Medicare Physician Payment Policy Hearing

The House Ways and Means Health Subcommittee will hold a hearing on May 7, 2013, entitled, “Developing a Viable Medicare Physician Payment Policy,” which will examine options for repealing the Sustainable Growth Rate (SGR) formula and reforming the Medicare physician payment system to reward quality and value. Subcommittee Chairman Kevin Brady (R-TX) said the hearing will enable the Subcommittee members the opportunity to hear from various stakeholders with experience and “ideas” on how to develop a “fair, reliable, and fiscally responsible” payment policy. The House Ways and Means and Energy and Commerce Committees have previously released two drafts of an SGR repeal and replacement framework proposal.

CMS Issues Proposed Inpatient Payment Regulation

The Centers for Medicare & Medicaid Services (CMS) released a proposed rule to update the fiscal year 2014 Medicare payment policies and rates for inpatient stays. The proposed rule would increase IPPS operating rates by 0.8 percent after accounting for inflation and other adjustments required by the law. CMS will increase overall hospital payments (capital and operating) by $27 million and launch a new Affordable Care Act patient safety program in FY 2015, aimed at reducing hospital-acquired infections.

CMS will accept comments on the proposed rule until June 25, 2013, and will respond to comments in a final rule to be issued by August 1, 2013. The proposed rule will appear in the May 10, 2013 Federal Register and can be downloaded from the Federal Register after that date at:

Compounding Pharmacy Recalls

Recent Food and Drug Administration (FDA) inspections of Balanced Solutions Compounding Pharmacy and Nora Apothecary & Alternative Therapies led to the voluntary recall of their sterile products. Both companies cited a lack of sterility assurance, although there have been no reports of illness or injury associated with the recalled products. The FDA has asked Congress for expanded oversight powers for compounding pharmacies.

Senate HELP Committee Releases Bipartisan Drug Compounding Legislation

Due in part to stories such as the one immediately above, the Senate Health, Education, Labor and Pensions (HELP) committee released a draft drug compounding proposal to give the Food and Drug Administration (FDA) authority to regulate certain compounding pharmacies. The draft measure establishes a “clear boundary” between the two kinds of compounding pharmacies: traditional drug compounders, and those that produce large batches of compounded drugs without receiving specific prescriptions and selling them across state lines.

The bill would give states continued primary oversight of the traditional compounding pharmacies, while the FDA would regulate the compounding manufacturers. It also contains a $15,000 yearly establishment fee and reinspection fees to support new oversight activities, which would be subject to Good Manufacturing Practices and adverse event reporting requirements. The HELP committee will hold a hearing to discuss the legislation on Thursday, May 9, 2013.

FDA to Use Smartphone App in Device Safety Monitoring

The FDA has approved a smartphone application for use by physicians in informing the agency of any injuries and deaths tied to medical devices. The agency also is working to automate its medical device surveillance to allow it to identify potentially dangerous flaws in high-risk products early.

Potiga (Ezogabine): Linked To Retinal Abnormalities and Blue Skin Discoloration

FDA has warned consumers that the anti-seizure medication Potiga (Ezogabine) can cause blue skin discoloration and eye abnormalities characterized by pigment changes in the retina. This may result in serious eye disease with loss of vision. Scleral and conjunctival discoloration has been
observed as well. In some cases, retinal abnormalities have been observed in the absence of skin
discoloration. It is not known if these changes are permanent or if the retinal pigment changes
caused by use of the drug can lead to vision problems.

Ophthalmologists should be aware of this safety alert. All patients taking Potiga should have a
baseline eye exam and periodic eye exams that should include visual acuity testing and dilated
fundus photography, and may include fluorescein angiograms (FA), ocular coherence tomography
(OCT), perimetry, and electroretinograms (ERG). Healthcare professionals should report adverse
events or side effects related to the use of this product to the FDA’s MedWatch Safety Information
and Adverse Event Reporting Program.

Read the MedWatch Safety Alert, including links to the Drug Safety Communication at:

**FDA Comment Request: Informed Consent**

The FDA is soliciting comments on the regulations that provide protection for human subjects of
clinical investigations for FDA-regulated products. These regulations involve informed consent and
the composition and responsibilities of institutional review boards (IRB).

Submit either electronic or written comments by June 24, 2013.


The FDA released a draft guidance entitled “Use of International Standard ISO–10993, ‘Biological
Evaluation of Medical Devices Part 1: Evaluation and Testing.’” The scope of this document is
limited to the biological evaluation of sterile and nonsterile medical devices that come into direct or
indirect contact with the human body. This Guidance updates the May 1, 1995 Office of Device
Evaluation (ODE) General Program Memorandum #G95–1 entitled “Use of International Standard
When final, this guidance will therefore replace #G95–1, however this draft guidance is not final nor is it in effect at this time. Comments should be received by July 22, 2013 to be considered before FDA begins work on their final guidance.


**Burwell Confirmed as OMB Director**

The Senate voted April 24 to confirm Sylvia Mathews Burwell as the new director of the Office of Management and Budget. "Her experience will be especially important as we continue our efforts to replace the indiscriminate budget cuts" from sequestration, President Obama said in a statement later that day. She was approved by a vote of 96-0.