



Rx TWO PHARMACY SERVICES, INC.

MEDICATION NEWSLETTER

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Medicare News

CMS Revises Fallback Plan for Dual Eligibles Missed During Auto-Enrollment

Centers for Medicare & Medicaid Services (CMS) issued a revised 12-step process late December for pharmacies to bill prescription transactions when a dual eligible individual has not been assigned to a Medicare Part D plan. This plan, along with a question and answer document about the transition billing process, and related documents, have been posted to the ASCP Web site at:

<http://www.ascp.com/MedicareRx>

The Centers for Medicare & Medicaid Services (CMS) announced has launched a Web toolkit to educate Medicare beneficiaries about prescribing choices. The first tool, the Medicare Prescription Drug Plan Cost Estimator, is linked from Medicare.gov and should help beneficiaries estimate how much they can save from the Medicare drug benefit based on their drug spending. The second tool, the Medicare Prescription Drug Finder is designed to assist people with no drug coverage. The drug finder will allow users who already know what drug plan they want, to go to one part of the finder to complete the enrollment process. If not, they can go to another part of the finder to enter what drugs they take and what pharmacy they use to get customized plan options. The third Web tool is the Medicare Personal Plan Finder, which will provide information comparing benefits offered by Medicare Advantage managed care plans with traditional Medicare benefits and those provided by Medigap plans. A demo of this Web site is available at:

<http://media.cms.hhs.gov/>

New FDA Approved Medications, Warnings, Indications and News:

Federal health advisers endorsed a proposed vaccine to help prevent shingles, an often-excruciating disease that afflicts as many as 1 million adults every year. The Food and Drug Administration's advisory panel on vaccines said the vaccine for shingles appeared to be safe and effective in people aged 60 and older. However, panelists worried its effectiveness may not last, and said it appeared to be less effective in people over 80. The vaccine, Zostavax, was developed by Merck & Co., which sought to have it approved for use in people aged 50 and older. But Merck conducted trials mostly on people 60 and older, leaving the members of the FDA panel on vaccines uncertain whether it was safe or effective for those in their 50's. Whether to approve the vaccine for sale is now in the hands of the FDA, which often follows the advice of its advisory panels. Even if the FDA approves it for use only in those 60 and older, doctors could still prescribe it for younger people. People develop shingles as they age because their immunity to the chickenpox virus wanes. The condition usually starts with pain or itching in a band on the skin, followed by a rash or blisters that can last for days or weeks. It can sometimes cause long-term nerve pain.

The FDA has approved a new indication for Depakote-ER (divalproex sodium extended-release tablets) for the treatment of acute manic or mixed episodes associated with bipolar disorder, with or without psychotic features. Depakote-ER offers patients the convenience of taking this medication once a day. Compared with Depakote (divalproex sodium delayed-release tablets), Depakote-ER taken once a day helps provide more

consistent levels of medication in the body. Approximately 2.3 million American adults have bipolar disorder, also known as manic-depressive illness. Depakote ER is also approved for simple and complex partial seizures and for migraine prevention in adults.

Wyeth announced that on November 18, 2005, the FDA approved Effexor XR (venlafaxine HCl) for the treatment of adults with panic disorder. This marks the first antidepressant approved for panic disorder since 2002. The efficacy of Effexor XR as a treatment for panic disorder was established in 2 double-blind, 12-week, placebo-controlled studies. Adult patients received fixed doses of 75 or 150 mg/day in one study and 75 or 225 mg/day in the other study. In these studies, Effexor XR was significantly more effective than placebo at all three doses. In a long-term (26-week), double-blind study, adult patients who had responded to Effexor XR (75-225 mg/day) during an initial 12-week open-label phase were randomly assigned to continue the same Effexor XR dose (75, 150, or 225 mg) or switch to placebo for a 6-month, double-blind treatment phase. Patients who continued to receive Effexor XR experienced a significantly longer time to relapse as compared to those patients who were switched to placebo. Panic disorder may be associated with conditions such as depression or other anxiety disorders. Effexor XR, a serotonin-norepinephrine reuptake inhibitor, is indicated not only for panic disorder but also for the treatment of adults with major depressive disorder, generalized anxiety disorder, or social anxiety disorder.

2006 JAN 5 - A survey conducted by Kline & Company has elicited differing opinions among physicians and pharmacists regarding the possible switch for some cholesterol-lowering drugs from prescription to over-the-counter (OTC) status in the United States. More than half of doctors and pharmacists surveyed by Kline said they believed OTC statins would safely and effectively treat elevated cholesterol levels and would provide patients with a cost-effective way to manage the condition.

However, a considerable number of respondents said that their concerns over the inability of consumers to use the drugs correctly without medical supervision led them to oppose the idea of switching statins from prescription to OTC status. Respondents from both groups cited concerns over the public's ability to accurately self-diagnose an asymptomatic condition, as well as the possibility of side effects, the necessity of liver testing, possible interaction with other medications, and the ability of the consumer to monitor cholesterol levels and use the medications correctly without supervision. The pursuit of an Rx-to-OTC switch for statins is now approaching its 11th year, and drug companies are still conducting consumer use studies to convince the FDA that the advantages outweigh the safety risks. Countries like Canada and Great Britain have addressed this conundrum by providing a middle ground: a behind-the-counter drug classification. In fact, Merck got its 10 mg Zocor Heart-Pro pill approved for BTC use in the U.K. and has been selling it there since July 2004. Kline's survey results, which are included in the recently published study, "U.S. Cholesterol-Lowering Drugs 2005: Rx Market Analysis and Switch Forecasts," show high support among both doctors and pharmacists for selling statins behind the counter. Such an arrangement would require consumers to speak with a pharmacist before purchasing the drug. A nationwide formalized BTC class of drugs does not currently exist in the U.S., although individual states can regulate pharmaceuticals sold behind the counter.

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.

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