

Recommendations for Oversight: Session Law 2021-110  
Related to Pharmacist Administration of Long-Acting Injectable Medication  
*Passed by NCPA Executive Council November 20, 2021*

**Background:** The North Carolina General Assembly passed Session Law 2021-110, which was signed into law by the Governor on August 20, 2021. The law authorizes an immunizing pharmacist to administer “a long-acting injectable medication, including testosterone injections and vitamin B12, to persons at least 18 years of age pursuant to a specific prescription order initiated by a prescriber following an examination of the patient which conforms to the standards of acceptable and prevailing medical practice by the prescriber.” The law allows immunizing pharmacists to administer any long-acting injectable psychotropic medication without restriction. A subcommittee of the North Carolina Medical Board and North Carolina Board of Pharmacy is to provide a degree of oversight by developing statewide written protocols for the newly authorized treatments. Until the protocols are developed or January 1, 2023 (whichever is later), the “State Health Director shall issue a standing order authorizing immunizing pharmacists to dispense, deliver, and administer [the newly authorized] medications . . .” The law specifies that the “standing order shall include protocols for the initiation, modification, and discontinuation of each therapeutic class of medication available pursuant to the standing order . . .”

**Issue:** Two specific long-acting injectable medications require special precautions: extended-release olanzapine (Zyprexa Relprevv) and extended-release buprenorphine (Sublocade).

According to the prescriber information, administration of Zyprexa Relprevv is governed by a Risk Evaluation and Management Strategy (REMS) program due to the risk of signs and symptoms consistent with olanzapine overdose including delirium and sedation.

ZYPREXA RELPREVV must be administered in a registered healthcare facility (such as a hospital, clinic, residential treatment center, or community healthcare center) with ready access to emergency response services. After each ZYPREXA RELPREVV injection, a healthcare professional must continuously observe the patient at the healthcare facility for at least 3 hours and must confirm that the patient is alert, oriented, and absent of any signs and symptoms of post-injection delirium/sedation syndrome prior to being released. All patients must be accompanied to their destination upon leaving the facility . . . If post-injection delirium/sedation syndrome is suspected, close medical supervision and monitoring should be instituted in a facility capable of resuscitation . . .

Due to the risk serious harm or death associated with intravenous injection of Sublocade, the medication is closely regulated by the Sublocade REMS Program. The Sublocade REMS program certifies healthcare providers, healthcare settings, and pharmacies. Sublocade must only be dispensed to certified health providers for administration in a healthcare setting. Provisions of the REMS program require that healthcare settings and pharmacies that order and dispense Sublocade must be certified in the Sublocade REMS Program and must establish processes and procedures to verify Sublocade “is provided directly to a healthcare provider for administration by a healthcare provider, and the drug is not dispensed to the patient.” Furthermore, if Sublocade is administered too soon after a patient has used opioids, the patient is at risk of experiencing precipitated withdrawal, an intense opioid withdrawal reaction that often requires pharmacologic management.

Most, if not all, free-standing pharmacies will not be able to fulfill the safety requirements for administration of either medication.

**Recommended Action:** For the health and wellbeing of our patients, the North Carolina Psychiatric Association seeks to

- Alert the North Carolina Medical Board to the risks posed by administration of these medications
- Urge the Board to restrict immunizing pharmacists from administering current and future long-acting psychotropic medications with REMS requirements
- Request that the Board include this restriction in the statewide written protocols for immunizing pharmacists.

Sources: Session Law 2021-110, Prescriber information for Zyprexa Relprevv, & Prescriber information for Sublocade