Draft Bill for LTCF Registration is Released

In the latest development in the ongoing issues with Drug Enforcement Administration (DEA) policies, the Senate Special Committee on Aging, under the direction of Senator Herb Kohl (D-WI), and in conjunction with the Senate Judiciary Committee, has released a discussion draft of an untitled bill proposing to amend the Controlled Substances Act (CSA), which would create a registration category for nursing homes. The objective of the proposed new CSA authority is to promote the timely administration of controlled substances in nursing home settings. The draft discussion bill was released publicly following a meeting between Aging Committee staff and officials from the Drug Enforcement Administration (DEA) and the Department of Justice (DOJ). To establish this new category, referred to as a "controlled substance custodian," the bill would require the Attorney General to work with CMS to promulgate regulations within 1 year of enactment that would:

- Outline registrant qualifications and responsibilities;
- Require contractual agreements between the LTCF and the pharmacy;
- Require the LTCF to develop policies and procedures that would identify LTCF personnel positions (not individuals) that are authorized to act as agents of the prescriber and transmit prescriptions, including chart orders, to the pharmacy;
- Require the LTCF medical director and each physician to establish a contractual agreement that would, in effect, share responsibility/liability for the actions of agents;
- Requires physicians and the medical director to receive and maintain records for training on controlled substance prescribing, dispensing, pain management and diversion detection; and
- Requires HHS in consultation with DEA to promulgate regulations within 1 year of enactment defining a chart order.

ASCP will continue to monitor the development of this situation closely and continue its communication with Senate Aging Committee staff.

Source: ASCP.com

Bill Pushes for Survey Consistency

In 1987, Congress approved and President Reagan signed legislation that fundamentally altered the way nursing homes are inspected. More than two decades later, a Democratic Senator from Wisconsin wants to take a closer look at how the new rules are working out.

Russ Feingold’s measure would call on the Institute of Medicine to study the survey and certification process. Among the issues the IOM would be required to assess:

- Alternatives to the current survey and certification system.
- Current survey methods for evaluating nursing homes.
- The relationship between nursing homes/the industry and CMS and how such a relationship impacts efforts to improve quality.
- The methodology used by CMS

Continued on Page 2
The new MDS 3.0 is scheduled to be implemented in October, 2010. This major revision of the assessment tool for categorizing care into a RUG group for both financial and quality improvement purposes will have a major impact on skilled nursing facilities. It is important that nursing home leaders become familiar with the MDS 3.0, and begin to prepare for its implementation.

The new MDS 3.0 is going to have more opportunities for residents to voice their needs through resident interview. Through validation studies and the STRIVE initiative, efforts have been made to increase the accuracy of the tool and how it reflects time required for care. Initial studies show that reimbursement based on RUG IV is less than RUG III. The major impact of the implementation of MDS 3.0 is the discontinuation of a look back period into the hospital for extensive services. The look back period data collection component will be changing. The pre-admission activities, such as oxygen and IV therapy that are collected on the new MDS will be used for care planning purposes-- not for reimbursement. Concurrent therapy time, when multiple residents receive therapy from one therapist at the same time, will be divided among the number of residents receiving therapy, and not on a one to one ratio as was the case with RUG III. Section T, which predicts therapy to be given on the initial 5-day assessment and allowed payment based on that prediction whether or not it actually occurred, is being eliminated. OMRA (Other than Medicare Required Assessments) will be required within 8 to 10 days following the cessation of therapy, and therapy started in the middle of a payment period does not trigger a change in payment.

Congress has delayed the implementation of RUG IV until October, 2011. The new RUG categories have been expanded, and the changes in the MDS 3.0 have resulted in significant changes in how patients will be categorized by the new RUG system. The biggest significance to the current distribution of RUG scores and the anticipated change after RUG IV is the tremendous decrease in Rehab with Extensive Services. This is due to the elimination of the hospital look-back for extensive services-- only allowing extensive services provided during the SNF stay to be included.

Source: www.mds3point0.com

The Senate unanimously passed S. 3397, the "Secure and Responsible Drug Disposal Act of 2010," sponsored by Sens. Amy Klobuchar (D-MN) and John Cornyn (R-TX). The proposed legislation would amend the Controlled Substances Act (CSA) to provide for take-back programs for the disposal of unused prescription controlled substances in order to decrease the risk of diversion and decrease the impact on the environment. The bill, if passed by Congress, would allow consumers as well as long-term care facilities to properly dispose of unused controlled drugs through take back programs. As non-DEA registrants, consumers and long-term care facilities are not authorized to transfer dispensed controlled drugs, leaving them few convenient and legal methods of disposing of unused or expired drugs. This poses a threat to the environment through unsafe disposal methods, and raises the risk of these unused drugs getting into the hands of persons intending to abuse them. This proposed legislation would allow DEA to promulgate regulations.

Source: www.mds3point0.com

Continued on Page 4
Mounting evidence of adverse cardiovascular effects continues to erode justification for rosiglitazone. For more than 10 years, thiazolidinediones (TZDs) have been prescribed for diabetes therapy in the U.S. on the sole basis of evidence that they improve glycemic control. An association of TZDs with heart failure is relatively well-established; however, recent data have implicated rosiglitazone in other adverse cardiovascular events as well.

Two new studies further address the risks of rosiglitazone. In an observational cohort study, 227,571 Medicare patients (median age, 74.4) began therapy with either rosiglitazone or pioglitazone between July 2006 and June 2009. During a median follow-up of 105 days, rosiglitazone recipients were significantly more likely than pioglitazone recipients to experience adverse events including stroke (hazard ratio, 1.27); heart failure (HR, 1.25); death from any cause (HR, 1.14); and a composite of acute myocardial infarction (AMI), stroke, heart failure, and death (HR, 1.18). The risk for AMI alone did not differ between the two groups. For the composite endpoint, the estimated overall number needed to harm was 60 patients treated for 1 year.

In an extension of a well-known 2007 meta-analysis of clinical trials of rosiglitazone (JW Cardiol May 21 2007), researchers examined 56 trials involving 35,531 patients randomized to receive rosiglitazone or a control therapy for more than 24 weeks. Treatments used in the control groups included placebo, usual care, and non-TZD antidiabetic therapies. Compared with controls, patients in the rosiglitazone groups had a significantly higher risk for MI (odds ratio, 1.28) but not for cardiovascular mortality. Separate analyses that either included or excluded studies with no adverse cardiovascular events yielded similar results.

New generic versions of venlafaxine will create confusion as there’s already confusion between Effexor XR capsules and Venlafaxine Extended Release tablets. These are both brand-name products. They are bioequivalent when given with food but they’re NOT AB-rated because they’re different dosage forms. Now, these two brands will each have their own generic. Effexor XR and Venlafaxine Extended Release Tablets can be switched to the generic capsules, but the prescriber should advise if the switch is between dosage forms. Prescribers should be encouraged to write for "venlafaxine extended release caps or tabs" so the patient can have whichever he prefers. Claims that Pristiq (desvenlafaxine) is a new and improved version of venlafaxine is enticing, but this metabolite isn’t any more effective or better tolerated than Effexor XR.

New generic versions of venlafaxine will create confusion as there’s already confusion between Effexor XR capsules and Venlafaxine Extended Release tablets. These are both brand-name products. They are bioequivalent when given with food but they’re NOT AB-rated because they’re different dosage forms. Now, these two brands will each have their own generic. Effexor XR and Venlafaxine Extended Release Tablets can be switched to the generic capsules, but the prescriber should advise if the switch is between dosage forms. Prescribers should be encouraged to write for "venlafaxine extended release caps or tabs" so the patient can have whichever he prefers. Claims that Pristiq (desvenlafaxine) is a new and improved version of venlafaxine is enticing, but this metabolite isn’t any more effective or better tolerated than Effexor XR.

Rumor vs. Truth

RUMOR: Savella (milnacipran) is dangerous and should be pulled from the market.

RUTH: Savella is no more dangerous than other SNRIs such as venlafaxine. It can increase blood pressure, heart rate, and suicidal thoughts but these aren’t new problems. All SNRIs (venlafaxine, Cymbalta, etc) carry these risks. A new study shows another SNRI, Meridia (sibutramine), increases the risk of heart attacks and strokes in patients with cardiovascular disease. But so far there’s no evidence that Savella is as risky as Meridia or that it’s riskier than Cymbalta (duloxetine) or venlafaxine. At issue is the balance between efficacy and safety in fibromyalgia, Savella’s only approved indication. The consumer group, Public Citizen, thinks Savella’s cardiovascular and psychiatric risks outweigh its marginal fibromyalgia benefits. And they want it pulled from the market. Fibromyalgia symptom relief is often modest with meds. Patients on Savella should watch for side effects that overshadow benefits and monitor blood pressure. An increase of about 3 mmHg is expected but more than that could signal a problem. Mood changes using Savella need to be reported especially those taking higher doses or who have a history of depression. Patients with fibromyalgia and cardiovascular disease or patients whose blood pressure increases too much should try other options such as Lyrica (pregabalin), amitriptyline, etc. Savella can cause withdrawal symptoms such as irritability, dizziness, confusion, agitation, etc. Taper or discontinue it if it’s not tolerated or if there’s no notice of any improvement while on it.

Source: PharmacistsLetter.com
Eating too much red meat has long been a no-no for people with high cholesterol and other risk factors for heart disease. But it hasn't always been clear how much is too much. Now, a new study suggests that you don't have to cut out red meat altogether to improve your heart health. If you eat red meat more than once a day, cutting back to one serving every other day can substantially reduce your risk of having a heart attack or dying from heart disease, the study found.

Replacing the red meat in your diet with other, less fatty sources of protein -- such as nuts and fish -- can lower your risk even further, the researchers say.

Women who eat two servings of red meat per day have a 30 percent increased risk of heart disease compared with women who average three to four servings per week (or half a serving per day), according to the study, which appears in the journal Circulation. "This gives you an understanding of what moderation means," says Steinbaum, who was not involved in the new research. "It gives you something to grab on to."

Some types of red meat appear to be worse for your heart than others. Eating one serving of beef per day increases a woman's heart-disease risk by only about 8 percent, compared with eating it never or rarely. But eating one hamburger, one serving of bacon, or one hot dog per day ups a woman's risk by 42 percent, 41 percent, and 35 percent, respectively, compared with eating those foods once or twice a month (if ever), according to the study.

The saturated fat in meat may only be partly to blame. Iron and other minerals found in red meat may contribute to heart-disease risk as well, Bernstein says. (Consuming high-fat dairy items -- such as ice cream, sour cream, and butter -- also increased the risk of heart disease in the study, but less so than red meat.)

Replacing red meat with healthier sources of protein will go a long way toward reducing heart risk, the researchers say.

For instance, they estimate that swapping one serving of red meat per day for one serving of beans will lower a woman's long-term heart-disease risk by about one-third. Replacing a daily serving of red meat with one of several other foods -- including nuts (30 percent), fish (24 percent), chicken or other poultry (19 percent), and low-fat dairy (13 percent) -- will also reduce heart-disease risk, the study found.

Though these are estimates, they represent the first time that researchers have been able to quantify the heart benefits of these food swaps.

"We know that red meat is not as good as other protein sources," says Karen Congro, a registered dietitian at the Brooklyn Hospital Center, in New York City. "Now we actually have the numbers to put next to them."

The study "doesn't mean that red meat is a horrible thing," says John Bisognano, the director of outpatient cardiology at the University of Rochester Medical Center, in New York. "People like to eat, and all you can hope to do is shift them a little bit away from foods that may have less of a benefit to them to those that have more of a benefit to them."