Ohio State Medical Association

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Draft Compounding Rule Highlights

Summary and Q & A based on discussion with the Ohio State Board of Pharmacy 2-28-19

Physicians are exempt* from the necessity of obtaining a TDDD (and following compounding rules) if *only* doing these compounding procedures:

- Drug device preparation
- Reconstitution according to label
- Dilution of a dangerous drug right before administration to patient
- Compounding of non-sterile, non-hazardous drug
- Possession of compounded drug by an outsourcing facility

*Keep in mind that very few physicians are exempt from obtaining a TDDD. Many physicians have to obtain a TDDD for non-compounding related dangerous/controlled drug ordering and/or administration. Currently, only a sole shareholder practice would qualify for any exemptions under this rule and the TDDD statute.

Physicians who hold a TDDD license are exempt from having to follow the compounding rules in the following situations:

- Preparation of a drug device per manufacturer's label beyond use date (BUD), if no BUD exists, the device must be used in 6 hours. Must follow aseptic technique-but not USP.
- Reconstitution of sterile dangerous drug according to label, adherence to BUD label and if no BUD exists, reconstituted drug must be used in 6 hours. Must follow aseptic technique-but not USP.
- Reconstitution of non-sterile drug according to label, adherence to BUD label and if no BUD exists, reconstituted drug must be used in 6 hours.
- Physicians who dilute drugs and immediately administer the medication (within 1 hr.). *(this exemption is pending board approval)*

In the instances above, (other than dilution) the device or compounded drug must be used within 1 hour or labeled according to the rule. If there is no BUD on the label, they may be used in 6 hrs., but requires labeling if not immediately administer. *To reiterate, when compounding per the exemptions stated above, physicians are not required to follow the requirements of the compounding rules.*

Further Clarification from the Pharmacy Board:

- Clarification of the following rule provision: Manufacturer labeling that uses the phrase "should" as it pertains to a beyond-use-date or timeframe for use shall be construed by the licensee as required.

    - The pharmacy board clarified that in the event the manufacturer's label states a drug "should" be used by a certain date, the physicians should construe that "should" as a "must". Pharmacy board staff indicated that they would be open to rewording this section if offered a language suggestion.

- Many physicians are concerned that they would have to follow the onerous requirements of USP when performing certain low-risk compound procedures (like buffering lidocaine). It doesn't appear that this rule would create that exemption or consideration.

    - They can compound if using less than 3 products and less than 2 entries (they can use a dispensing pin device to minimize puncture) as immediate use and have 6 hr. BUD. The Board will consider the allowance of anticipatory compounding (i.e. prepping batch doses) at the March meeting. Currently, the rule does not allow them to do anticipatory or batch compounding.

- The immediate-use rule allows 6 hours. OSMA brought up the fact that 8 hours (based on a traditional work day) seems more reasonable. The pharmacy board indicated that they would review any information that supports adding additional time, if presented, but for now, the rule stands at 6 hours.

- The Pharmacy Board feels that the compounding record keeping rule is necessary to ensure that, in the event of a recall or patient harm, they would be able to quickly reference information related to what drugs were used in the compounding process and which patients received the drugs. OSMA offered the opinion that the rule provisions seemed over burdensome and, while the intent was understood and appreciated, these rules, as written, would create an administrative burden in physician offices. Ms. Hayhurst stated that she would talk to physician practices and research what they are currently documenting and learn what additional administrative time this rule might create. The physician community may be able to offer suggestions to amend this rule to reach the same intent without creating a disruption to existing documentation procedures*. It is important to note that the record keeping requirement would NOT apply when physicians fall under certain exemptions (i.e., reconstituting or immediate (1 hr.) administration of a diluted drug.)*