Frequently Asked Questions in Regard to:

"Pharmacy, Office Compounding and In Office Use update - Rule changes from the FDA/USP and their effects on your office compounding practices"

Compiled and Presented for the AANP and other agencies – July 2015 by Paul S. Anderson

What rules apply to me as a clinician and to my clinic as a facility?

Many apply. The attached document spells out as succinctly as possible the intersecting rules relating to clinical practice that are involved in compounded and manufactured prescription use, injections and other forms of medications and guidelines influenced by multiple Federal agencies.

What is the "patient specific" rule and does it apply to all prescription products now?

It essentially states that a pharmacy can still offer a compounded prescription on physician order if it is specific to a patient and then the compounding pharmacy will not be considered a manufacturer for regulatory purposes. It renders that prescription specific to the patient it was compounded for.

Can I use anything for "office use" anymore?

Any non-compounded medication (currently) can be used, and in some States the patient specific rule is not currently enforced by the Board of Pharmacy or Department of health.

What are the rules for single and multi-dose sterile vials?

These have not changed and have the 28 day use for multi-dose and single use for single-dose product – with some qualifications noted in the main document.

I have heard I need a clean room to make my syringes and IV bags. Is that true?

Possibly. The rules depend upon the "risk level" of what you are making. Simple compounds may not require this and many commonly compounded injections and IV's will. This is a bit complex but a great deal of information in regard to this is contained in the main document.

I have a "fume hood" already, can I use that?

If it is really a fume hood then no. Those hoods are used to prepare or manipulate dangerous products and exhaust the workspace air out of the building. The laminar flow hoods for compounding move purified air through the workspace and out of the hood, increasing sterility in the workspace.

I went to a presentation a few years ago and they said my IV bags fit the "immediate use exemption" and therefore I did not need a hood?

Most of the immediate use exemption is no longer valid. A few items meet this, but not very many. In the main document a great deal of detail is given to this rule.

Why did my pharmacy say the IV bag had a "9 day beyond use date" and in my recent IV class they told us to use the IV the same day it was made?

This is mixing the technical "use by date" the FDA and USP give a particular product with the pharmacologic stability of the compound. A great deal of information is given in the main document outlining this confusing issue.

Can I just ignore all these rule changes? What would happen anyway?

It would be best to learn the rules and comply the best way you can. Should an inspection happen or an adverse event occur the burden of compliance would be immediately on the practitioner and clinic.