Vermont Pharmacist Association
877.483.2646
Building One Voice for Pharmacy!

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Marci Wood, Editor

Vermont News

Spring CE Conference

How do you dose Toujeo? Are you comfortable showing a patient how to use Afrezza? Become comfortable with Glyxambi, Tanzeum, Toujeo, Afrezza, and other new diabetes drugs when you attend the Vermont Pharmacists Association Continuing Education Program, 2015 Diabetes Update, on **Sunday, May 31, 2015**. The event will be held at the Capitol Plaza in Montpelier. A last chance CE before the July, 2015 renewal arrives! Watch your email and for future updates.

Pharmacy Board Rule Revisions Invitation to Comment

The Board of Pharmacy is revising its Administrative Rules. A copy of the proposed rules can be found on the OPR web site.

Under “Meetings and Announcements” you will see copies of the “Proposed Annotated” and “Proposed Clean” versions. In the annotated version new language is underlined like this. Deleted language is stricken like this.

An important proposed change is the requirement for all pharmacy technicians to be certified by July 1, 2016 (see Section 5 of proposed rules).

If you wish to submit comments, please do not wait. The earlier you write, the sooner the Board can consider your comments. Please refer specifically to the number of any rule that you provide a comment about. **Comments can be submitted by:**

▪ **Email** to sos.pharmacy@sec.state.vt.us with the subject “Comments to Pharmacy Rules”
▪ **Mail** addressed to: Board of Pharmacy c/o Peter Comart, Office of Professional Regulation, 89 Main St., 3rd Floor, Montpelier, Vermont, 05620-3402
▪ A **Public Hearing** will be held on **April 29, 2015, at 1:00 p.m**. at the Office of Professional Regulation Conference Room, 89 Main Street, 3rd Floor, (City Center) in Montpelier. If you comment at the hearing, we ask that you also submit a written summary of your comments. The comment period ends on May 8, 2015.
Once the Board considers all of the written and hearing comments, the Board will make final revisions to the proposed rules for review by the Legislative Committee on Administrative Rules.

If you have any questions about the process, please do not hesitate to contact Peter Comart, at 802-828-2808 or email: Peter.Comart@sec.state.vt.us

Recent Pharmacy Robberies and Arrests

Multiple Vermont pharmacies were the target of robbery in the month of March.

The Kinney Drugs in Essex Junction was robbed on March 10th, with police still looking for a suspect. Police say a man wearing a dark jacket, blue jeans, and a scarf covering his face demanded narcotics and got away with the drugs. The suspect displayed no weapon and no one was harmed during the robbery. Any information can be provided to Essex police at 802-878-8331.

On March 17th, the Kinney Drugs in Milton was robbed when a suspect handed a pharmacist a note demanding painkillers and claimed to have a weapon. The suspect fled in a car. Police have two suspects in custody, Leroy Hughes and Siobhan Bird, both from Fairfax. Both suspects face armed robbery charges.

2015 Membership Reminder

The Vermont Pharmacists Association would like to thank all those that have sent in their memberships for 2015, and remind everyone that your membership is critically important to our ongoing efforts to increase our professional voice throughout Vermont and is greatly appreciated. The VPA works diligently to support pharmacy in Vermont and get information out to all pharmacists on upcoming legislation and happenings that affect the pharmacy profession. We are working on dates for upcoming Continuing Education meetings and will get that information out to you when we get dates confirmed. Membership forms are available through our website using PayPal at www.vtpharmacists.com. Click on the menu link in the upper right hand corner, then "membership" from the drop down menu. Alternatively, check or money order can be sent to P.O. Box 818, Milton VT, 05468.

Upcoming Board of Pharmacy Meeting

The next meeting of the Board of Pharmacy is scheduled for **April 22nd at 9 AM**. The meeting will be held on the 3rd floor of the City Center, 89 Main Street in Montpelier.

National Pharmacy News

Fair PBM Auditing Focus Across the Country

Pharmacists across the country are fighting to change current auditing practices by PBMs, which in some cases require paying large sums of money for errors such as misspelling a person's name. In an article published in Pharmacy Today, Ohio Pharmacist John Coler discussed his issues with auditing practices for reasons that did not alter patient outcomes or the payer negatively. Coler was part of a group that assisted in crafting PBM audit reform legislation that will set guidelines on when and how audits are done in Ohio. Matt DiLoreto, the Senior Director of State Government Affairs at the National Community Pharmacists Association (NCPA) is quoted in the article supporting the legislation of states like Ohio to control PBM auditing. DiLoreto stated that while the PBM audits for the purpose of finding fraud, waste, and abuse are supported, "…PBMs seem to take advantage of their role, oftentimes targeting minor administrative typographical errors and recouping the entire costs of medications and some dispensing fees too.". Charles Cote, representing the association of America's PBMs, stated that this legislation would make it more difficult to find wasteful spending and for businesses to reduce health care costs while protecting employee benefits.

In total, 30 states have PBM audit reform legislation in effect, including Vermont. In 2013, the Vermont Pharmacists Association helped support the approval of the strictest audit bill in the United States by the Vermont Legislature.

US Prescription Drug Spending Up 13.1% in 2014

A report published by Express Scripts says prescription drug spending in the US has increased by 13.1% in 2014, the highest since 2003. The PBM attributes the increase to specialty medicines, which increased 30.9% in 2014. New hepatitis C therapies Sovaldi, Viekira Pak, and Exviera represent 45% of the total increase in spending in 2014. Express Scripts predicts that specialty drug costs will increase at a rate of more than 20% per year between 2015-2017.

Data Support LDL Lowering of New Cholesterol Drugs, Safety Questionable

Further data about a new class of cholesterol-lowering drugs, PCSK9 inhibitors, supports the LDL cholesterol lowering potential of these drugs, but safety and tolerability are still not clear. The inhibition of proprotein convertase subtilisin-kexin type 9 (PCSK9) receptors has been shown to significantly lower LDL cholesterol in short term studies. Long-term study data of two PCSK9 inhibitors currently under development, evolocumab (Amgen) and alirocumab (Sanofi), were examined in a recent study published in the New England Journal of Medicine.

For evolocumab, results from 2 open-label studies of 140 mg injections of drug every 2 weeks or 420 mg injected every month compared to standard therapy. Either evolocumab treatment resulted in a LDL reduction of approximately 60%, a large decrease that was expected based on short-term trial data. Adverse effects were similar for evolovumab compared to standard therapy, but there was a slightly increased risk of neurocognitive events in patients treated with evolovumab. Initial assessment of cardiovascular event outcomes was lower for patients in the evolovmab group, however only a small number of events were included in the analysis. At the completion of the FOURIER trial, an ongoing trial involving 27,500 patients, both cardiovascular and neurocognitive events will be assessed. The estimated end-date of this trial is in 2018.

The trial involving alirocumab similarly looked at LDL lowering effect and long-term safety, and involved 2,341 patients. As with evolovumab, a 60% lowering of LDL was seen in patients treated with 1 mL injectable alirocumab every 2 weeks. Alirocumab treatment was associated with an increased risk of injection-site reactions, myalgia, neurocognitive events, and ophthalmologic events, but preliminary analysis showed a decrease risk of major cardiovascular adverse events compared to placebo.

Dinutuximab Approved for High-Risk Neuroblastoma

The FDA has approved dinutuximab for as part of first-line therapy for pediatric patients with high-risk neuroblastoma, the first therapy approved for this indication. Dinutuximab will be used as part of a regimen that also includes surgery, chemotherapy, and radiation therapy for patients that show some response to prior first-line therapies.

Safety and efficacy were evaluated in a clinical trial involving 226 children with high-risk neuroblastoma. These children showed improvement after treatment with chemotherapy and surgery, followed by bone marrow transplant and radiation therapy. Patients were randomly assigned to receive isotretinoin (RA) or dinutuximab along with IL-2 and granulocyte-macrophage colony stimulating factor, which are thought to stimulate the immune system. Three years after treatment assignment, 63% of patients in the dinutuximab treatment group were alive and free of tumor growth, compared to 46% of patients treated with RA.

A boxed warning of dinutuximab alerts that the drug irritates nerve cells, causing severe pain that requires treatment with IV narcotics. It can also cause nerve damage and other life-threatening reactions, including upper airway swelling, difficulty breathing, and severe hypotension. These reactions can occur during or shortly after completion of the infusion. Other serious adverse effects include infections, eye problems, electrolyte imbalances, and bone marrow suppression. Common side effects include pain, fever, low platelet counts, infusion reactions, hypotension, elevated liver enzymes, and capillary leak syndrome.

Please note our mailing address:

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