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

- On July 27, 2017, the House passed H.R. 3219, the Defense Appropriations Act for fiscal year 2018.  This legislation authorizes $696 billion in defense spending in fiscal year 2018, well above President Trump's request.  The bill also includes a measure supplying $1.6 billion for border fencing and improvements as part of Trump's promise to build a wall along the U.S. boundary with Mexico.

- The Senate failed to pass bills to repeal and replace or simply to repeal the Affordable Care Act (ACA) this week.  The Senate is now debating a “skinny” health care bill that would repeal the individual and employer mandate and the tax on medical devices.  The goal is to get something passed so the House and Senate can come to an agreement in conference.

MILITARY HEALTH CARE NEWS

- The Army chief of staff announced Maj. Gen. Michael C. O'Guinn, U.S. Army Reserve will be assigned to deputy surgeon general for mobilization and reserve affairs (Individual Mobilization Augmentee), Office of the Surgeon General, Falls Church, Virginia.  He
previously served as commanding general (Troop Program Unit), Medical Readiness and Training Command, San Antonio, Texas.

- The Defense Health Agency announced the Secretary of Defense has renewed the Non-FDA Approved Laboratory Developed Tests Demonstration Project, which began in September 2014.

Hospitals and labs, including those run by the military, can create and use these tests without seeking the FDA’s approval. The Military Health System uses the Laboratory Joint Working Group, a body of clinical and lab experts from all of the military services, to prioritize and review a test.

The criteria of that evaluation are based on a hierarchy of reliable evidence of proven medical effectiveness (such as scientifically valid data and information published in refereed medical and scientific literature), as well as TRICARE’s rules involving rare diseases. The group then forwards its recommendation to the director of the Defense Health Agency for final approval for use. The sticking point came in care given outside of military treatment facilities for TRICARE’s beneficiaries. TRICARE requires that all tests it covers meet FDA approval, automatically eliminating many lab-developed tests from even being considered.

The demonstration allows TRICARE to evaluate these tests for safety and value and approve their use. More than 100 tests have been given the green light. Those include tests for diagnosing cancers as well as blood or clotting disorders, genetic diseases or syndromes, and neurological conditions. Some tests are only for specific conditions or rare diseases.

Military hospitals already have their own lab-developed tests. The tests are similar to, but not exactly the same as, those covered under this TRICARE demonstration program. Army Lt. Col. George Leonard, a pathologist in charge of medical oversight for the laboratory at Madigan Army Medical Center at Joint Base Lewis-McChord in Washington state, said they have several tests that help them respond more quickly when treating patients.

“For example, we developed an assay for Bordetella pertussis, better known as whooping cough,” said Leonard. “This allowed us to diagnose Bordetella pertussis within hours, instead of culture testing, which takes days. If you have something that is potentially very contagious and you can’t give a diagnosis until days later, you’ve really gotten yourself behind the curve when it comes to preventive medicine or epidemiologic control of that organism.”

Leonard pointed out that while a patient is being diagnosed over a number of days, disease could spread to a larger community. If caution dictated, everyone who may have come in contact with a patient being tested would be quarantined for several days under the old test. That’s a tremendous amount of lost work and productivity if the test came back negative. The lab-developed tests also help avoid misdiagnosing a disease.

“Bordetella parapertussis (a closely related to but a distinct species from Bordetella pertussis) might present almost the same clinically,” he said. “While culture may only detect pertussis, our assay can tell us if a patient has a related disorder so we can treat them correctly.”

Leonard also wanted to dispel any perception that these lab-developed tests, while not FDA-approved, are not up to par. “We apply the same rigorous standards for accuracy and validity for lab-developed tests as the FDA approved ones. Our tests give accurate and reproducible results,” he said.

Black said these types of testing, under the demonstration project and in use at military facilities, are just one more tool the Military Health System uses to keep up with the rapid pace of innovation in health care.

“The demonstration allowed us to develop a process to evaluate these tests for safety and efficacy,” said Black. “Using lab-developed tests, we’ve made great strides in care.”
Secretary Shulkin made the following statement on the agreement reached on funding to increase veterans access to health care and strengthen VA workforce:

“On behalf of the Department of Veterans Affairs (VA) and the nation’s Veterans, I want to commend the leadership of the House and Senate Veterans’ Affairs Committees on their agreement on legislation that will greatly benefit Veterans.

“Recently, I notified the committees of an issue that arose from Veterans’ increased use of the Veterans Choice program. Because of this surge in usage, VA needs replenishment of Veterans Choice funding earlier than expected.

“The Committees have responded to this urgent need. In a truly bipartisan way, they have put together legislation that provides $2.1 billion to avoid a disruption in the Veterans Choice program and strengthens VA’s internal capacity by authorizing 28 major medical leases.

“This will allow VA to bring new facilities closer to where Veterans live, and those facilities will bring increased convenience and access to VA health care.

“The Committees included measures that will improve VA’s most valuable asset – its employees. The legislation will make it easier to hire the most sought after medical specialists, as well as establish innovative human resources programs to strengthen workforce management.

“I urge the House of Representatives to act swiftly, so this legislation can be considered in the Senate before the August recess begins.”

Veterans Affairs Secretary David Shulkin wrote an OpEd piece in USA Today on July 24, 2017. In it, he asserting that the VA will not be privatized under the Trump Administration. [https://www.usatoday.com/story/opinion/2017/07/24/veterans-health-care-will-not-be-privatized-david-shulkin-column/499417001/](https://www.usatoday.com/story/opinion/2017/07/24/veterans-health-care-will-not-be-privatized-david-shulkin-column/499417001/)

The U.S. Department of Health and Human Services (HHS) Office on Women’s Health (OWH) announced 16 awards to public and private nonprofit entities across the nation.

The projects were selected to address the primary and/or secondary prevention of prescription and illegal opioid misuse by women across the lifespan. Funds will be used to reach girls aged 10-17 years, women of reproductive age, and women aged 50 years and older in underserved populations.

Last month a [report - PDF](https://www.ncbi.nlm.nih.gov/books/NBK524257/) issued by the Agency for Healthcare Research and Quality found that hospitalizations involving opioid pain relievers and heroin increased 75 percent for women between 2005 and 2014, compared to a 55 percent increase among men. Additionally, according to the Centers for Disease Control and Prevention, between 1999 and 2015, overdose deaths from prescription pain killers increased 218 percent in men, while for women it increased over 471 percent. Between 2002 and 2013, heroin use among men increased 50 percent, compared to 100 percent in women.

The organizations each receiving awards of approximately $100,000 are:

- Volunteers of America of Los Angeles, Los Angeles, California
- Women Organized to Respond to Life-Threatening Diseases, Oakland, California
- Community Clinics Health Network, San Diego, California
The Wheeler Clinic Inc., Plainville, Connecticut
Northeast Florida Healthy Start Coalition Inc., Jacksonville, Florida
Parent Child Center Community Wellness Center, Oak Park, Illinois
Iowa Department of Public Health, Des Moines, Iowa
Capitol Area Human Services District, Baton Rouge, Louisiana
Western Maryland Area Health Education Center, Cumberland, Maryland
Institute for Health and Recovery Inc., Cambridge, Massachusetts
Minnesota Department of Health, St. Paul, Minnesota
National Council on Alcoholism and Drug Dependence of Middlesex, East Brunswick, New Jersey
Rowan University School of Osteopathic Medicine, Stratford, New Jersey
Cardea Services, Austin, Texas
The Lakes Community Health Center, Inc., Iron River, Wisconsin
City of Janesville, Janesville, Wisconsin

In addition to the grant awards, OWH also recently issued a report that examined the impact of the opioid epidemic on women and highlighted promising practices that address their specific needs.

For additional information on the HHS Secretary's Initiative aimed at reducing prescription opioid and heroin related overdose, deaths, and dependence, visit: www.hhs.gov/opioids.

REPORTS/POLICIES

- There were no health care reports published this week.

HILL HEARINGS

- There are no relevant hearings scheduled next week.

LEGISLATION

- **H.R.3358** (introduced July 24, 2017): the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2018 was placed on the Calendar. Sponsor: Representative Tom Cole [R-OK-4]

- **H.R.3394** (introduced July 25, 2017): To reauthorize section 340H of the Public Health Service Act to continue to encourage the expansion, maintenance, and establishment of approved graduate medical residency programs was referred to the House Committee on Energy and Commerce. Sponsor: Representative Cathy McMorris Rodgers [R-WA-5]

- **H.R.3417** (introduced July 26, 2017): To authorize the Secretary of Health and Human Services to carry out a pilot program to improve community-based care infrastructure was referred to the House Committee on Energy and Commerce. Sponsor: Representative Janice D. Schakowsky [D-IL-9]
- **H.R.3360** (introduced July 24, 2017): To promote and expand the application of telehealth under Medicare and other Federal health care programs and for other purposes was referred to the Committee on Energy and Commerce. Sponsor: Representative Gregg Harper [R-MS-3]

- **H.R.3368** (introduced July 24, 2017): To amend title 38, United States Code, to improve the access to childcare for certain veterans receiving health care at a facility of the Department of Veterans Affairs was referred to the House Committee on Veterans’ Affairs. Sponsor: Representative Brian. Higgins [D-NY-26]

### MEETINGS


- The 2017 AMSUS Annual Continuing Education Meeting will be held on **Nov. 27- Dec. 1, 2017**, at the Gaylord National Harbor, Md. [http://www.amsus.org/annual-meeting/](http://www.amsus.org/annual-meeting/)

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