

## Tips to Prepare for a DOPL Pharmacy Inspection

This is by no means an all-inclusive list of items that need to be addressed during a DOPL pharmacy inspection. Each pharmacy should be aware and in full compliance with all rules and regulations that govern pharmacy including both State and Federal rules and laws. As random inspections have increased over the past two years, a trend has been recognized in a lack of compliance with the following items.

First and foremost, review and become compliant with the DOPL self-inspection form for Class A pharmacies and the DOPL compounding self-inspection form (both can be found on the DOPL website). Before checking an item off on either list, validate a mechanism, process, or program is in place to appropriately sign-off on that particular item.

### **General Class A Pharmacy Inspections:**

<b>Corresponding # from self-inspection</b>	<b>Non-compliance Item</b>
#1	Wear name tags with title at all times.
#8	A current list of all licensed employees which includes individual licensee names, license classifications, license numbers, and license expiration dates. Make sure employees that are no longer employed are removed. It is advisable to have a copy of student licenses while they are on rotation.
#11	The facility shall have current and retrievable editions of listed references (bookmarked). Make sure employees know where they are and how to access them.
#12	Cleanliness (no dust on any shelves, keep sinks clean-no dishes and no food, keep clutter to a minimum).
#16	No expired medications-Create an inventory control program to catch expired medications before they expire. Schedule routine (monthly) shelf checks to remove expired drugs and mark items that will expire in the next 3 months.
#21/#22	Room temperature of the pharmacy, refrigerator and freezer logs maintained
#38	Annual inventory shall be conducted every 12 months, following the inventory date of each year and may be taken within four days of the specified inventory date. Include signature of the PIC within 72 hours and date and time stamp or clearly mark before or after closing. Must be maintained for 5 years and be readily available upon inspection. See attachment-Controlled Substances Inventory Log.

### **Compounding Class A Pharmacy Inspections:**

<b>Corresponding # from compounding self-inspection</b>	<b>Non-compliance Item</b>
#5	Training program logs-documentation of training for all employees engaged in compounding
#14/#15/#22	BUD's extended beyond 795/797 and not appropriately verified

#17	Written SOP's- The compounding task force has created USP 795 and 797 guidelines to help become compliant in this area. The guidelines can be found on the DOPL website. Performing a gap analysis may aid in finding areas of non-compliance as well.
#18	Quality assurance programs-monitors and evaluates personnel performance
#9/#10/#11	Master worksheets and preparation worksheets contain all necessary information (sample labeling information)
	Outdated or expired bulk chemicals and expired compounded products for anticipatory use.
#7	MSDS sheets need to be readily available; Electronic versions are permissible

After talking with DOPL investigators and inspectors and the State Board, above are key areas to make sure you are in complete compliance. To date this year, they have inspected more than 150 of the 490 Class A retail pharmacies, with plans to do all of them in two years, in order of reports or when last visited or in the area.