

# Federal Health Update

AUG 21, 2015

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

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***The Update will not be published on Aug. 28, 2015.***

## EXECUTIVE AND CONGRESSIONAL NEWS

- **The House and Senate are in recess until Sept. 8, 2015.**

## MILITARY HEALTH CARE NEWS

- **On Aug. 14, the Army chief of staff announced that Brig. Gen. Robert D. Tenhet, commanding general, Northern Regional Medical Command, Fort Belvoir, Va., to director, National Capital Medical Directorate, Defense Health Agency, Arlington, Va.**
- **On Aug. 23 the National Museum of Health (NMHM) and Medicine and the Armed Forces Health Surveillance Center (AFHSC), and the Armed Forces Medical Examiner System (AFMES) at Dover Air Force Base, Delaware, will become part of the Defense Health Agency (DHA).**

NMHM was founded as the Army Medical Museum in 1862 and is home to a National Historic Landmark collection of more than 25 million objects. NMHM was instituted as a center for the study of battlefield medicine during the Civil War, making several historic contributions to the field of military medicine throughout the 150 years since that war, including the X-ray.

AFMES provides worldwide comprehensive medico-legal services and investigations. Board-certified forensic pathologists, forensic anthropologists, medical-legal death investigators and photographers are available 24 hours a day to conduct forensic investigations into military deaths throughout the world. The Armed Forces DNA Identification Laboratory provides scientific consultation, research and education services in the field of forensic DNA analysis to the Department of Defense and other agencies. In addition, the medical examiner system has DoD's centralized laboratory for performing routine toxicological testing for military aircraft, ground and ship (sea) mishaps; military autopsies; biological specimens from AFOSI, CID and NCIS criminal investigations; blood for legal alcohol and drug tests in DUI and DWI medico-legal determinations; blood and urine in fitness-for-duty interrogations; and selected cases of national interest.

Both NMHM and AFMES will fall under DHA's Research, Development & Acquisitions directorate.

After its transition AFHSC is becoming the Armed Forces Health Surveillance Branch, part of DHA's Healthcare Operations Directorate. The branch's mission is to protect the health and readiness of the military against illness or injury during training exercises as well as deployment. The HSB serves as a central, integrated and customer-focused epidemiologic resource for the Department of Defense, and as a global health surveillance resource for the U.S. Armed Forces.

The addition of the three entities is part of the DHA's overall work toward full operational capability scheduled for Oct. 1, 2015. For more information about DHA and its mission, go to [www.health.mil/dha](http://www.health.mil/dha).

- **Starting Oct. 1, TRICARE beneficiaries with long-term prescriptions for brand-name medications to treat chronic conditions will need to fill them by mail or through a military pharmacy.**

[Under an interim rule published by the Defense Department on Aug. 6](#), TRICARE will begin requiring these beneficiaries to use the TRICARE Mail Order Pharmacy System or pick up their prescriptions at a military hospital or clinic.

"Maintenance medications" means all prescriptions for chronic health issues, from high blood pressure medicine and cholesterol-lowering drugs to painkillers, antidepressants and more. The new rule will not apply to prescriptions for generic drugs, for drugs prescribed to treat acute illnesses and for prescriptions covered by other medical insurance, according to the interim regulation.

Congress mandated the change in the fiscal 2015 National Defense Authorization Act, signed into law Dec. 19. It is similar to a pilot program introduced in February 2014 that requires TRICARE For Life beneficiaries to fill all long-term prescriptions by mail or at a military facilities.

Defense officials say 61 million prescriptions were filled under TRICARE at retail pharmacies in fiscal 2014, at a cost to the government of \$5.1 billion. The new rule is expected to save money, since the government pays 32 percent less for brand-name maintenance medications filled by mail or through military pharmacies than at retail stores. Defense officials estimate the program could save at least \$88 million a year. DoD savings over the first year of the TRICARE For Life pilot program totaled \$123 million.

Defense officials stress that the new requirement not only will save the government money, it will also help beneficiaries. DoD estimates that beneficiaries may save an average of \$176 per prescription a year by moving their brand-name prescriptions from retail to home delivery or a military treatment facility, since co-payments are lower and most prescriptions available through mail are filled for 90 days.

Under the interim rule, the Defense Health Agency will maintain a list of the medications it considers maintenance drugs and will publish the list on the TRICARE Pharmacy Program

website and make it available through the TRICARE Pharmacy Program Service Center telephone system.

Under the new program, patients can fill new prescriptions for maintenance medications at a military treatment facility or receive a 30-day or less supply from a retail pharmacy. They will then be required to refill the prescription at the MTF or by mail.

TRICARE will grant case-by-case waivers for personal hardship, emergency or "other special circumstance," according to the rule. Waiver requests will have to be made through Express Scripts, TRICARE's pharmacy benefits management company.

Currently, TRICARE beneficiaries can fill a 90-day prescription for a generic medication at no cost by mail or pay \$8 for a 30-day supply at a retail pharmacy. They must pay \$16 for a 90-day prescription for brand names by mail and \$20 for a 30-day brand-name prescription at retail pharmacies.

Medications not listed in TRICARE's formulary run \$47 for a 30-day prescription at a retail pharmacy and \$46 for a 90-day prescription by mail. Prescriptions filled at military pharmacies are available to beneficiaries at no cost.

## VETERANS AFFAIRS NEWS

- **The Department of Veterans Affairs (VA) announced that it has revised its regulation regarding the presence of animals on VA property.**

The updated regulation will ensure VA practices remain consistent with applicable federal law. It will also assist individuals entering VA facilities in developing a clear and consistent understanding of the criteria governing facility access for service animals.

Under the revised regulation, only dogs that are individually trained to perform work or tasks on behalf of an individual with a disability will be considered service animals. Other animals will not be permitted in VA facilities, unless expressly allowed as an exception under the regulation for activities such as animal-assisted therapy or for other reasons such as law enforcement purposes. The regulation further confirms that service animals may access VA property subject to the same terms that govern the admission of the public to VA property, and may be restricted from certain areas on VA properties to ensure that patient care, patient safety, and infection control standards are not compromised.

In accordance with required practices, the revised regulation was published in the Federal Register in November 2014, to obtain feedback from Veterans, advocacy organizations and other stakeholders.

## GENERAL HEALTH CARE NEWS

- **A new anthrax vaccine that could be easier and faster to produce than the existing licensed product will undergo initial clinical studies through an agreement between the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR) and Pfenex, Inc. of San Diego.**

The anthrax vaccine currently licensed by the Food and Drug Administration is for use before exposure to anthrax-causing bacteria. Its wide-scale use after an exposure would require emergency use authorization from the FDA.

BARDA is pursuing next-generation recombinant vaccines that target the anthrax cell-binding protein, called the protective antigen, which stimulates an immune response. Vaccines using a

purified recombinant form of protective antigen have the potential to reduce both the number of doses needed for the vaccine and the costs associated with manufacturing each dose, which could result in significant cost savings over time.

Pfenex's experimental vaccines, Px563L and RPA563, performed well in nonclinical studies. Under the approximately \$15.9 million, 30-month contract, BARDA will support the clinical development of the vaccine, beginning with an evaluation of the vaccine's safety in a small number of healthy human volunteers.

The contract can be extended with additional funding over five years. Under the extension, the company would conduct additional clinical studies to determine how well the vaccine stimulates the human immune system and the minimum number of doses required to achieve the desired immune response.

If this finding is replicated in humans, protection would occur with fewer doses than with the currently licensed vaccine which requires three doses administered over four weeks under emergency use authorization for post-exposure prophylaxis.

Under this new project the company also will compare the safety and efficacy of Px563L, which incorporates an adjuvant, and RPA563, which does not include an adjuvant. Adjuvants stimulate the immune system with less antigen, the active ingredient in vaccine. As a result, fewer doses are needed, making more vaccine regimens available from a given amount of antigen.

More information about public health and medical emergency preparedness, response, or recovery is available at [www.phe.gov](http://www.phe.gov). To learn more about advanced research and development of medical countermeasures, visit [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov). Contract opportunities and awards are announced at [www.fbo.gov](http://www.fbo.gov).

- **The Centers for Medicare & Medicaid Service (CMS) announced that more than 2,100 acute care hospitals, skilled nursing facilities, physician group practices, long-term care hospitals, inpatient rehabilitation facilities, and home health agencies transitioned from a preparatory period to a risk-bearing implementation period in which they assumed financial risk for episodes of care.**

The participants include 360 organizations that have entered into agreements with CMS to participate in the Bundled Payments for Care Improvement initiative and an additional 1,755 providers who have partnered with those organizations. CMS defines an episode of care as the set of services provided to treat a clinical condition or procedure, such as a heart bypass surgery or a hip replacement.

Bundling payment for services that patients receive across a single episode of care is one way to encourage doctors, hospitals and other health care providers to work together to better coordinate care for patients, both when they are in the hospital and after they are discharged. Through the Bundled Payments for Care Improvement initiative, CMS is testing how bundled payments for clinical episodes can result in better care, smarter spending, and healthier people. Today's announcement means several hundred providers are advancing into a program that rewards them for increasing quality and reducing costs while also penalizing them if costs exceed a set amount.

The initiative includes four models of bundled payments tied to inpatient hospital admission. The models vary by the types of providers involved and the length of the bundle after the hospitalization.

CMS recently announced a new Medicare Part A and B payment model, the [Comprehensive Care for Joint Replacement Model](#). Although the Comprehensive Care for Joint Replacement Model is distinct from the Bundled Payments for Care Improvement initiative, both initiatives are

part of the innovative framework established by the Affordable Care Act to move our health care system toward one that rewards providers based on the quality, not quantity, of care they deliver to patients. The Administration earlier this year announced the goal of tying 30 percent of Medicare payments to quality and value through alternative payment models by 2016 and 50 percent of payments by 2018.

To learn more about the Bundled Payments for Care Improvement initiative and to see the list of participants for Models 1, 2, 3 and 4, visit: <http://innovation.cms.gov/initiatives/bundled-payments>.

## REPORTS/POLICIES

- **The GAO published “*Electronic Health Records: Outcome-Oriented Metrics and Goals Needed to Gauge DOD's and VA's Progress in Achieving Interoperability*,” (GAO-15-530) on Aug. 13, 2015.** GAO evaluated the actions taken by DOD, VA, and the IPO to plan for and measure the progress toward achieving interoperability between the departments' electronic health record systems. GAO reviewed relevant program documents and interviewed agency officials.” <http://www.gao.gov/assets/680/671979.pdf>

## HILL HEARINGS

- There are no hearings scheduled next week.

## LEGISLATION

- There was no legislation published the last two weeks.

## MEETINGS

- The 2015 AHRQ Research Conference, “Producing Evidence and Engaging Partners to Improve Health Care”, will be held **Oct. 4–6, 2015**, in Crystal City, Va. <http://www.ahrq.gov/news/events/conference/index.html>
  - The AUSA 2015 Annual Meeting & Exposition will be held **Oct. 12-14, 2015**, in Washington DC. <http://ausameetings.org/2015annualmeeting/>
  - 2015 AMSUS Annual Continuing Education Meeting - The Society of Federal Health Professionals will be held on **Dec. 1-4, 2015**, in San Antonio, Texas. <http://amsusmeetings.org/annual-meeting/>
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