4-2018

Administration of Long-Acting Injections

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Publication Information

Noel, Christopher and Williams, Karl (2018). "Administration of Long-Acting Injections." *NYS Pharmacist* April 2018, 22-24.

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Abstract

Expanding the scope of pharmacy practice demonstrates that the profession has been successful at improving public health. Despite being a late adopter, New York's limited experience with vaccines has improved immunization rates and lowered rates of disease. During emergencies, the 2017-2018 flu season for example, the state has turned to pharmacists to go beyond what the pharmacy practice law permits, in this case enabling immunizations in pediatric patients.[1] This illustrates recognition of untapped potential within the profession to contribute to the public health. Another opportunity for pharmacists to enhance the public health is embodied in a Bill introduced in the New York State Legislature that would amend the pharmacy practice law to enable administration of "long-acting injectables" designed to treat mental health disorders including schizophrenia and substance use disorder ("SUD"). The goal of this paper is to review the proposed amendment, the relevant background, and to discuss the implications for patients and the pharmacy profession.

Disciplines

Pharmacy and Pharmaceutical Sciences

Comments

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Administration of Long-Acting Injections

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Expanding the scope of pharmacy practice demonstrates that the profession has been successful at improving public health. Despite being a late adopter, New York's limited experience with vaccines has improved immunization rates and lowered rates of disease. During emergencies, the 2017-2018 flu season for example, the state has turned to pharmacists to go beyond what the pharmacy practice law permits, in this case enabling immunizations in pediatric patients.[1] This illustrates recognition of untapped potential within the profession to contribute to the public health. Another opportunity for pharmacists to enhance the public health is embodied in a Bill introduced in the New York State Legislature that would amend the pharmacy practice law to enable administration of "long-acting injectables" designed to treat mental health disorders including schizophrenia and substance use disorder ("SUD"). The goal of this paper is to review the proposed amendment, the relevant background, and to discuss the implications for patients and the pharmacy profession.

The Legislation

Assembly Bill A08661, sponsored by Assemblyman John McDonald, explains the thinking behind this proposal in its "Justification" section. New York is among a minority of states (eleven) that does not permit pharmacists to administer "non-vaccine items" such as long-acting injections ("LAIs") for mental health disorders. Lack of adherence to oral forms of medication is one of the key reasons cited for this legislation. Inability, or unwillingness, to take medication as prescribed results in clinical relapse, patient suffering, and high rates of readmission to facilities for inpatient care. Non-adherent patients are five-times more likely to require additional inpatient care than adherent patients. The justification further explains that community pharmacies are ideal partners in the care of these patients because the better proximity to, and accessibility by patients. Perhaps less intuitive, but more important, there is a stigma associated with reporting to a mental health clinic periodically for medication. No such stigma attaches to community pharmacies.

The Bill amends Article 137 of the Education Law relating to the practice of pharmacy by expanding those medications that pharmacists may provide under the definition of "Administer". Currently limited to a very short list of vaccines, the proposal creates a new subsection (6802(22)(b)) that includes: "medications for the treatment of mental health and substance use disorder, as prescribed or ordered by a licensed prescriber in this state and in accordance with regulations promulgated by the commissioner in consultation with the board of pharmacy."

In addition, the Bill would add a new subdivision, six, to the "Definition of pharmacy practice". Section 6801(6) explicitly states that a "licensed pharmacist may administer injectable medications for mental health and substance use disorder."

Schizophrenia

Schizophrenia is a serious and disabling mental illness that affects 1.1% of the US population.[2] The first antipsychotic medication was introduced in the 1950s; shortly thereafter, it was clear that adherence to these medications was a major issue. In the mid-late 1960s, the first long-acting injectable (LAI) antipsychotic was introduced—however, buy-in was not universal as some were skeptical of increased side effects, lack of efficacy, and questions of the ethics of this dosage formulation.[3]

Patients and doctors have a wide variety of attitudes regarding the use of LAI antipsychotics. There is a more negative attitude held by treating clinicians, especially in those recently diagnosed with schizophrenia versus more chronic patients. A European study determined that, of nearly 900 healthcare professionals (physicians and nurses) surveyed, 40% preferred LAIs in first-episode psychosis (FEP) where 90% would prefer them in patients who have had two to five psychotic episodes.[4] Patients may have negative attitudes about LAIs as well, but this may be due to a lack of information coming from their provider. In one study, when an LAI was offered to an LAI-naïve patient, more often the response was neutral or favorable (63%) versus unfavorable (37%).[5] Multiple studies have confirmed that attitudes toward LAI antipsychotics is majorly dependent on previous exposure—many patients who have tried LAIs prefer this treatment over oral medications as they "feel better", have a more "normal life" and find the injections "easier to remember".[2] Other advantages that LAIs have over oral medications that are supported by the literature are the lack of need for daily administration, transparency of adherence, a lower likelihood of relapse rates and rebound symptoms, reduced peak-trough plasma levels, and improved patient satisfaction and outcomes.[2]

LAIs have gained favor in the eyes of clinicians and

patients. These are now starting to be recommended for those experiencing first-episode schizophrenia (FES) and are regularly recommended for those with chronic multi-episode schizophrenia or adherence issues (Table 1).

TABLE 1	PORT 2009	WSFBP 2012	AFPBN 2013	NICE 2014	Canadian 2017
FES	Oral SGA or FGA (not CLOZ or OLZ)	Oral SGA > Oral FGA	LAI SGA	Antipsychotic decided by patient and doctor together	Antipsychotic decided by patient and doctor together
Failure of two antipsychotics	CLOZ	CLOZ	N/A	CLOZ	CLOZ
Long-term maintenance or non-adherence	LAI	LAI	LAI	LAI	Maintenance: Oral or LAI depending on patient-preference

Substance Use Disorder

Substance use disorder, opioids in particular, continues to be one of the most vexing diseases, resulting, since 1999, in escalating morbidity and mortality. Despite broad recognition, the epidemic continues to advance. In November 2017, the Centers for Disease Control reported that nationwide data for the period October 2015 through October 2016 showed fatal overdoses continued to increase, killing over 42,000 people – a five-fold increase over 1999, and netting out to more than 600,000 people.[6] Chillingly, this represents 115 deaths each day.

Medications available to treat opioid use disorder are methadone, buprenorphine, and naltrexone – all of which come in various dosage formulations with only certain formulations proving to be more efficacious than placebo in controlled studies. Methadone, the most widely studied and used medication for opioid use disorder, comes in tablet and liquid formulations; it has been shown to reduce illicit opioid use, treat opioid use disorder, and retain patients in treatment better than placebo or no medication.[7] Two medications available as a LAI and focused on herein are extended-release (monthly) subcutaneous injectable buprenorphine and extended-release (every 4 weeks) intramuscular naltrexone.

Buprenorphine retains patients in treatment and reduces illicit opioid use better than placebo.[6] Compared to methadone's full mu-agonist properties, it is a partial agonist with a ceiling effect, which makes it less likely to cause respiratory depression and safer in overdose (although not free of risk in overdose situations). The monthly subcutaneous injectable formulation of buprenorphine is FDA-approved for moderate to severe opioid use disorder in patients who are started on transmucosal buprenorphine for at least 7 days. The medication is injected into the subcutaneous tissue of the abdomen of the patient at a dose of 300 mg for the first two months, and then 100 mg monthly thereafter. Extended-release naltrexone is more effective than placebo in reducing risk of return to opioid use and is proven to be non-inferior to daily buprenorphine in terms of treatment retention and reduction of illicit opioid use in a 12-week Norwegian trial (n=159). It is FDA-approved to prevent return to opioid dependence following medically supervised opioid withdrawal. The medication is injected into the muscle of the upper outer quadrant of the gluteal area at a dose of 380 mg every 4 weeks. Interestingly, a Cochrane review (13 trials, n=1,158) concluded that oral naltrexone was not superior to placebo in treatment retention or illicit opioid use reduction.

In December 2016, the National Alliance of State Pharmacy Associations (NASPA) and the College of Psychiatric and Neurologic Pharmacists (CPNP) gathered to specifically discuss pharmacist administration of LAIs.[8] In addition to these and other pharmacy organization representatives, there were representatives from the American Psychiatric Association, the Department of Defense, the Substance Abuse and Mental Health Service Administration, the National Alliance on Mental Illness, and the United States Public Health Service, among others.[9] The unmet need to provide patients increased access to these medications was addressed. When it comes to those diagnosed with schizophrenia, about half are not taking their medications as prescribed. For this reason, LAIs have gained favor but certain barriers remain including scheduling challenges, limited personnel and inventory in clinics, reimbursement issues, and lack of transportation for the patient to and from the clinic. The conclusions of the stakeholder meeting were that 1) pharmacists can play a vital role in the effort to improve patient access to these medications and 2) states that do not currently have legislation for pharmacist administration of LAIs should consider incorporating new policies.

Discussion

This amendment to the pharmacy practice law comes at a time that the pharmacy profession here in New York is well-positioned to help address the medication adherence-related public health issues identified in the Bill. Viewed as a public health resource, the profession has developed the 'infrastructure' to fulfill the goals of the A08661. In 2008 the

scope of practice expanded to permit pharmacists to administer a short list of vaccines. In response, pharmacy schools, the profession, and the Board of Pharmacy mobilized to provide additional education and training necessary to administer these injectable products safely and effectively. As a result, the framework is in place to include additional medications and disease states envisioned in the Bill. Training would include medication-specific information, the patient-specific counseling, and other aspects of care. These are now cornerstones of our profession.

Assembly Bill A08661 will only narrowly expand the list of those medications that trained pharmacists can administer. While it is intuitive that A08661 will improve the public health as intended in connection with schizophrenia, it could go further.

Thirty-nine states permit pharmacists to administer any medication. For example, in Kentucky the "Practice of Pharmacy" includes sweeping language permitting "administration of medications or biologics in the course of dispensing or maintaining a prescription drug order."[10] Also, seven states currently permit pharmacists to prescribe controlled substances.[11] The Drug Enforcement Administration characterizes pharmacists in these states as "mid-level practitioners". With help from Congress and New York State pharmacists could work collaboratively with other health professions, *prescribing* buprenorphine under protocol permitting profoundly greater access to necessary care.

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New Legislation

PSSNY has developed bill language very similar to the Governor's budget proposal last year that would register and license PBMs. We are in conversations with Assembly member Gottfried and Senator Hannon to negotiate language acceptable to both houses and to identify bill sponsors. Once the budget passes, this will be PSSNY's top priority.

Influence of Media Coverage

PSSNY has retained a consultant to build a media presence that has helped us get to where we are today. We are continuing the effort to increase awareness of PBM practices, the role of the pharmacist on the healthcare team and the impact both have on the care of the patient.

Some of the more powerful pieces include:

- States Fight Back Against Unfair Prescription Pricing Practices, (WNYT.com, March 5, 2018)
- Regulators Push to End Prescription Gag Clauses, (NBC News NY, February 27, 2018)
- Why Your Pharmacist Can't Tell You That $20 Prescription Could Cost Only $8, (New York Times - February 25, 2018)

To see the most recent coverage, please visit: PSSNY's Press Room: www.PSSNY.org/PressRoom.

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