Vermont Pharmacist Association
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Building One Voice for Pharmacy!

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Marci Wood, Editor

Vermont News

VPA Fall Conference: October 25th

Mark your calendars for the upcoming Fall CE meeting! The 5 CE credit hour meeting will be held **Sunday, October 25th** at the ACPHS-VT campus in Colchester. Watch your email this month for more information.

Electronic Prescribing for Controlled Substances Reminder

The Vermont Board of Pharmacy recently amended its administrative rules to allow electronic prescribing of controlled substances. The rules which were approved by the legislature on August 28, 2015 became effective on September 15, 2015.

The rules permit the use of electronic prescribing for Schedule II controlled substances if the prescriber has software that has been certified by the Drug Enforcement Agency (DEA). Prescribers should contact their e-prescribing software vendor to request an upgrade that meets the DEA standards for prescribing controlled substances. Surescripts, a networking company that routes most electronic prescriptions to pharmacies, reports that although many vendors will upgrade the software at no cost, some vendors charge for the upgrade.

Electronic prescriptions must be transmitted to the pharmacy either directly or through an electronic transmission intermediary. The prescription must include the prescriber's phone number for verbal confirmation, the time and date of the transmission and the identity of the pharmacy intended to receive the transmission.

Please direct questions to Madeleine Mongan, Deputy EVP of the Vermont Medical Society at 802-223-7898 or email: mmongan@vtmd.org.

Save the Date: Vermont Legislative Day

Next year's Vermont Pharmacists Day will be held on January 22nd at the Statehouse in Montpelier.

Upcoming Board of Pharmacy Meeting

This month's meeting of the Board of Pharmacy will be held at 9 AM on October 28th. The meeting will be held on the 3rd floor of the City Center, 89 Main Street in Montpelier.

National Pharmacy News

NIH Study Supports More Intensive Blood Pressure Management

Preliminary reports from the Systolic Blood Pressure Intervention Trial (SPRINT) sponsored by the NIH show that more intensive management of blood pressure significantly reduces rates of cardiovascular events and lowers risk of death in adults with hypertension 50 years of age and older. Patients were treated to a goal systolic blood pressure of 120 mmHg, rather than the currently suggested goal of 140 mmHg. This showed reduced rates of heart attack, heart failure, and stroke by around one-third, and reduced risk of death by almost a quarter. Investigators state results from the study support treating patients over 50 years of age with hypertension and at least one additional risk factor for heart disease to a more intensive blood pressure goal.

The SPRINT trial began in 2009, and included more than 9,300 participants aged 50 years or older from various medical centers in the United States and Puerto Rico. It is the largest study assessing how treating to a lower systolic blood pressure goal impacts cardiovascular and kidney disease, but did not include patients with diabetes, prior stroke, or polycystic kidney disease. The results promoted the closure of the SPRINT trial by the NIH ahead of its scheduled date to more quickly publish the significant preliminary results. Publication of final results is expected in the next few months. Until these results are published, maintaining and treating patients to previously identified blood pressure treatment goals is recommended.

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FDA Updates Clozapine Monitoring for Neutropenia

To address safety concerns with clozapine use and severe neutropenia, a potentially life-threatening condition caused by a dangerously low number of neutrophils, the FDA has changed some requirements for treating patients with the drug. Clarification in the prescribing information for monitoring patients for neutropenia was provided, and a clozapine REMS (risk evaluation and mitigation strategy) program was approved. The REMS program is expected to reduce possible confusion related to the previous system of having separate registries for individual clozapine medications and improve monitoring and management for patients with neutropenia.

To prescribe and dispense clozapine, prescribers and pharmacies will require certification in the REMS program. Starting on October 12th, 2015 pharmacies must be certified in the REMS program to dispense clozapine and will no longer be able to enroll or manage patients through other clozapine patient registries. Starting on December 14th, 2015 outpatient pharmacies will be required to obtain a pre-dispense authorization from the clozapine REMS program before clozapine can be dispensed.

For more information about the new FDA regulations, see the safety announcement on the FDA website. Additional information for pharmacies is available at the bottom of the page.

Two New Insulin Products Gain Approval

The FDA has cleared two new drugs, insulin degludec U-100 and U-200 injections (Tresiba—Novo Nordisk) and insulin degludec/insulin aspart injection (Ryzodeg 70/30—Novo Nordisk), for adults with diabetes. Insulin degludec injection, a long-acting insulin analog, was approved to improve glycemic control in adults with type 1 or type 2 diabetes. The drug is administered subcutaneously once a day. Insulin degludec/insulin aspart injection, a combination of a long-acting insulin analog and a rapid-acting insulin analog, was approved to improve glycemic control in adults with type 2 diabetes. The most frequently reported adverse events with the two insulin products in clinical trials were hypoglycemia, allergic reactions, injection site reactions, pitting at the injection site, itching, rash, edema, and weight gain. The FDA notes that neither drug should be used in adults who have diabetic ketoacidosis.

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FDA Strengthens Bone Risk Warning for Canagliflozin

A strengthened warning for Invokana and Invokamet related to increased risk of bone fractures has led the FDA to add a new Warning and Precaution and revise the Adverse Reactions section on the labels for these drugs. An ongoing evaluation of the risks of bone fractures with other drugs in the SGLT-2 drug class to determine in further labeling changes are needed. Bone fractures may occur in patients as early as 12 weeks after starting canagliflozin, and has been associated with decreases in bone mineral density at the hip and lower spine.

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New Drug Approved to Treat Schizophrenia and Bipolar Disorder

Vraylar (cariprazine, Forest Laboratories and Actavis Pharma) was approved to treat schizophrenia and bipolar disorder in adults. Efficacy was shown in three 6-week clinical trials with 1,754 patients. In each of these trials, Vraylar was shown to reduce schizophrenia symptoms compared to placebo. For bipolar treatment assessment, three 3-week clinical trials of 1,037 patients showed reduced symptoms with use of Vraylar compared to placebo. The most common side effect reported in both patients with schizophrenia and bipolar disorder were extrapyramidal symptoms. Other commonly seen symptoms included the urge to move, indigestion, vomiting drowsiness, and restlessness.

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DPP-4 Inhibitors Linked to Severe Joint Pain

The FDA has released a warning that medications stiagliptin, saxagliptin, linagliptin, and alogliptin used for the treatment of type 2 diabetes may cause joint pain that can be severe and disabling for patients. This has been added to the Warning and Precaution to the label of all DPP-4 inhibitors. Symptoms of joint pain often occur within the first month of treatment, but can happen any time during therapy. The FDA recommends that healthcare professionals consider medications in this class as a possible source of severe joint pain, and discontinuing the drug if appropriate.

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