



**THE NUMBERS LISTED  
BELOW ARE FOR FEE-FOR-  
SERVICE SUPPORT**

**PHARMACY SUPPORT CENTER**

**1-800-432-7005**

24 hours per day/7 days per week  
For claim assistance, early refill  
overrides, and lock-in overrides

**CLINICAL SUPPORT CENTER**

**PRIOR AUTHORIZATIONS**

**1-800-477-3071**

24 hours per day/7 days per week

**DIABETIC SUPPLY QUESTIONS**

Prior Authorization

**1-800-477-3071**

**CLAIM INQUIRY**

**1-800-432-7005**

**Please Note:** Questions regarding  
claims prior to October 5, 2010,  
should be directed to  
1-800-807-1232.

**PROVIDER SERVICES**

**1-877-838-5085**

M–F, 10:30 a.m.–4:30 p.m. (ET)  
Providers should contact Provider  
Services for inquiries regarding  
enrollment and changes.

**MEMBER SERVICES**

**1-800-635-2570**

M–F, 8:00 a.m.–5:00 p.m. (ET)  
Recipients should contact Member  
Services for medication replacement  
requests and co-pay and benefit  
information.

**WEBSITES**

Kentucky Department for  
Medicaid Services  
<http://chfs.ky.gov/dms/Pharmacy.htm>  
Magellan Medicaid Administration  
<https://kentucky.magellanmedicaid.com>

**ONSITE PROVIDER EDUCATION**

For onsite education presentations,  
please contact Magellan Medicaid  
Administration at  
[kyproviders@magellanhealth.com](mailto:kyproviders@magellanhealth.com).  
This education is free of charge.

**ICD-10: How Will Your Practice Be Impacted?**

The practice of medicine has changed dramatically in the last 25 years with the discovery of new illnesses, disease states and the medical devices to assist with detection and treatment. The ICD-9 code set was not designed to capture all of this progress and has become inundated with many types of modifications to attempt to capture information. The ICD-10 code set is much better at describing the current practice of medicine and has the flexibility to adapt as medicine changes.

Have you thought about all of the areas that may be impacted in your practice? Revising patient and clinical documents to adhere with the ICD-10 updates is an important step in the readiness process. Providers should expect to make changes to HIPAA forms, referrals, clinical assessment forms, consultation requests and other clinical and/or patient related documents.

Diagnosis codes and procedure codes permeate almost every business process and system in both health plans and provider organizations. Diagnosis codes are key to determining covered services and treatment plans. From plan design to statistical tracking of disease, these codes are a crucial part of the way health plans — including State Medicaid agencies — run their programs.

Unlike the annual update of ICD-9 codes, the ICD-10 codes are markedly different from their predecessors, and because ICD-9 codes are used in almost every clinical and administrative process in a health care setting, substantial system and procedural changes will be necessary to implement and correctly use the new codes. The updated code sets will allow and require significant changes in the way health plans reimburse for services, and how coverage of services is determined. ICD-10 will enable significant improvements in care management, public health reporting, research, and quality measurement.

For more information about ICD-10, please visit <http://www.cms.gov/ICD10/>.

**Pharmacy Provider Alert**

This is a reminder that all pharmacies must ensure a valid license is on file with Kentucky Medicaid. If the license is not updated by 8/30/2015, your claims will begin to reject for **“Pharmacy not contracted with Plan on Date of Service.”** You may verify your license has been updated by logging onto KYHealthNet. Please contact KY Provider Licensing Branch at 1-877-838-5085 if you have questions regarding your status as a Medicaid provider.

To log onto KYHealthNet, please visit the website at <http://www.kymmis.com> and click the “KYHealthNet” option on the left sided menu options given.

## FDA Releases Final Rule on Pregnancy and Lactation Labeling

The FDA published a final rule requiring labeling changes for prescription drugs and biological agents regarding their use during pregnancy and lactation. The FDA states that the current letter categories, A, B, C, D and X, can be misinterpreted as a grading system which can lead to an over-simplified view of the product risks. The new labeling will include three subsections: Pregnancy, Lactation, and Females and Males of Reproductive Potential. The Pregnancy and Lactation subsections will be further divided with subheadings of Risk Summary, Clinical Considerations, and Data. The new subsections will provide detailed explanations of the potential risks and benefits for the mother, fetus, and breastfeeding child to aid in prescribing and counseling decisions. The new format will be required for all newly approved drug and biological applications as of June 30, 2015, and will be phased in for existing products. Draft guidance is available by the FDA to help industry meet the terms of the new labeling requirement.

## FDA MedWatch: SGLT-2 Inhibitors

The FDA issued a drug safety communication on May 15, 2015, warning that the sodium-glucose cotransporter-2 (SGLT2) inhibitors used to treat type 2 diabetes, canagliflozin (Invokana®; Janssen), dapagliflozin (Farxiga®; AstraZeneca), and empagliflozin (Jardiance®; Boehringer Ingelheim), may lead to ketoacidosis. Twenty cases of diabetic ketoacidosis (DKA), ketoacidosis, or ketosis were reported to the FDA in patients treated with SGLT2 inhibitors from March 2013 to June 6, 2014. All 20 patients required emergency department visits or hospitalization to treat the ketoacidosis. DKA is not an uncommon occurrence in diabetic patients; however, DKA most commonly occurs in patients with type 1 diabetes and is usually accompanied by high serum sugar levels. The cases reported to the FDA were unusual because most of the patients had type 2 diabetes and their blood sugar levels, when reported, were only slightly increased compared to typical cases of DKA. Healthcare providers are urged to monitor patients receiving a SGLT2 inhibitor closely for signs of ketoacidosis, including difficulty breathing, nausea, vomiting, abdominal pain, confusion, and unusual fatigue or sleepiness. The FDA continues to investigate this issue to determine if any change to the labeling of the SGLT2 inhibitors is necessary. Side effects involving SGLT2 inhibitors should be reported to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page on the FDA website ([www.fda.gov](http://www.fda.gov)).

## Drug Information Highlights

- The FDA has issued a safety alert regarding the first confirmed case of death due to progressive multifocal leukoencephalopathy (PML) associated with dimethyl fumarate (Tecfidera®; Biogen), an oral agent used as first-line treatment of relapsing forms of multiple sclerosis (MS). PML, a rare and serious brain infection that can lead to severe disability or death, is caused by the John Cunningham (JC) virus, which is common and harmless in most individuals, but can lead to PML in those who are immunocompromised. PML occurred in a patient who had been taking dimethyl fumarate for over four years. The patient was not taking other drugs that affect the immune system or are thought to be associated with PML. The patient had experienced prolonged lymphopenia, a risk factor for PML. The patient died due to complications of pneumonia. Incidence of PML have been previously reported in patients while on oral fingolimod (Gilenya®; Novartis) or intravenously administered natalizumab (Tysabri®; Biogen).
- The FDA is cautioning that the benefit and safety of prescription testosterone products have not been established for the treatment of low testosterone levels due to aging. These products are approved only for men who have low testosterone levels caused by certain medical conditions. The labels of all prescription testosterone products will clarify the approved uses of these medications. The FDA is also requiring product labels to include a warning of a possible increased risk of heart attacks and strokes in patients taking testosterone.
- On May 22, 2015, the US Court of Appeals ordered Actavis to continue sales of their Alzheimer's agent, Namenda® (memantine) immediate-release (IR) tablet, until August 10, 2015. This decision allows patients to continue treatment with the product until the availability of generic memantine IR tablets, expected to be launched as early as July 11, 2015. Recommended dosing of Namenda® IR is twice daily. Actavis also distributes Namenda oral solution dosed twice daily and the once-daily extended-release formulations, Namenda XR® (memantine) and Namzaric® (memantine / donepezil), for the treatment of Alzheimer's type dementia.