

Federal Health Update

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Welcome to Federal Health Update. This newsletter is a compilation of the latest news in the federal health care sector.

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EXECUTIVE AND CONGRESSIONAL NEWS

- **The House and Senate are in recess until after the election.**

MILITARY HEALTH CARE NEWS

- **The Penn State Hershey College of Medicine, American Red Cross, Health Net Federal Services LLC and the Adler School of Professional Psychology are hosting the continuing medical education event on Dec. 8, 2012.**

The event, *"Meeting the Needs of Returning Military Service Members, A Symposium for Primary Care and Mental Health Professionals,"* will bring together behavioral health experts to address the health care needs of service members returning from combat environments with post-traumatic stress disorder or traumatic brain injury.

The symposium will be held from 7:30 a.m. to 4:15 p.m. at the Adler School of Professional Psychology in Chicago, Ill. Visit www.hnfs.com, call 717-531-6483, or email ContinuingEd@hmc.psu.edu to register and to access more information.

- **The Administrative Review Board ("ARB") has issued its decision in OFCCP v. Florida Hospital of Orlando, ruling that Florida Hospital is not a federal subcontractor and therefore not subject to the jurisdiction of the Office of Federal Contract Compliance Programs ("OFCCP").**

The OFCCP is a federal agency that enforces equal employment opportunity and affirmative action laws. Entities subject to its jurisdiction have numerous affirmative action obligations. The ARB's decision addresses whether the OFCCP can establish jurisdiction over hospitals and other health care entities based solely on their contracts to provide medical services for beneficiaries of TRICARE.

This ruling comes as good news for hospitals and other health care institutions who are concerned that they may be subjected to the OFCCP's jurisdiction, as a result of their

participation in TRICARE. Although several judges concurred but dissented from the plurality, possibly leaving open the door for the OFCCP to find another avenue to attempt to assert jurisdiction based on TRICARE contracts, it unclear as to whether the OFCCP will seek to do so.

For details on the decision, please visit:

<http://www.lexology.com/library/detail.aspx?g=cf4a7bef-fa75-4ce4-8081-88887241fa9f>.

VETERANS AFFAIRS NEWS

- **An annual review of the St. Louis Veterans Administration Health Care System finds no major faults — a big improvement after years of citations for problems with patient care.**

The *St. Louis Post-Dispatch* reports that the Department of Veterans Affairs released the report, giving the John Cochran and Jefferson Barracks medical centers high marks for leadership, painkiller management and colon cancer screening programs. Investigators did cite problems with cleanliness, training and safety, but a spokeswoman says those problems did not impact patient care or patient outcomes.

The Cochran facility has been cited numerous times in recent years for problems. Citations were reported in June after a 58-year-old man died after kidney dialysis. The hospital also faced concerns about sterilization problems in 2010 and 2011.

GENERAL HEALTH CARE NEWS

- **The National Institutes of Health has awarded a contract to PatientCrossroads to operate a new Down syndrome registry. The company has created patient-centric registries for muscular dystrophy and many rare disorders.**

The registry allows people with Down syndrome or their family members to enter contact information and health history in an online, secure, confidential database. Registry participants will be able to customize their profile, update it online, and choose which information they would like to display, including reminders about their own medical care and general information about Down syndrome. They also will be able to compare their own medical information to that of other registrants in a confidential and anonymous manner.

If a participant gives permission to be contacted, clinicians and researchers who are authorized to access the database will be able to contact these individuals to see if they are interested in participating in a research study.

Ultimately, the registry will be able to link to biorepositories of tissue samples and other resources, with the goal of making it easier for patients to take part in clinical studies for new medications and other treatments for Down syndrome.

The contract, which will support the creation of the registry through September 2013, received \$300,000 in funding for its first year.

Down syndrome most frequently results from an extra copy of chromosome 21 in the body's cells. Infants with Down syndrome are likely to have certain physical characteristics, such as short stature and distinctive facial features, as well as health conditions like hearing loss, heart malformations, digestive problems, and vision disorders. Although Down syndrome most commonly results in mild to moderate intellectual disability, the condition occasionally involves severe intellectual disability. In

addition, some individuals with Down syndrome age prematurely and may experience dementia, memory loss, or impaired judgment similar to that experienced by individuals with Alzheimer disease.

Development of a patient registry was a leading recommendation in the 2007 NIH Down Syndrome Research Plan, which sets goals and objectives for the Down syndrome research field. Together with the Global Down Syndrome Foundation, the NICHD sponsored the Down syndrome National Conference on Patient Registries, Research Databases, and Biobanks to solicit the advice of a number of experts from the advocacy community, federal agencies, industry, and the clinical and research communities on how best to establish a Down syndrome registry.

The plan for the registry was supported by the public-private [Down Syndrome Consortium](#), which was established by the NIH in 2011 to foster the exchange of information on Down syndrome research, and to implement and update the Research Plan. Membership on the Consortium includes individuals with Down syndrome and family members, representatives from prominent Down syndrome and pediatric organizations, and members of the NIH Down Syndrome Working group, an internal NIH group that coordinates NIH-supported Down syndrome research.

- **Health and Human Services (HHS) Secretary Kathleen Sebelius announced the final rule implementing the part of the health care law that delivers higher payments to primary care physicians serving Medicaid beneficiaries.**

The new rule raises rates to ensure doctors are paid the same for treating Medicare and Medicaid patients and does not raise costs for states.

The final rule implements the Affordable Care Act's requirement that Medicaid pay physicians practicing in family medicine, general internal medicine, pediatric medicine, and related subspecialists at Medicare levels in Calendar Years 2013 and 2014.

This payment increase goes into effect in January of 2013.

In addition to payment improvements, the health care law includes numerous initiatives designed to bolster primary care and strengthen the primary care workforce, including an expansion of medical residency positions for primary care physicians, new investments in physician assistant and nurse practitioner training, and an unprecedented expansion of the National Health Service Corps, which provides scholarships and loan repayments to primary care providers who practice in underserved areas.

To view a copy of today's final rule visit:
www.ofr.gov/inspection.aspx.

- **The Food and Drug Administration (FDA) released a report on the New England Compounding Center (NECC), which was the source of the steroids causing the outbreak of fungal meningitis.**

The FDA observed and has since confirmed contaminated products and listed a number of observations regarding conditions in the clean room at NECC's Framingham, Mass. facility.

The investigators also observed problems with NECC's ability to maintain its clean room, which is the enclosed space that is designed and maintained to have a controlled environment with low levels of airborne particles and surface contamination. Production of sterile drug products in a properly functioning and maintained clean room reduces the risk of the introduction of microbial contamination into the drug during processing, including filling into its final container.

The FDA issues a Form 483 at the end of an inspection when the investigators believe that they observed conditions or practices that, in their judgment, may indicate violations of the Federal Food, Drug, and Cosmetic Act, or related regulations.

The 483 does not constitute a final FDA determination that any observation listed on the 483 is a violation of the Federal Food, Drug, and Cosmetic Act or any related regulations.

The FDA considers the 483 along with an Establishment Inspection Report (EIR), prepared by FDA investigators, and any other relevant information, including any responses received by the company. The agency then considers whether further action, if any, is appropriate. The inspection report for NECC has not been completed and is not being shared at this time.

The FDA continues to work closely with the U.S. Centers for Disease Control and Prevention and state partners, including the Massachusetts Board of Registration in Pharmacy, to investigate the outbreak of fungal meningitis among patients who received NECC's compounded preservative-free methylprednisolone acetate (80mg/ml), an injectable steroid.

REPORTS/POLICIES

- **The GAO published “Medicare: Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions,” (GAO-12-966) on Oct. 31, 2012.** This report examines trends in the number of and expenditures for self-referred and non-self-referred advanced imaging services; how provision of these services differs among providers on the basis of whether they self-refer; and implications of self-referral for Medicare spending. <http://www.gao.gov/assets/650/648988.pdf>
- **The Institute of Medicine (IOM) published “Reducing Tobacco-Related Cancer Incidence and Mortality - Workshop Summary,” on Nov. 1, 2012.** This report examines current challenges in tobacco control and explored potential policy, outreach, and treatment strategies that could overcome these challenges and reduce tobacco-related cancer incidence and death. <http://www.iom.edu/Reports/2012/Reducing-Tobacco-Related-Cancer-Incidence-and-Mortality.aspx>

HILL HEARINGS

- There are no hearings scheduled.

LEGISLATION

- No legislation was proposed this week.

MEETINGS

- The International Society for Traumatic Stress Studies (ISTSS) 28th Annual Meeting will be held on **Nov. 1-3, 2012**, in Los Angeles, Calif. <http://www.istss.org/Home1.htm>
- The AMIA 2012 Annual Symposium will be held on **Nov. 7-11, 2012**, in Chicago Ill. <http://www.amia.org/amia2012>

- The 118th AMSUS Annual Continuing Education Meeting will be held **Nov. 11-15, 2012**, in Phoenix, Ariz. <http://amsusmeeting.org>
 - The 2012 American Academy of Medical Administrators (AAMA) Annual Conference will be held on **Nov. 13 - 16, 2012**, San Antonio, Texas
<http://www.aameda.org/Conference/Annual/AnnualMain.html>
 - The Radiological Society of North America (RSNA) 2012: Patients First will be held on **Nov. 25-30, 2012**, in Chicago, Ill. http://www.rsna.org/Annual_Meeting.aspx
 - The 2012 Special Operations Medical Association (SOMA) Conference will be held on **Dec. 15-18, 2012**, in Tampa, Fla. <http://www.specialoperationsmedicine.org/>
 - The International Meeting of Simulation in Healthcare (IMSH) 2013 will be held on **Jan. 26-30, 2013**, in Orlando, Fla. <http://ssih.org/events/imsh-2013-central>
 - The 2013 Military Health System Conference will be held **Feb. 11-14, 2013**, in National Harbor, Md.
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If you need further information on any item in the *Federal Health Update*, please contact Kate Theroux at (703) 447-3257 or by e-mail at katetheroux@federalhealthcarenews.com.