

Federal Health Update

JULY 1, 2016

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Happy Fourth of July!

EXECUTIVE AND CONGRESSIONAL NEWS

- **The House and Senate is in recess until July 6, 2016.**
- **On June 30, 2016, President Obama signed into law S. 2487, the "Female Veteran Suicide Prevention Act."** This legislation requires the U.S. Department of Veterans Affairs to identify and track mental health care and suicide prevention programs and metrics that are effective in treating female veterans.
- **Democrats blocked a vote on the Senate's Military Construction and Veterans Affairs appropriations bill this week due to a dispute over the funding to fight the Zika virus.**

The bill included \$176.9 billion in VA funding starting in October, \$7.9 billion for military construction projects and \$1.1 billion for Zika prevention, which was short of the \$1.9 billion requested by the Administration.

The legislation totaled \$74.4 billion in discretionary spending for VA programs in 2017, nearly 4 percent more than the 2016 budget year but about \$700 million less than what the White House requested in its budget plan.

But Democrats' objections focused mainly on the Zika provisions, money that was carved out from other government programs instead of supplying supplemental funding to address the public health issue.

The legislation was tabled in hopes of taking it up after the Fourth of July break.

MILITARY HEALTH CARE NEWS

- **The Department of Defense (DoD) announced that transgender individuals will now be able to openly serve in the U.S. armed forces.**

The DoD policy announced also establishes a construct by which service members may transition gender while serving, sets standards for medical care and outlines responsibilities for military services and commanders to develop and implement guidance, training and specific policies in the near and long-term.

The policy will be phased in during a one-year period. Effective immediately, service members may no longer be involuntarily separated, discharged or denied reenlistment solely on the basis of gender identity. Service members currently on duty will be able to serve openly.

Not later than October 1, 2016, DoD will create and distribute a commanders' training handbook, medical protocol and guidance for changing a service member's gender in the Defense Eligibility Enrollment System (DEERS). At this point, the services will be required to provide medically necessary care and treatment to transgender service members according to the medical protocol and guidance, and may begin changing gender markers in DEERS. Prior to October 1, 2016, requests for medical treatment will be handled on a case-by-case basis consistent with the spirit of the Directive Type Memorandum and the DoD Instruction issued today.

Over the course of the next year, the Department will finalize force training plans and implementation guidance, revise regulations and forms, and train the force, including commanders, human resources specialists, recruiters and service members. Acting Under Secretary of Defense for Personnel and Readiness Peter Levine will work with the military services to monitor and oversee this effort.

At one year, the services will begin allowing transgender individuals to join the armed forces, assuming they meet accession standards. In addition, an otherwise-qualified individual's gender identity will not be considered a bar to admission to a military service academy, or participation in the Reserve Officers' Training Corps or any other accession program if the individual meets the new criteria.

The full policy must be completely implemented no later than July 1, 2017.

To support service members, medical professionals and commanders during the implementation period, the DoD has set up a central coordination cell which will serve as a central point of contact for technical questions and concerns. The coordination cell is made up of legal experts, policy experts and medical professionals familiar with the issue.

- **The Department of Defense (DoD) and the Department of Veterans Affairs (VA) are streamlining the system to make sure veterans, service members and their families are well served as the population ages.**

As a result, there is a cooperative partnership between the DoD, VA and the private sector, known as the Interagency Care Coordination Committee (IC3), which include more than 50 programs that serve wounded warriors. IC3 helps all agencies better coordinate to solve the

physical, mental and emotional problems of those hurt on the battlefield.

The effort is designed to ease the burden for service members and veterans, who have suffered illnesses or injuries so severe as to require the expertise provided by multiple care specialties throughout both departments.

The lead coordinator will offer personal guidance and assist service members and their families in understanding the benefits and services to which they are entitled. Service members, veterans and their families, working with their lead coordinator, will have someone to whom they can turn when they have a question or issue as they actively participate in their care, officials explained, adding that the first phase of lead coordinator training was completed in November. Officials expect that 1,500 DoD and 1,200 VA people will serve as lead coordinators.

This effort comes as a result of the work of the DoD-VA Interagency Care Coordination Committee, established in 2012 to implement a joint, standard model of collaboration for the most complex cases of care that will require a warm handoff from the DoD to the VA system of care, as well as within the departments, officials said. It is based on many of the best practices of collaboration that have been created over the last decade.

IC3 gives both the DoD and VA one policy and one plan to get there. That way, individuals have one comprehensive treatment plan that sticks with them wherever they go.

VETERANS AFFAIRS NEWS

- **There was no news released from the Department of Veterans Affairs this week.**

GENERAL HEALTH CARE NEWS

- **The Department of Health and Human Services (HHS) has selected nearly 200 physician group practices and 17 health insurance companies to participate in a care delivery model that supports and encourages higher quality and more coordinated cancer care.**

The Medicare arm of the Oncology Care Model includes more than 3,200 oncologists and will cover approximately 155,000 Medicare beneficiaries nationwide. The Oncology Care Model begins on July 1, 2016 and runs through June 30, 2021.

Cancer is one of the most common and devastating diseases in the United States: more than 1.6 million new cases of cancer will be diagnosed and cancer will kill an estimated 600,000 Americans in 2016. According to the National Institutes of Health, based on growth and the aging of the U.S. population, medical expenditures for cancer in the year 2020 are projected to reach at least \$158 billion (in 2010 dollars) – an increase of 27 percent over 2010. A significant proportion of those diagnosed are over 65 years old and Medicare beneficiaries.

The Oncology Care Model encourages practices to improve care and lower costs through episodic and performance-based payments that reward high-quality patient care. The model is one of the first CMS physician-led specialty care models and builds on lessons learned

from other innovative programs and private-sector models.

As part of this model, physician practices may receive performance-based payments for episodes of care surrounding chemotherapy administration to Medicare patients with cancer, as well as a monthly care management payment for each beneficiary. The two-sided risk track of this model will be an Advanced Alternative Payment Model under the newly proposed [Quality Payment Program](#), implementing provisions from the Medicare Access and CHIP Reauthorization Act of 2015.

Practices participating in the five-year Oncology Care Model will provide treatment following nationally recognized clinical guidelines for beneficiaries undergoing chemotherapy, with an emphasis on person-centered care. They will provide enhanced services to beneficiaries who are in the Oncology Care Model to help them receive timely, coordinated treatment. These services may include:

- Coordinating appointments with providers within and outside the oncology practice to ensure timely delivery of diagnostic and treatment services;
- Providing 24/7 access to care when needed;
- Arranging for diagnostic scans and follow up with other members of the medical team such as surgeons, radiation oncologists, and other specialists that support the beneficiary through their cancer treatment;
- Making sure that data from scans, blood test results, and other tests are received in advance of patient appointments so that patients do not need to schedule additional visits; and
- Providing access to additional patient resources, such as emotional support groups, pain management services, and clinical trials.

For more information about the model including the names of those practices and payers participating, visit: <http://innovation.cms.gov/initiatives/Oncology-Care/>.

- **The Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR) will begin developing a vaccine using its Center for Innovation in Advanced Development and Manufacturing (CIADM) in Baltimore, Maryland.**

With funding and direction from ASPR's Biomedical Advanced Research and Development Authority (BARDA), the CIADM led by Emergent BioSolutions, Inc., will conduct a variety of studies to move quickly through early stages of vaccine development and submit an investigational new drug request to FDA to begin clinical studies. To further speed development time, the CIADM will use vaccine technology similar to that used in vaccines being developed to protect against similar viruses, such as Dengue.

Over the next 30 months, BARDA will provide more than \$17.9 million to Emergent with the potential for additional work for a total of approximately \$21.9 million. At any stage in development, BARDA could transfer the technology to other vaccine manufacturers to utilize the technology for to produce and market the Zika vaccine.

In addition to the CIADM, BARDA can call on other aspects of our National Medical Countermeasure Response Infrastructure which provide expertise in regulatory, non-regulatory, clinical, nonclinical, and manufacturing processes needed to develop a vaccine.

BARDA has used the CIADMs to accelerate development of therapeutics for Ebola, develop a second-generation anthrax vaccine, and manufacture experimental vaccines to protect against influenza viruses with pandemic potential.

In addition to this vaccine development, BARDA is sponsoring development of pathogen reduction technologies to reduce the risk from Zika in the blood supply. BARDA also is using its clinical studies network to collect blood samples needed to speed development of diagnostic tests.

BARDA is seeking additional proposals for products that could be used to prevent or detect Zika or other illnesses and injuries associated with public health emergencies. Visit www.medicalcountermeasures.gov to request a meeting.

- **The Centers for Disease Control and Prevention (CDC) has awarded \$26 million to support applied research at five academic medical centers as part of a patient safety effort known as Prevention Epicenters Program.**

Together with CDC, these Prevention Epicenters develop and test innovative approaches to preventing infections and improving patient safety in healthcare settings. The new funding more than doubles previous awards and expands and extends the Prevention Epicenters program to 2020.

The Prevention Epicenters funded from 2016 to 2020 are Chicago Prevention and Intervention Epicenter at Rush University Medical Center and Cook County Health and Hospitals System; Duke University and the University of North Carolina; The Harvard Pilgrim Health Care and University of California, Irvine; The University of Pennsylvania; and Washington University School of Medicine in St. Louis and BJC Healthcare Prevention Epicenter.

Examples of new research the Epicenters are conducting to prevent healthcare-associated infections (HAIs) and the spread of dangerous bacteria include:

- Determining factors that predict which patients in intensive care units (ICUs) will become colonized with an antibiotic-resistant germ, specifically looking at the role of environmental and personal microbiomes;
- Discovering how antibiotics disrupt the gut microbiome of ICU patients, putting them at risk for infections;
- Testing new strategies for regional, rather than single-facility, approaches to prevent infections and track transmission of antibiotic-resistant germs;
- Finding the best way to disinfect patient skin to prevent infections in ICU patients;
- Determining how microbiome restoration can treat infections caused by antibiotic-resistant germs; and
- Automatically detecting outbreaks from lab data.

Funding for the five Prevention Epicenters begins immediately and extends through 2020. Additionally, the Rush University Medical Center and Cook County Health and Hospitals System Epicenter received \$4.45 million from CDC's Safety and Healthcare Evaluation and Research Development (SHEPHERD) contract to develop and test regional approaches for preventing transmission of antibiotic-resistant germs between healthcare facilities.

About one in 25 patients in U.S. hospitals gets an infection while receiving medical treatment for other conditions, leading to sepsis or death in many cases. In some hospitals, antibiotic-resistant bacteria cause one in four catheter and surgery-related infections. The growing toll is described in CDC's Vital Signs.

For nearly 20 years, Prevention Epicenters have discovered and tested innovative ways to prevent and control infections in healthcare, including addressing scientific questions about antibiotic resistance.

For more information on the CDC Prevention Epicenter Program, visit:

REPORTS/POLICIES

- **The GAO published “Veterans Crisis Line: Additional Testing, Monitoring, and Information Needed to Ensure Better Quality Service,” (GAO-16-373) on June 27, 2016.** This report, among other issues, examines the extent to which VA meets response-time goals for VCL calls and text messages; how VA monitors VCL primary center call center operations; and how VA works with VCL service partners to help ensure veterans receive high-quality service.
<http://www.gao.gov/assets/680/677530.pdf>
- **The National Academies of Science, Engineering and Medicine published “The Role of Business in Multisector Obesity Solutions: Working Together for Positive Change—Workshop in Brief,” on June 29, 2016.** The goal of the workshop was to explore why companies should be involved in obesity solutions and how to encourage them to do so; identify reasons why businesses might be interested in being involved in obesity solutions; identify ways in which business can be engaged in obesity solutions.
<http://nationalacademies.org/hmd/reports/2016/role-of-business-in-multisector-obesity-solutions-wib.aspx>

HILL HEARINGS

- The Senate Appropriations Subcommittee on Military Construction and Veterans Affairs, and Related Agencies will hold a hearing on **July 13, 2016**, to examine a review of the Department of Veterans Affairs' electronic health record (VistA), progress toward interoperability with the Department of Defense's electronic health record, and plans for the future.

LEGISLATION

- **S.3101** (introduced June 27, 2016): the Good Samaritan Health Professionals Act of 2016 was referred to the Committee on Health, Education, Labor, and Pensions
Sponsor: Senator Bill Cassidy [LA]
- **S.3113** (introduced June 29, 2016): A bill to amend Public Health Service Act to authorize grants for training and support services for families and caregivers of people living with Alzheimer's disease or a related dementia was referred to the Committee on Health, Education, Labor, and Pensions.
Sponsor: Senator Amy Klobuchar [MN]
- **S.3115** (introduced June 29, 2016): A bill to amend the Public Health Service Act with respect to a national pediatric research network was referred to the Committee on Health, Education, Labor, and Pensions
Sponsor: Senator Roger F. Wicker [MS]

MEETINGS

- The Disaster Health Education Symposium: Innovations for Tomorrow will be held on **Sept. 8, 2016**, at the Uniformed Services University in Bethesda, Md. <https://ncdmph.usuhs.edu>.
- The AUSA 2016 Annual Meeting & Exposition will be held **Oct. 3-5, 2015**, in Washington DC. <http://ausameetings.org/2016annualmeeting/>
- 2016 AMSUS Annual Continuing Education Meeting will be held on **Nov. 29- Dec. 2, 2016**, at the Gaylord National Harbor, Md. <http://www.amsusmeetings.org/>

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.