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ATTENTION NONRESIDENT ALASKA PHARMACIES, DISTRIBUTORS AND 3PLS: STATE IMPLEMENTS NEW NONRESIDENT LICENSING CLASSIFICATIONS AND PRESCRIPTION REQUIREMENTS FOR CONTROLLED SUBSTANCES

Pharmacies, distributors and third-party logistics providers ("3PLs") that ship prescription drugs into Alaska should take careful note of the new Alaska Board of Pharmacy regulations that took effect on October 31, 2019.[1] Among other elements, the rules: 1) now require licensure of nonresident wholesale drug distributors ("WDDs"), 3PLs and outsourcing facilities ("OFs") to ship, mail or deliver prescription drugs to a licensed purchaser of prescription drugs in the state; 2) permit partial fills of Schedule II controlled substances; and 3) allow a pharmacy or pharmacist to accept drugs for return or exchange.

NEW LICENSING CLASSIFICATIONS

Nonresident WDDs, 3PLs and OFs must now be licensed in the state to operate under the new regulations.[2] In order to receive a license, nonresident WDDs, 3PLs and OFs must successfully submit a completed application with the applicable fees[3] and the relevant supporting documentation.[4] Once licensed, the new regulations provide for additional requirements for nonresident WDDs, 3PLs and OFs.[5] For example:

- Nonresident WDDs must verify the licenses of Alaskan purchasers of prescription drugs before shipping or distributing prescription drugs to them;[6]
- Nonresident OFs must be registered as an OF with the FDA under Section 503b of the Drug Supply Chain Security Act;[7] and
- Nonresident OFs and 3PLs must permit an authorized inspector or law enforcement official with proper identification to reasonably inspect certain property.[8]

PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCE PRESCRIPTION ORDERS

In addition to the new licensing classifications, the regulations permit partial fills of prescriptions for Schedule II controlled substances for terminally ill patients or patients residing in long-term care facilities, in accordance with DEA regulations.[9] Prescriptions for Schedule II controlled substances may also be partially filled for patients who are not terminally ill or residing in long-term care facilities if certain key conditions are met consistent with other state partial-fill requirements, including that each partial fill occurs at the pharmacy where the original prescription order is on file.[10]

This new regulation signals Alaska's shift toward enhanced patient safety with respect to controlled substances. Permitting partial fills of Schedule II controlled substances provides patients greater flexibility in filling only the amount initially desired while preserving the patient's ability to obtain the remainder of the prescribed amount within 30 days. As a result, this regulation helps curb patients receiving excess drug supplies that may be consumed unnecessarily or even dangerously.

RETURN OR EXCHANGE OF DRUGS

Finally, the new regulations also allow pharmacies and pharmacists to accept drugs for return or exchange after the drug has been removed from the premises where it was sold, distributed or dispensed if certain conditions are met.[11],[12]

PRACTICAL TAKEAWAYS

Entities that carry out national level mail-order pharmacy, distribution or 3PL activities should continue to monitor requirements for out-of-state activities nationally given recent attention by various state boards of pharmacy regarding out-of-state pharmacies and distributors.

Also, entities conducting pharmacy activities in the state should validate that their policies and procedures are up-to-date and reflect these

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revised requirements.

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[references]

[1] See Board of Pharmacy's filed permanent regulations to be codified under Chapters 52 and 02 of the Alaska Administrative Code, available at https://www.commerce.alaska.gov/web/portals/5/pub/2019200354.pdf and https://www.commerce.alaska.gov/web/portals/5/pub/2019200355.pdf, respectively.

[2] See SB 37 Sec. 08.80.159; 12 AAC 52.610(b); 12 AAC 52.696(b); and 12 AAC 52.697(b). Applications for the professional licensure are currently available on the Alaska Board of Pharmacy website. Although a business license is also required, these entities must first obtain a professional license.

[3] See 12 AAC 02.310(a)(1), (b)(8), (b)(9), and (b)(10) for the applicable fees.

[4] See 12 AAC 52.610(b) for a list of the application requirements for nonresident WDDs, 12 AAC 52.696(b) for nonresident OFs, and 12 AAC 52.697(b) for nonresident 3PLs.

[5] This includes, without limitation, those requirements under 12 AAC 52.610(c)–(e); 12 AAC 52.696(c)–(h); and 12 AAC 52.697(c)–(g).

[6] See 12 AAC 52.620(d).

[7] See 12 AAC 52.696(h).

[8] See 12 AAC 52.696(g) and 12 AAC 52.697(g).

[9] See 12 AAC 52.465(a)(1); see also 21 C.F.R. § 1306.13.

[10] See 12 AAC 52.465(a)(2).

[11] See 12 AAC 52.530(a)(1).

[12] See 12 AAC 52.530(a)(2).

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