Louisiana Board of Pharmacy

3388 Brentwood Drive
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BULLETIN No. 13-01

To: All Pharmacies

From: Malcolm J. Broussard

Date: January 7, 2013

Re: Notice of Emergency Rule & Delayed Publication of 2013 Law Book

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During their last meeting on December 13, 2012, the Board adopted a Declaration of Emergency as well as an Emergency Rule. A copy of the declaration and emergency rule may be accessed on the Board's website at www.pharmacy.la.gov. Made effective that same day, the emergency rule repealed the provisions that allowed pharmacies to compound preparations for practitioner administration without a prescription or prescription drug order. Further, the emergency rule also prohibits a pharmacy from engaging in manufacturing activities within the prescription department

In effect, pharmacies must now receive a patient-specific prescription in order to dispense a compounded preparation. We have been made aware of some misunderstandings by some pharmacists as to the term *'prescription drug order'* in the context of compounding, with some people erroneously believing a prescription is patient-specific and a prescription drug order is not. In Louisiana pharmacy law, the terms *'prescription'* and *'prescription drug order'* are synonymous and mean an order from a practitioner with lawful prescriptive authority that is patient-specific [La. R.S. 37:1164(44)]. Moreover, some pharmacists believe that compounding may be authorized by a medical order (which may or may not include a patient-specific prescription). In Louisiana pharmacy law, the definition of the term *'compounding'* includes a requirement for a prescription drug order and does not include any mention of a medical order [La. R.S. 37:1164(5)]. Again, pharmacies must now receive a patient-specific prescription in order to dispense a compounded preparation.

The preparation of drug products in the absence of a patient-specific prescription is now construed to be manufacturing. Manufacturing is a federally-regulated activity and requires proper credentials from the federal Food & Drug Administration (FDA). In the event the manufacturing activities within the state of Louisiana include controlled substances, a state controlled substance license is required from the Board of Pharmacy in order to qualify for the federal DEA registration. Please remember that the manufacturing facility may not co-exist within a pharmacy's prescription department.

The distribution of manufactured products into or within the state requires proper credentials from the La. State Board of Wholesale Drug Distributors. In the event the distribution activities include controlled substances, a state controlled substance license is required from the Board of Pharmacy in order to qualify for the federal DEA registration.

We ordinarily publish an annual update to the Louisiana Pharmacy Law Book in January. Since there are multiple new rules scheduled to take effect in February, we have delayed the publication of the 2013 annual update until late February or early March. Copies of all current rules may be accessed on the Laws & Rules page of the Board's website.