

Compounding pharmacies - a vanishing breed

Compounding Pharmacies - Service like it used to be

Why are my prescription medication prices increasing and not reimbursed?

Compounding pharmacies and the individualization of specific formulations is an integral part of antiaging, age management, functional medicine and similar holistic practices. There was a time in the distant past when most formulations were compounded. That is the source of the mortar and pestle that was so ubiquitous in all pharmacies. I think that symbol has vanished.



The advantage of compounding is preparation of very specific formulations, combinations and dosages. There are many nonstandard dosages that are not commercially available. Compounding pharmacies is a very dedicated group of highly professional caliber. Really good people. The old-fashioned pharmacist is rapidly vanishing. Maybe the same with solo private practices.

Stifling regulation and pressure from Big Pharma has contributed to the steady decline of compounding pharmacists throughout the Bay area and probably across the state of California. This is not a healthy trend. Furthermore, you have

seen most of the major insurance carriers are progressively denying all your compounded medications. Under the ruse of FDA non-approval. That is not the reason. They want you to buy prescription medications from large pharmacies. At a very high premium.

The one constant is an accelerating increase in the cost of all medications. I have never been an advocate of insurance coverage of medications. I know this a losing proposition. But it contributes to the subsidization of ever-increasing price increases. Medication prices are out of sight. And now that the major carriers are denying more and more coverage. So you are left with high prices without the subsidies. You are then forced into generic formulations. Generic drugs do not have the same degree of quality assurance and consistency as proprietary medications. I do not recommend generic preparations.

Stifling and onerous regulations - USP 800

✘ Here is a very personal summary of the onerous regulations in the state of California that will contribute to a manifest decline in the number of compounding pharmacists. And further price increases because of the costs of preparation. This is a direct quote from my good friend, Dana Gordon of [CAPRx](#). One of the best pharmacists in the business. A Pharm.D. A doctor of pharmacy with an advanced degree.

Well, "D-Day" or "USP 800-Enforcement Day" has arrived. Effective Jan 1, many substances that were commonly compounded under normal environmental/exposure conditions must now be handled/manipulated under specific environmental areas (dedicated, externally vented, negative pressure room with a minimum 13 air changes per minute . Also externally vented source capture units/hoods within the room).

Let me be clear, the drugs/substances have ALWAYS been considered "hazardous" if an individual was exposed to them at certain levels and under certain exposure routes (i.e. respiration, mucous membranes). Although the list

is quite extensive (see NIOSH link attached), some of the ones you are familiar with are: Progesterone, Estrogen, Testosterone, Thyroid, Anastrozole, Retinoic Acid, Fluconazole to name a few.

Understand, the language in USP 800 was pretty much already in existence for many years. What occurred is the renumbering of the chapter to an “enforceable” chapter. Prior to this, the chapter was only “voluntary”. Now, in addition to our 3 (three) accreditations for compounding that hold us accountable to this chapter, we now are potentially subject to FDA oversight should we be in violation of USP 800. Very few pharmacies are as decorated as we are. Our choice, our standards, our commitment to our patients, our providers and ourselves.

Although I have previously communicated with you the significance of this new law, its broad and extensive effects it will have on the compounding industry, and the enormous economic/cost impact it will have on those that have decided and/or are able to comply with the newly implemented regulations, both its repercussions and effects will now become quite evident.

In a nutshell and in summary

- 1) California version of USP Chapter 800 becomes effective Jan 1, 2017 (All California pharmacies must be compliant on this date)*
- 2) Official version of USP Chapter 800 becomes effective July 1, 2018 (California Pharmacies still must be compliant Jan 1, 2017)*
- 3) Hazardous Drug-Definition: See attached definition. Really, nothing has changed and nothing new has been discovered about the handling of all of these drugs. The purpose of USP 800 is to protect the individuals handling and manipulating such substances. How this will be translated to patients will require some delicacy and discretion. Regardless, literature will be provided with each drug categorized on the NIOSH list. This is a requirement. Also, such substances will be dispensed separately in a plastic bag titled “Hazardous”. Also a requirement.*
- 4) CAPRx has been painfully, expensively (over \$200K and still counting) invested in preparing for this eminent enforcement date for over a year. Also*

taxing was the BUD (Beyond-Use-Date) limitations that USP (795 and 797) has determined and now the California State Board of Pharmacy will enforce. All of this at the detriment of causing delays in the production and provision of compounded drugs.