Vermont Pharmacist Association
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Building One Voice for Pharmacy!

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Vermont News

Bill S.243 Signed into Law

Vermont has become one of the first states to grant 'provider' status to pharmacists! Governor Shumlin signed S.243 into law on June 8th. This legislation, primarily aimed at combating opioid abuse, paves the way for pharmacists to be recognized as health care providers with regards to clinical services. As more states sign HCP legislation, the ultimate goal will be a change in the Federal law so that our services will be reimbursable under Medicare Part B.

This rapid victory came about with the collaborative efforts of the Vermont Pharmacists Association, Vermont Health Systems Pharmacists, Vermont Retail Druggists, and the Albany College of Pharmacy & Health Sciences Vermont Campus.
Representatives of these groups were on hand along with the Governor, Speaker of the House Smith, Health Commissioner Chen, Sen. Claire Ayer, and others for the signing at the Community Health Center of Burlington.

VPMS Updates

With the signing of S.243, A Bill to Reduce Opioid Abuse, into law by Governor Shumlin recently, several changes will be coming to the VPMS:

- In July of 2016, pharmacies will be required to update their profile,
- In October of 2016, pharmacies must report data through ASAP Format 4.2
- In January of 2017, pharmacies must report data **daily** instead of weekly.

We hear that the VPMS will be sending information to pharmacists soon.

Vermont becomes first state to require drug transparency

Governor Peter Shumlin has signed a bill that will make Vermont the first state to require pharmaceutical companies provide justification concerning drug price changes through the state's Medicaid program. The Green Mountain Care Board and the Department of Vermont Health Access will develop a list of the 15 drugs whose prices increased through the Medicaid program each year, and require use of 340B pricing by Medicaid. Manufacturers will need to disclose "all the factors that have contributed to a price increase" and justify the increases to the Attorney General's Office.

Upcoming Board of Pharmacy Meeting

The next meeting of the Board of Pharmacy will be held at 9 AM on Wednesday, July 27th. The meeting will be held on the 3rd floor of the City Center, 89 Main Street in Montpelier.

National Pharmacy News

Updated CDC Guidelines on Opioid Prescribing for Chronic Pain

Recently published guidelines from the CDC synthesize evidence from published research to make 12 recommendations aimed at use of opioids in chronic pain outside of cancer and palliative care. These recommendations focus on opioid prescribing in the primary care setting, but are also applicable to other areas such as hospitals. Opioid medications are not recommended first line for chronic pain outside of cancer and end of life care. All other options (such as acetaminophen, NSAIDs, and antidepressants) should be considered before opioids. The guidelines recommend that primary care providers carefully weigh the decision to start chronic opioid therapy and discuss realistic treatment goals with patients, including that functional improvement and not pain relief is the goal of pharmacological therapy. The lowest effective dose of opioid medication should be used, and continued discussion throughout treatment concerning the benefits and risks of opioid medications are recommended.

The FDA Warns of Serious Complications of High Dose Loperamide

The FDA has issued a warning for serious cardiovascular problems associated with taking higher than recommended doses of Imodium. The maximum approved over the counter dose is 8 mg, however the FDA reports doses of up to 300 mg related to these adverse effects. Abuse or misuse of Imodium, which is structurally related to opioids, can cause serious heart problems such as QT prolongation, Torsades de Pointes, and cardiac arrest. In some patients, these complications have caused death. According to the FDA, the majority of reported serious complications occurred when the drug was intentionally misused in attempts to self-treat opioid withdrawal symptoms or to achieve feelings of euphoria. When loperamide is intentionally abused, individuals often use other drugs such as ranitidine in combination with loperamide to increase its absorption and penetration across the blood brain barrier, leading to inhibition of loperamide metabolism and increased euphoric effects.

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Systematic Review Questions Statin Use

Findings of a systematic review published in the BMJ Open journal found no association between LDL cholesterol and mortality in the 19 reviewed studies, which focused on an elderly population of patients 60 years and older. The authors of this study call for re-evaluation on the use of statins in this population, citing this review of literature as proof the benefits of statin treatment have been exaggerated.

However, this review has multiple limitations that leave its findings unreliable for this population of patients. Cohort studies, not randomized control trials, were included in the review, PubMed was the only database searched for trials, and the description of their methods was not adequate to fully determine the validity of the exclusion/inclusion criteria used. No other levels besides LDL cholesterol were reviewed, and the findings do not take into account statin use during observation periods of the study which may have impacted mortality.

A detailed review by the Centre for Evidenced Based Medicine (CEMB) further examines the limitations of this study, and concludes based on multiple flaws in design, interpretation of results, and description of analysis this review have limited validity. Peer reviews of this paper also highlight its many limitations, and can be read online.

New Combination Therapy for Hepatitis C Approved

Epclusa (sofosbuvir/velpatasvir, Gilead Sciences) received approval by the FDA to treat adult patients with Hepatitis C both with and without cirrhosis. For patients with moderate to severe cirrhosis, Epclusa is approved in combination with ribavirin. The addition of velpatasvir, a new drug, along with sofosbuvir allows Epclusa to treat all six major forms of HCV. It is the first hepatitis C medication to treat all six major forms. Efficacy and safety were assessed in three Phase 3 clinical trials of approximately 1,550 patients. The results of these trials demonstrated that 95-99% of patients treated with Epclusa had no virus detected in their blood 12 weeks after treatment, signifying cure of the infection. Further, the drug was studied in patients with decompensated cirrhosis found 94% of the 87 patients receiving Epclusa in combination with ribavirin had no detectable virus in their blood after 12 weeks.

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Atrial Fibrillation Patients May Need More Anticoagulation, Study Finds

More than one in three patients with atrial fibrillation who have an increased risk of stroke are treated only with aspirin instead of oral anticoagulants according to the results of a cohort study published in the Journal of the American College of Cardiology. Of 210,380 patients with intermediate thromboembolic risk (CHADS2 score >/= 2), 38.2% were treated with aspirin alone and 61.8% were treated with warfarin or a direct oral anticoagulant. Of 294,642 patients with high stroke risk (CHADS2VASc score > /= 2), 40.2% were treated with aspirin alone and 59.8% were treated with warfarin or a direct oral anticoagulant. Use of aspirin therapy only was associated with complications such as hypertension, dyslipidemia, coronary artery disease, prior myocardial infarction, unstable and stable angina, recent coronary artery bypass graft, and peripheral arterial disease. For oral anticoagulant prescriptions, associations of more frequent prescriptions included male sex, higher body mass index, prior stroke/transient ischemic attack, prior systemic embolism, and congestive heart failure.

First Combination of Beta Blocker and ARB Approved

The FDA announced the approval of Byvalson 5/80 mg tablets (nebivolol and valsartan, Allergan) for the treatment of hypertension. This medication is the first and only fixed-dose combination product that includes a beta blocker and angiotensin II receptor blocker. The drug was studied in Phase 3 trials lasting 8 weeks and was found to be safe and effective.

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