

Federal Health Update

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EXECUTIVE AND CONGRESSIONAL NEWS

- **The Obama administration is postponing online enrollment in some of the small-business exchanges scheduled to open Oct. 1, according to *Politico*.**

Small businesses looking to enroll in coverage on so-called SHOP exchanges run by the federal government will be able to submit a paper application on Oct. 1 – they just won't be able to enroll online.

- **On Sept. 20, 2013, the House passed H. Res. 59, making continuing appropriations for fiscal year 2014 until Dec. 15, 2013.** The bill also contained a provision that defunds the Patient Protection and Affordable Care Act PPACA. It is unlikely to pass the Senate, which took up the bill on Thursday. The federal government will shut down on Oct. 1 if both chambers Congress don't come to an agreement.

MILITARY HEALTH CARE NEWS

- ***Military Update* reports that one of the goals for the new Defense Health Agency (on Oct. 1) is to increase base hospital usage to reach at least 70 percent of capacity.**

Currently, Usage of base hospitals has dropped to about 33 percent of capacity, a trend aggravated by years of war when medical staffs routinely deployed to care for wounded in theater. Officials believe this will reduce costs because care at base hospitals (direct care) costs one third less than TRICARE purchased care.

DHA anticipates realizing savings by centrally managing 10 "shared services" of military health care, beginning with TRICARE support contracts and pharmacy operations, medical facilities planning, medical logistics and health information technology. DHA will assume responsibility for medical education and training; research and development; acquisition and contracting; budgeting and resourcing; public health by the fall of 2015.

Under DHA there will be six "enhanced multiservice markets," led by flag or general officer responsible for integrating resources and adhering to five-year marketing plans developed jointly. These enhance markets are the Washington D.C. area; San Antonio, Texas; Colorado Springs, Colo.; the Puget Sound region of Washington State; the Tidewater area of Virginia, and Oahu Island in Hawaii.

To read the full story, please visit: <http://www.military.com/benefits/2013/09/26/defense-health-agency-aims-to-expand-on-base-care.html?comp=7000024213943&rank=3>

- **The Center for the Study of Traumatic Stress at the Uniformed Services University of the Health Sciences has published a new book titled, “Disaster, Disease and Distress: Resources to Promote Psychological Health and Resilience in Military and Civilian Communities.”**

Available for free download on the center’s website, the book is a compilation of fact sheets and educational resources developed over the past 10 years that address important health and mental health issues of service members and their families impacted by deployments to Iraq and Afghanistan.

The resources are geared toward civilian communities around the globe affected by natural and human-made disasters, such as hurricanes, earthquakes and mass shootings.

The book has four sections:

- Caring for our Nation’s Soldiers, Sailors, Airmen and Marines: The Role of Medical and Social Service Providers;
- Military Family Health;
- Disaster Preparedness and Response; and
- Special Populations.

To read the book, please visit: http://www.cstsonline.org/wp-content/uploads/CSTS_3D_FS_Book_WEB.pdf

- **On Sept. 26, 2013, the Defense Department (DoD) announced that its policy on the antimalarial drug mefloquine, which has been in use for decades, is consistent with a stronger, updated warning about the drug from the Food and Drug Administration (FDA).**

On July 29, the FDA posted on its website a public advisory about neurologic and psychiatric side effects associated with mefloquine hydrochloride, a drug used to prevent and treat the deadly mosquito-borne disease.

The regulatory agency added a boxed warning -- the most serious kind -- to modify the drug’s

label and revise the patient medication guide and wallet-information card given with each prescription to include the possibility that the neurologic side effects could persist or become permanent if the drug is used.

The FDA uses a boxed warning when an adverse reaction is so serious in proportion to the drug's potential benefit that prescribers should consider this when evaluating the drug's risks and benefits. The warning also is used to alert prescribers that they can prevent or reduce a serious adverse reaction in patients by using the drug appropriately.

Neurologic side effects can include dizziness, loss of balance or ringing in the ears. Psychiatric side effects can include anxiety, mistrust, depression, or hallucinations.

Mefloquine was designated as the antimalarial drug of last resort in April, according to a DoD policy letter issued in April by Dr. Jonathan Woodson, assistant secretary of defense for health affairs.

Malaria is rare in the United States, only about 1,700 cases were reported here in 2010 and all were acquired outside the country, leading to six deaths.

Mefloquine is effective in preventing malaria, with a demonstrated success rate of 91 percent, according to studies of travelers to East Africa, military health officials said.

On Aug. 12, Woodson notified all military health care providers of the FDA mefloquine boxed warning and labeling change due to potential neurologic and psychiatric side effects associated with the drug.

Woodson said the April 2013 DOD guidance reiterated that mefloquine should be reserved for those who can't take first-line medications and reinforces the need to evaluate each patient for contraindications before starting mefloquine.

Such contraindications include a history of traumatic brain injury and posttraumatic stress disorder, and in those with psychiatric diagnoses, specifically depression, schizophrenia and anxiety disorders, he said.

Mefloquine use at all points of service for all TRICARE beneficiaries during calendar year 2012 was 5,370 prescriptions given to 4,770 individuals, defense officials said. Of these beneficiaries, 2,030 were active-duty personnel.

- **The *Marine Corp Times* reported that more than 3,000 Europe Regional Medical Command patients are being notified they received the wrong prostate cancer screening test if they were examined between August 2009 and May 2012 at a military treatment facility in the region.**

The U.S. Army is sending letters to 3,280 service members and TRICARE beneficiaries who received a test meant as a secondary screening for prostate-specific antigens instead of the standard initial test known as the "Total PSA" test.

The Total PSA is used to detect elevated levels of PSA, the protein produced by prostate gland cells, in the bloodstream. Elevated PSA blood levels can be associated with prostate cancer. The follow-on test, called the "Free PSA" test, is used as a secondary test to the Total PSA to help determine whether a growth is slow-growing or aggressive.

It is not recommended for initial screenings.

According to Landstuhl Regional Medical Center division medical chief Col. Thomas Frank, the mistake occurred because when the Free PSA test became available and was introduced to the command's alphabetically organized lab order database, many physicians simply ordered the first test in the database not realizing it was not the comprehensive test.

In February 2012, laboratory staff at Landstuhl, where the tests are analyzed, noticed the

increase in Free PSA requests. They corrected the database and notified physicians of the change. In May 2013, command became aware of the situation when a patient was diagnosed with prostate cancer after receiving a series of Free PSA tests and no comprehensive test.

Officials said physicians are unaware of any other missed prostate cancer diagnoses as a result and added they are "aggressively working to let [patients] know they have not been screened for prostate cancer when we thought they had."

Affected patients include those residing in Germany, Italy, Belgium, Kosovo and assigned to U.S. Central Command.

VETERANS AFFAIRS NEWS

- **The Secretary of the Veterans Affairs is convening a commission to recommend candidates to the President for appointment as the Under Secretary for Health (USH) for the Veterans Health Administration (VHA), the largest integrated health care system in the country.**

Following a 40-year career serving veterans as a VA physician, teacher, and administrator, Dr. Robert A. Petzel, will retire in 2014 as planned, following a four-year tenure as Under Secretary for Health.

VA is required by law to convene a commission to seek the next Under Secretary for Health. Due to the length of the process, VA is initiating the commission in advance of Dr. Petzel's retirement.

As Under Secretary for Health since February 2010, Dr. Petzel has directed a health care system with over 286,000 employees and a medical care budget of \$53.1 billion, overseeing the care of more than 6.3 million veterans. Dr. Petzel has led VHA's innovative efforts at moving toward a new model of care and pursuing eConnected health, in which VA providers use mobile devices and technology to extend health care beyond traditional visits.

The commission will be launched this fall. Suitable candidates to serve as members of this important commission will be selected based upon criteria outlined in the law and their skills, knowledge and attributes as leaders, managers and educators.

- **In the event of a government shutdown, the Department of Veterans Affairs, which is funded by multi-year Congressional appropriations, would continue operations, although some services could be affected, including the processing of new claims.**

VA officials said medical facilities and clinics would remain fully operational and benefits payments would continue. Claims processing for education, life insurance, home loans and other benefits would also continue, but may be delayed, officials said. VA call centers and hot lines would stop operating, however. Processing of new benefits claims would be suspended and regional Veterans Benefits Administration offices could be closed.

GENERAL HEALTH CARE NEWS

- **A new report by the Centers for Disease Control and Prevention's (CDC) shows that the number of state and local health departments receiving electronic reports from laboratories has more than doubled since 2005.**

In the past year, the number of individual reports received electronically increased by 15 percent. States and local health departments now estimate that nearly two-thirds (62 percent) of total lab reports were received electronically. The number of reports received through ELR

varied by jurisdiction, the types of labs reporting and by disease reported. The report shows that only about a quarter of the nation's labs are reporting electronically. And ELR for some diseases lags behind others. For example, 76 percent of reportable lab results for general communicable diseases were sent via ELR, compared to 53 percent of HIV results and 63 percent of results for sexually transmitted diseases.

The advances in ELR implementation have been accomplished through funding from the Prevention and Public Health Fund of the Affordable Care Act, distributed through CDC's Epidemiology and Laboratory Capacity (ELC) cooperative agreement. Through the ELC platform, CDC provides funding to all 50 state health departments, 6 local health departments (Los Angeles County, Philadelphia, New York City, Chicago, Houston, and the District of Columbia), Puerto Rico, and the Republic of Palau. Grants provided through ELC help pay for epidemiologists, lab technicians, and health information systems staff.

Speeding the nation's response to infectious disease outbreaks is part of the CDC's ongoing 24/7 work to connect state and local health departments across the U.S., recognizing disease patterns and making state responses to health problems more effective. Increasing ELR is only part of CDC's effort.

For more information on CDC's ELC cooperative agreement, please visit <http://www.cdc.gov/ncezid/dpei/epidemiology-laboratory-capacity.html>.

- **The U.S. Food and Drug Administration has awarded seven grants totaling more than \$3.5 million to various pediatric device consortia to boost the development and availability of medical devices for children.**

A panel of experts with experience in the clinical, business, and regulatory aspects of pediatric device development reviewed applications for the grants, which will be administered by the FDA's Office of Orphan Products Development. The grant recipients are:

- James Geiger, M.D., University of Michigan Pediatric Device Consortium
- David Ku, M.D., Ph.D., Atlantic Pediatric Device Consortium
- Peter Kim, M.D., National Capital Consortium for Pediatric Device Innovation
- Rick Greenwald, Ph.D., New England Pediatric Device Consortium
- Yaniv Bar-Cohen, M.D., Southern California Center for Technology and Innovation in Pediatrics
- Matthew Maltese, M.S., Ph.D., Philadelphia Regional Pediatric Medical Device Consortium
- Pedro del Nido, M.D., Boston Pediatric Device Consortium

Children differ in terms of size, growth, and body chemistry and present unique challenges to device developers. In addition, the activity level and ability to manage some implantable or long-term devices may vary greatly among children. While this program is administered by the OOPD, it is intended to encompass devices used in all pediatric diseases, not just rare diseases.

Medical device legislation passed by Congress in 2007 established funding to be distributed as grants for nonprofit consortia to help stimulate projects to promote the development and availability of pediatric devices. This legislation was re-authorized as part of the FDA Safety and Innovation Act of 2012.

Those receiving grants will:

- Encourage innovation and connect qualified individuals with good pediatric device ideas

to potential manufacturers

- Mentor and manage pediatric device projects through their development, including prototype design and marketing
- Connect innovators and physicians to existing federal and non-federal resources
- Assess the scientific and medical merit of proposed pediatric projects and provide assistance and advice on business development, training, prototype development and post-marketing needs.

This is the third time since 2009 that the FDA has awarded grants to consortia which advance the development of pediatric medical devices. This year's awards have been granted to consortia that each bring together teams with excellence and expertise in delivering business, regulatory, legal, scientific, engineering, and clinical services for children. While a small portion of the grants fund specific projects, the real spirit of this grant program is to provide advisory resources to promote multiple projects.

REPORTS/POLICIES

- **The Institute of Medicine (IOM) published “An Update on Research Issues in the Assessment of Birth Settings - Workshop Summary,” on Sept. 23, 2013.** The report reviews research findings that advance understanding of the effects of maternal care services in different birth settings, including hospitals, birth centers and homes; on labor, clinical and other birth procedures; and birth outcomes. <http://www.iom.edu/Reports/2013/An-Update-on-Research-Issues-in-the-Assessment-of-Birth-Settings.aspx>

HILL HEARINGS

- There are no hearings scheduled this week.

LEGISLATION

- **H.R.3165** (introduced Sept. 20, 2013): To repeal the Patient Protection and Affordable Care Act and to take meaningful steps to lower health care costs and increase access to health insurance coverage without raising taxes, cutting Medicare benefits for seniors, adding to the national deficit, intervening in the doctor-patient relationship, or instituting a government takeover of health care was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Education and the Workforce, Natural Resources, the Judiciary, House Administration, Rules, and Appropriations.
Sponsor: Representative Tom Latham [IA-3]
- **H.R.3170** (introduced Sept. 23, 2013): To provide that the only health plans that the federal government may make available to federal employees responsible for the administration of the Patient Protection and Affordable Care Act are those created under such Act or offered through a health insurance exchange, and for other purposes was referred to the Committee on Oversight and Government Reform, and in addition to the Committees on Energy and Commerce, House Administration, and Appropriations.
Sponsor: Representative Bill Posey [FL-8]
- **H.R.3171** (introduced Sept. 23, 2013): To require the Secretary of Health and Human Services to approve waivers under the Medicaid Program under title XIX of the Social Security Act that are related to State provider taxes that exempt certain retirement communities was referred to the House Committee on Energy and Commerce.

Sponsor: Representative Steve Womack [AR-3]

- **S.1546** (introduced Sept. 25, 2013): A bill to promote minimum State requirements for the prevention and treatment of concussions caused by participation in school sports, and for other purposes referred to the Committee on Health, Education, Labor, and Pensions.
Sponsor: Senator Richard Durbin [IL]

MEETINGS

- The MGMA 2013 Annual Conference will be held on **Oct. 6-9, 2013**, in San Diego, Calif. <http://www.mgma.com/mgma-conference/>
 - The AMSUS Annual Continuing Education Meeting will be held **Nov. 3-8, 2013**, in Seattle Wash. AMSUSMeeting.org
 - The 29th Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) will be held **Nov.7-9, 2013**, in Philadelphia, Pa. <http://www.istss.org/Home.htm>
 - The AMIA 2013 Annual Symposium will be held on **Nov. 16-20, 2013**, in Washington DC. <http://www.amia.org/amia2013>
 - The Radiological Society of North America (RSNA) 2013: **Dec. 1-3, 2013**, in Chicago, Ill. http://www.rsna.org/Annual_Meeting.aspx
 - The 2013 Special Operations Medical Association (SOMA) Conference will be held on **Dec. 14-17, 2013**, in Tampa, Fla. <http://www.specialoperationsmedicine.org/>
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