FLORIDA HEALTHCARE
LAW FIRM

DRS. IV OZONE CERTIFICATION EVENT

June 7, 2024
TAMPA

ASSUMPTIONS/ CONSIDERATIONS

The need for clinical leadership in any wellness model (Examine, Prescribe, Treat, Document)

Cash Only Model (vs. insurance or insurance "mixing")

- Licensure
- Advance notice to patients
- Self referral

The Need for External Clinical Validation

Regulatory Environment

KEY REQUIREMENTS

Corporate Model (e.g., CPOM)

APRN and PA Scope of Practice

Physician Supervision Requirements

- Autonomous certification

Applicability of Pharmacy Regs (e.g. compounding)

- Applicability of USP 797

Informed Consent

Marketing Wording (e.g., materials and website)

STATE LAW

High Dose Vitamin C/Methylene Blue and IV Ozone

In Oregon, a licensee must submit proof of completion of Board approved education before administering Chelation IV Therapy or IV Ozone therapy.
https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=289269

The Alabama Board of Medical Examiners.
The BME doesn't regulate such procedures. But notified the doctor that the procedure is experimental and investigational (and not FDA approved). The Board said it might act if there were patient complaints.

Nothing specific in Florida yet (e.g., re ozone), but see 458.331(1)(u)

1. The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(u) Performing any procedure or prescribing any therapy which, by the prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed, and written consent.

STATE LAW

High Dose Vitamin C/Methylene Blue and IV Ozone

The Florida Administrative Code stipulates that performing experimental treatment without informed consent can lead to penalties, including suspension, revocation or denial of a medical license, and administrative fines. https://www.law.cornell.edu/regulations/florida/Fla-Admin-Code-Ann-R-64B8-8.001.

There have already been instances where physicians have had their licenses revoked for performing experimental treatments without obtaining informed consent from their patients Clark v. Department of Professional Regulation, Bd. of Medical Examiners, 463 So. 2d 328§ 120.68.

The Florida Patient's Bill of Rights and Responsibilities (381.026) states that a patient has the right to know if medical treatment is for purposes of experimental research and to give his or her consent or refusal to participate in such experimental research.

FEDERAL LAW

The FDA has rejected the medical application of ozone (21 CFR 801.415)

Ozone is a toxic gas with no known useful medical application in specific, adjunctive, or preventive therapy. In order for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals.

"Right to Try Act" (Chapter V of the Federal Food, Drug, and Cosmetic Act)

•Signed into law on May 30, 2018

•Permits patients who have been diagnosed with life-threatening diseases or conditions who have tried approved treatment options and are not able to participate in a clinical trial to access unapproved medical treatments.

FEDERAL LAW

To be eligible to access these unapproved medical treatments under Right to Try, a patient must satisfy all of the 3 below requirements:

1. Been diagnosed with a life-threatening disease or condition, meaning
    a. Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and
    b. Diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival.
2. Exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug (this must be certified by a physician who is in good standing with their licensing organization or board and who will not be compensated directly by the manufacturer for certifying); and

1. Provided, or their legally authorized representative has provided, written informed consent regarding the eligible investigational drug to the treating physician

FEDERAL LAW

"Eligible investigational drug" is one:

- For which a Phase 1 clinical trial has been completed
- That has not been approved or licensed by the FDA for any use
- For which an application has been filed with the FDA or is under investigation in a clinical trial that is intended to form the primary basis of a claim of effectiveness in support of FDA approval and is the subject of an active investigational new drug application submitted to the FDA
- Whose active development or production is ongoing, and that has not been discontinued by the manufacturer or placed on clinical hold by the FDA

Federal Case Law: Courts have consistently held that there is no fundamental right for a patient to use new or experimental drugs.

EXPANDED/COMPASSIONATE USE

Patients also may have access to expanded use ("compassionate use"), of experimental or unapproved medical products outside of clinical trials. This is available when there are "no comparable or satisfactory alternative therapy options".

Expanded access may be appropriate when all of the following apply:

1. Patient has a serious or immediately life-threatening disease or condition.
2. There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
3. Patient enrollment in a clinical trial is not possible.
4. Potential patient benefit justifies the potential risks of treatment.
5. Providing the investigational medical product will not interfere with investigational trials that could support a medical product’s development or marketing approval for the treatment indication.