IMPORTANT INFORMATION ON NEW MISSOURI LAW GOVERNING THIRD-PARTY LOGISTICS PROVIDERS & DRUG OUTSOURCERS

The Missouri General Assembly recently amended Chapter 338, RSMo, to establish a new license category for third-party logistic providers (3PLs) and drug outsourcers. The new law became effective on August 28, 2018, and applies to both resident and non-resident 3PLs and drug outsourcers. This document includes information on the new licensing requirements and how to apply for a 3PL or drug outsourcer license.

NEW LAW

Under the new law, drug outsourcers and 3PLs must now have a Missouri drug outsourcer or 3PL license issued by the Board. Specifically, § 338.333.1, RSMo, provides:

*Except as otherwise provided by the board of pharmacy by rule in the event of an emergency or to alleviate a supply shortage, no person or distribution outlet shall act as a wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider without first obtaining license to do so from the Missouri board of pharmacy and paying the required fee.*

A third-party logistics provider (3PL) is defined as:

- An entity that provides or coordinates warehousing or other logistics services of a product on behalf of a drug manufacturer, wholesale drug distributor, or dispenser of a legend drug, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product. [§ 338.330.(5)]

A “drug outsourcer” is defined as:

- An outsourcing facility as defined by 21 U.S.C. Section 353b of the federal Drug Quality and Security Act. [§ 338.330.(1)]

To be eligible for licensure, drug outsourcers must be registered with the United States Food & Drug Administration (FDA) as a 503(b) drug outsourcer pursuant to 21 U.S.C. Section 353b of the federal Drug Quality and Security Act.

The Board has filed emergency rules to implement the new law and will begin offering drug outsourcer and 3PL licenses on December 11, 2018. The emergency rules are available on the Board’s website at: [https://pr.mo.gov/pharmacists-rules-statutes.asp](https://pr.mo.gov/pharmacists-rules-statutes.asp)

LICENSING PROCEDURES (New Applicants)

Applicants that are not currently licensed as a Missouri drug distributor license must submit a new 3PL or drug outsourcer application to the Board with the applicable fee. Applications are
LICENSING PROCEDURES (Currently Licensed Missouri Drug Distributors)

Currently licensed Missouri drug distributors do not have to take any action if you will not be providing or offering to provide 3PL or drug outsourcer activities in the state of Missouri.

If you will be providing or offering to provide 3PL or drug outsourcer activities in Missouri, you will now need a Missouri 3PL or a Missouri drug outsourcer license. Licensees in this category have two options:

1) **Option 1 (For entities only engaged in 3PL or drug outsourcer activities):** Licensees may convert their current Missouri drug distributor license to a 3PL or drug outsourcer license. In this case, your current license number will remain the same, however, your license category will officially change to a 3PL or drug outsourcer. Once your license category is changed, you may only provide 3PL or drug outsourcer services as reflected on your license. Option #2 is required if the licensee is engaged in or would like to provide other drug distribution activities.

2) **Option 2 (For entities engaged in drug distribution and 3PL or drug outsourcer activities):** Licensees engaged in both drug distribution and 3PL or drug outsourcer activities will need to have two licenses: a Missouri drug distributor license and a 3PL or drug outsourcer license (whichever is applicable). For example, an entity engaged in distributing medication under its ownership (drug distribution) and also distributing medication for a manufacturer/wholesaler without taking ownership (a 3PL activity) would be required to have both a Missouri 3PL and a Missouri drug distributor license. Your 3PL or drug outsourcer license will be a separate license and have a new license number. Your Missouri drug distributor license will not change. **Note: A drug outsourcer will not need a separate drug distributor license to distribute their own product.**

Amended applications for currently licensed Missouri drug distributors are available online at: [https://pr.mo.gov/pharmacists-forms.asp](https://pr.mo.gov/pharmacists-forms.asp). The Board will waive 3PL and drug outsourcer application fees for currently licensed Missouri drug distributors if the application is received on or before March 1, 2019. Applications received after March 1, 2019, will be assessed the full application fee ($300).

**Controlled Substance Registrations:**
Licensees should contact the DEA and the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) for additional information regarding your controlled substance registration(s). The Board cannot answer controlled substance registration questions. However, BNDD has provided the following information:

- **Third-Party Logistics Providers:** 3PLs located in the state of Missouri should currently have a BNDD drug distributor controlled substance registration if the entity is storing/handling controlled substances. BNDD has advised that an additional controlled substance registration is not required if a Missouri licensed drug distributor changes to or adds a 3PL license.
• **Drug Outsourcers:** The DEA and BNDD have advised that drug outsourcers compounding non-patient specific medication must have a DEA/BNDD manufacturer controlled substance registration. Licensees should contact BNDD and the DEA if you are handling/storing controlled substances and do not have a manufacturer controlled substance registration.

**QUESTIONS?**

Licensure questions may be submitted to Laura Henke at drugdistributor@pr.mo.gov or (573) 526-6985.