



Rx TWO PHARMACY SERVICES, INC.

MEDICATION NEWSLETTER

Volume 3 No. 3 phone (866) 739-7700 e-mail: spatel@rxtwopharmacy.com

Medicare News

A new rule requiring U.S. citizens to prove their citizenship when applying for or renewing Medicaid benefits is expected to jeopardize coverage for several million qualified citizens, from elderly people in nursing homes to foster children, according to a national survey conducted by the Center on Budget and Policy Priorities, a Washington-based research group. The rule, which takes effect July 1, requires native-born citizens to produce a passport or birth certificate (except in rare cases) to begin or continue Medicaid coverage. Its main effect is likely to impede or delay coverage for millions of eligible U.S. citizens. Three to five million Medicaid beneficiaries -- including between 1.4 million and 2.7 million children -- could see their coverage jeopardized because they do not have a U.S. passport or U.S. birth certificate in their possession, according to data from a nationally representative survey.

The federal Centers for Medicare and Medicaid Services have sanctioned prescription drug plans participating in Medicare's Part D program more than 1,000 times since the universal drug benefit was launched January, the agency said. CMS said it has sent warning letters 651 times since January, the most common action taken. In 318 instances, the agency has ordered insurers to submit business plans to correct matters such as call-center performance or incorrect marketing information. In 75 instances, the agency temporarily restricted companies from marketing their plans on Medicare's online plan directory, the "Medicare Personal Plan Finder." Such cases included instances in which plans continued to provide incorrect information about drug prices and formularies.

New FDA Approved Medications, Warnings, Indications, Formulations and News:

The FDA has approved Exelon (rivastigmine tartrate) for the treatment of mild to moderate dementia associated with Parkinson's disease, a disorder of the central nervous system. Exelon was previously approved for the treatment of mild to moderate dementia of the Alzheimer's type. It is estimated that about 0.2 percent to 0.5 percent of people over 65 years of age are affected by Parkinson's dementia and experience such symptoms as impairments in executive function, memory and attention. The approval of Exelon for the treatment of Parkinson's dementia is based on the results of a randomized, placebo-controlled clinical study with 541 patients who showed symptoms of mild to moderate dementia two years or later after their diagnosis for Parkinson's disease. At the end of the 24-week trial, the condition of the Exelon-treated patients, as shown on a scale that measures mental processes, was significantly better than the condition of the patients on placebo. In some patients with Parkinson's disease, treatment with Exelon was associated with a worsening of tremor.

The FDA has approved Pfizer's antismoking pill, Chantix (varenicline). Chantix, the first new prescription medication approved for smoking cessation in nearly a decade, received priority review designation by the FDA because of its potential to be a significant therapeutic advance over existing therapies. Chantix is unique because it is specifically designed to partially activate the nicotinic receptor and reduce the severity of the smoker's craving and the withdrawal symptoms from nicotine. Moreover, if a person smokes a cigarette while receiving treatment, Chantix has the potential to diminish the

sense of satisfaction associated with smoking. This may help to prevent the cycle of nicotine addiction. In trials, Chantix was generally well tolerated with the most common side being nausea, changes in dreaming, constipation, gas and vomiting. Because smokers need considerable support to successfully quit, Chantix will be available to patients with a support program designed to help address behavioral components of smoking dependence. This personalized program will be free and easy to use.

Teva Pharmaceutical Industries Ltd. (TEVA) announced that it has received approval from the FDA for once-daily Azilect (rasagiline tablets) as a treatment for Parkinson disease. The compound was approved both as initial monotherapy in early Parkinson disease patients and as adjunct therapy to levodopa in moderate-to-advanced stages of the disease. This drug is a monoamine oxidase type-B inhibitor that blocks the breakdown of dopamine. Dopamine sends information to the parts of the brain that controls movement and coordination. Parkinson's disease is caused by the destruction of the brain cells that control movement and coordination. Rasagiline may be associated with hypertensive crisis if patients also consume tyramine-rich foods or beverages (e.g. cheese, red wine) or dietary supplements or amines contained in many cough and cold meds.

Novartis has received marketing approval from the FDA for two new dosing strengths of Lotrel® (amlodipine besylate/benazepril HCl), 5/40 mg and 10/40 mg. Lotrel will now be marketed in six different dosage strengths.

The FDA has approved Emsam® (Selegiline) as the First Transdermal Patch for the treatment of severe depression. This medication functions as a monoamine oxidase inhibitor (MAOI) that may be used at its lowest dose (6mg/24 hour period) without the need for previous MAOI dietary restrictions. A mild skin reaction at the site of patch application was the most commonly reported adverse event in placebo-controlled trials, while light-headedness due to a drop in blood pressure

was also reported in a small number of individuals. The medication labeling advises that direct heat (from heating pads, electric blankets, heat lamps, saunas, hot tubes, or prolonged exposure to sunlight) should be avoided as such exposures may result in an increased release and subsequent absorption of the drug from the patch. For more information, visit <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01326.html>

The FDA has approved Zostavax® (Zoster Vaccine Live) by Merck & Co for the prevention of herpes zoster (commonly known as shingles) in people 60 years of age and older. It is not indicated for the treatment of shingles or postherpetic neuralgia and may not be effective for those who already had shingles. Zostavax® must be stored frozen at an average temperature of -15° C (+5° F) and protected from light until it is reconstituted. The diluent for reconstitution is provided with the vaccine and should be stored separately at room temperature (20-25° C, 68-77° F) or refrigerated (2-8° C, 36-46° F). Once the vaccine has been reconstituted, it must be used within 30 minutes. Do not freeze reconstituted vaccine. For more info visit http://www.merck.com/product/usa/pi_circulars/z/zostavax/zostavax_pi.pdf

Generic Drug Approvals:

- Pravastatin (Pravachol) 10, 20 & 40mg tabs
- Simvastatin (Zocor) 5, 10, 20, 40, 80mg tabs
- Finasteride (Proscar) 5mg tabs
- Sertraline (Zoloft) 25, 50, 100mg tabs and 20mg/ml concentrate

Rx Two Pharmacy Services, Inc. was formed by a group of dedicated and seasoned LTC pharmacy professionals with the goal of providing comprehensive pharmacy services for our contracted nursing centers and their residents by utilizing state of the art computer technology and good old fashioned hard work.

Prepared by Sailesh Patel, PharmD, FASCP
Vice President, Clinical Services