of fairness despite the individual's financial abilities, race, religion, gender, and/or sexual orientation.

**Nonmaleficence** is to do no harm. This is the most well-known of the main principles of nursing ethics. More specifically, it is selecting interventions and care that will cause the least amount of harm to achieve a beneficial outcome.<sup>11</sup> <https://nurse.org/education/nursing-code-of-ethics/>

With these 4 standards in mind, when a nurse evaluates their care and approach of using their skills and training, does it line up with an IV spa hydration setting? Is this nursing? Am I being taken advantage of because of my patient care training and complex skill training of IV insertion?

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## Nurses – Registered Nurses and Licensed Practical Nurses

The profession of nursing remains the most trusted profession by the public. Even with recent events of the pandemic, mandates and court cases, this profession overall demonstrates compassion, intelligence and dignity of care. Conflict of interest is an inherent risk to ethical nursing practice in the provision of IV spa hydration. Licensed Practical Nurses function in the healthcare team in a directed role. Registered Nurses direct LPN practice and duties, however they cannot diagnose, write a prescription, or treat or dispense.

### Nurse Practitioners

Along with the above points of ethical practice, nurse practitioners as advanced practice registered nurses (APRNs) bear full accountability for practice that is aligned with graduate education, board certification and licensed practice role with one or more population foci.

The fundamental premise of practice alignment is that the APRN has the knowledge to differentially diagnose and manage most conditions/potential adverse outcomes that will be encountered for a particular patient population (Buppert, 2017)<sup>2</sup>. Advanced practice nurses have the added skills of diagnosing, treating, and prescriptive authority. This is a huge advantage to providing increased access to care. It should also cause the APRN to stop and ask these questions, “Is this how I want to use my skills?” “Is this nursing?” “Am I being taken advantage of because of my status as a licensed provider?”

## Final Note

As new trends emerge in health care, nurses are called upon to deliver safe nursing care, and must realize their responsibility to stay aware of current evidence-based practice standards, along with all applicable laws and rules related to their area of nursing practice. Board staff recommend that nurses exercise caution and critical thinking when considering practicing in a setting that offers elective IV spa hydration and vitamin therapy. This ensures that patients are receiving the safe, high quality health care they deserve.

*This article is an edited and amended version of an article written by Ginger Rogers, DNP, APRN, Nurse Consultant, Nebraska Board of Nursing, and printed in the Winter 2022 issue of Nebraska Nursing News. It has been shortened to fit space requirements and relevant Arkansas regulations.*

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