Guidance & Updated Resolution: Terminal Distributor’s License for Prescribers Compounding Dangerous Drugs

UPDATED 6-6-2016

The Board has recently been informed by a number of prescribers that they were unaware of the need to obtain a terminal distributor of dangerous drugs license if they were compounding on-site or ordering compounded drugs to their offices (ORC 4729.541). This requirement impacts all prescriber practices that were previously exempted from licensure, including those who are engaged in a form of compounding commonly referred to as reconstitution (which can include vaccines).

So as to not disrupt patient care, the Board is using its authority under section 4729.25 of the Ohio Revised Code to grant an extension to all prescribers that are performing drug compounding (including reconstitution) or ordering compounded drugs to their offices from the requirement to obtain a terminal distributor of dangerous drugs license. This extension is hereby valid until September 1, 2016.

Adopted: 5/2/2016

Updated Guidance (6-6-2016)

Due to recent feedback regarding the prescriber compounding rules, Board staff are advising previously exempted prescriber practices to refrain from application to the Board as a Terminal Distributor of Dangerous Drugs (TDDD) until further notice.

Due to the significant amount of feedback provided in the days leading up to the June meeting, the Board needs additional time to consider the scope of rule 4729-16-04 and will have further guidance following the July 2016 meeting.

Prescribers and prescriber associations are encouraged to sign up for web updates by visiting: www.pharmacy.ohio.gov/update.

Please note: This does not impact the implementation and enforcement of OAC 4729-16-11 for hazardous prescriber drug compounding.