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

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ktheroux@federalhealthcarenews.com

May everyone impacted by Hurricane Matthew remain safe.

EXECUTIVE AND CONGRESSIONAL NEWS

- The Senate and House are in recess until Nov. 12 and 14, 2016, respectively.

- On Sept. 30, 2016, the President signed into law: S. 1878, the “Advancing Hope Act of 2016,” which modifies the Food and Drug Administration priority review voucher program for rare pediatric diseases and extends authority for the program through Dec. 31, 2016.

MILITARY HEALTH CARE NEWS

- The Defense Health Agency announced that Walmart will be part of the TRICARE pharmacy network, effective Dec. 1, 2016.

  All CVS pharmacies, including those inside Target stores, will no longer be considered “in network.”

  TRICARE officials said the network agreement reached with Walgreens will “provide better value
and maintain convenient access for beneficiaries.”

The network will have roughly 58,000 locations, with 98 percent of TRICARE beneficiaries living within 5 miles of a network store, officials said.

Under the agreement, all prescriptions filled at a CVS store after Dec. 1 will be considered non-network prescriptions. Beneficiaries will have to pay the full cost of their medication up front and file a claim with TRICARE for partial reimbursement.

Express Scripts would be contacting patients who take specialty medications to help them transfer their prescriptions without a gap in coverage.

Other retail pharmacies not affiliated with CVS will remain in the network, including Rite Aid.

VETERANS AFFAIRS NEWS

- The Department of Veterans Affairs (VA) has selected the Department of Agriculture (USDA) as its federal shared service provider to deliver a modern financial management solution that will replace the existing system and improve financial transparency and processing across the Department.

  In making this selection, VA also leveraged best practices and lessons learned from Office of Management and Budget (OMB), the Government Accountability Office (GAO), Department of Homeland Security (DHS), Department of Housing and Urban Development (HUD), and others.

  Partnering with USDA allows VA to utilize an established and proven IT solution to better serve its financial management needs. This partnership demonstrates VA’s commitment to work with other agency partners to reduce duplication and redundancy across the government, while also improving both the quality and agility of administrative services.

- Hearing loss, including tinnitus, which is a ringing, buzzing or other type of noise that originates in the head, is the most prevalent service-connected disability among veterans, with more than 30 million veterans suffering from a form of it due to frequent exposure to loud noises from weaponry and aircraft.

  Because of the pervasiveness of hearing loss among veterans, the Department of Veterans Affairs (VA) is recognizing October as Audiology Awareness Month by highlighting important VA research on the subject and advances made in treating veterans with hearing loss.

  VA researchers conduct a wide range of studies in audiology—from biomedical investigations to large clinical trials and epidemiologic database studies. Much of the work takes place at VA’s National Center for Rehabilitative Auditory Research in Portland, Oregon, one of the world’s leading facilities for research in the field. Studies include older veterans whose hearing problems have been compounded by aging and younger veterans who may have suffered hearing loss as a result of blasts in Iraq or Afghanistan.

  Recent VA research includes the following:

  - In 2013, researchers at the VA Puget Sound Health Care System published the results of a study comparing group and individual visits for hearing aid fittings and follow up. The team found no differences in how well the hearing aids performed, or how often they were worn. They concluded that group visits could reduce costs while providing community support for patients.

  - In 2014, VA researchers in Loma Linda, Calif., linked exposure to jet propulsion fuel with auditory processing problems—changes that occur inside the brain rather than the ear.

  - A 2015 VA study yielded promising results on transcranial magnetic stimulation as a tinnitus treatment. The therapy involves holding a magnetic coil to the head. The team
now hopes to conduct a larger trial.

- A 2016 study of nearly 200 veterans with tinnitus explored the impact of Post-Traumatic Stress Disorder (PTSD) on how Veterans manage the hearing condition, and offered guidance for clinicians.

In addition to VA’s audiology research work, the Department announced last month – ahead of National Audiology Awareness Month – that veterans who need routine audiology appointments will be able to directly schedule them, without the need for a referral from their primary care provider. The move is expected to get Veterans into appointments more quickly. The new expedited process was piloted at three VA sites last year and is now being rolled out nationwide.

For more information VA’s audiology services, visit www.ncrar.research.va.gov. Information about VA research on audiology may be found at www.research.va.gov/topics/hearing.cfm.

### GENERAL HEALTH CARE NEWS

- **HHS’s Office of the Assistant Secretary for Preparedness and Response (ASPR)** announced it is purchasing two medical products to treat injuries to bone marrow in victims of radiological or nuclear incidents. Bone marrow is essential to producing blood.

  The two products, called colony stimulating factors, stimulate bone marrow to produce blood cells including neutrophils that reduce the body’s risk of developing an infection and decrease risk of death from acute radiation syndrome. Infections often occur after exposure to high doses of radiation. These types of products are used commonly to reduce the risk of infection in patients with cancer.

  ASPR’s Biomedical Advanced Research and Development Authority (BARDA) is purchasing the first of these two leukocyte growth factor products, called Neulasta, from Amgen USA, Inc. of Thousand Oaks, Calif., under an approximately $37.7 million agreement.

  BARDA will purchase the second product, called Leukine, from Sanofi-Aventis U.S., LLC of Bridgewater, N.J., under a $37.6 million agreement. Sanofi-Aventis is a subsidiary of Sanofi.

  Neulasta is approved by the U.S. Food and Drug Administration (FDA) to treat adults and children exposed to high levels of radiation that damage bone marrow. BARDA continues to work with Sanofi-Aventis to support the studies needed to request FDA approval of Leukine.

  BARDA will purchase both products using funding and authority provided through the Project BioShield Act of 2004.

  Under the Project BioShield Act, the U.S. government supports the advanced development and procurement of new medical countermeasures – drugs, vaccines, diagnostics, and medical supplies – to protect health against chemical, biological, radiological and nuclear threats.

  The products add to the available treatment options in the Strategic National Stockpile for acute radiation syndrome. Previously, BARDA sponsored advanced development and purchased another leukocyte growth factor product called Neupogen, which is now also FDA-approved for use in treating adults and children exposed to levels of radiation that damage the bone marrow.

  To learn more about ASPR and preparedness, response and recovery from the health impacts of disasters, visit the HHS public health and medical emergency website, www.phe.gov. Contract opportunities are announced at www.fbo.gov.

- The Department of Health and Human Services (HHS) has awarded cooperative agreements totaling $350,000 to strengthen the ability of health care and public health
sector partners to respond to cybersecurity threats.

The agreements will foster the development of a more vibrant cyber information sharing ecosystem within the health care and public health sector.

HHS’ Office of the National Coordinator for Health Information Technology (ONC) awarded a cooperative agreement to the National Health Information Sharing and Analysis Center (NH-ISAC) of Ormond Beach, Fla. to provide cybersecurity information and education on cyber threats to healthcare sector stakeholders. It also has an agreement with NH-ISAC to help build the infrastructure necessary to disseminate cyber threat information securely to healthcare partners.

Security breaches and ransomware attacks on the healthcare system have been on the rise in recent years, as has the average cost associated with these attacks. Today, the cost of cybersecurity breaches averages $3.8 million per attack, according to a recent study. While some healthcare entities have adequate resources to contract with information sharing and analysis organizations that could to inform them about cyber incidents, smaller healthcare entities often do not.

Through a streamlined cyber threat information sharing process, HHS will be able to send cyber threat information to a single entity, which then will share that information widely to support the full range of stakeholders. This approach helps ensure that smaller health care providers have the information they need to take appropriate action.

The agreements also will help build the capacity of NH-ISAC to receive cyber threat information from member healthcare entities. Information about any system breaches and ransomware attacks will be relayed through a more robust cyber information sharing environment, as will information about steps healthcare entities should take to protect their health information technology systems.

ASPR leads HHS in preparing the nation to respond to and recover from adverse health effects of emergencies, supporting communities’ ability to withstand adversity, strengthening health and response systems, and enhancing national health security. To learn more about ASPR, visit the HHS public health and medical emergency website, phe.gov.

- CDC has awarded more than $14 million to fund new approaches to combat antibiotic resistance.

The awards, made through CDC’s Broad Agency Announcement (BAA), support activities in the CDC Antibiotic Resistance Solutions Initiative. The initiative, which also provides funding for state health departments and other partners, implements the tracking, prevention, and antibiotic stewardship activities outlined in the National Action Plan for Combating Antibiotic-Resistant Bacteria.

The majority of the projects are being conducted through universities across the country and one by a commercial company and two by a nonprofit.

Awardees include: Brown University, Columbia University, Cornell University, Emory University, Georgia Institute of Technology, The Joint Commission, Ohio State University, OpenBiome, Pennsylvania State University, Rutgers University, Synthetic Biologics, Inc., University of Georgia, University of California Berkley, University of California Davis, University of Cincinnati, University of Colorado, University of Maryland, University of Michigan, University of Pennsylvania, University of Virginia, University of Oregon, University of Utah, Virginia Commonwealth University, Washington University and Yale University. Some awardees are conducting multiple projects.

For more information on the BAA and the list of antibiotic resistance funded projects, please visit
the Antibiotic Resistance Solutions Initiative webpage.

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<th>HILL HEARINGS</th>
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<th>MEETINGS</th>
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<td>▪ 2016 AMSUS Annual Continuing Education Meeting will be held on <strong>Nov. 29- Dec. 2, 2016</strong>, at the Gaylord National Harbor, Md. <a href="http://www.amsusmeetings.org/">http://www.amsusmeetings.org/</a></td>
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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.