

# Federal Health Update

JULY 29, 2016

*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

- **The House and Senate are in recess until Sept. 5, 2016.**
  
- **On July 22, 2016, President Obama signed into law:**
  - H.R. 5588, the “Veterans’ Compensation COLA Act of 2016,” which provides for a cost-of-living adjustment (COLA) for the beneficiaries of veterans' disability compensation and dependency and indemnity compensation equal to the Social Security COLA.
  - S. 524, the “Comprehensive Addiction and Recovery Act of 2016,” which addresses prescription opioid abuse and addiction by, among other provisions: (1) authorizing grant programs for abuse prevention and education, including prescription monitoring; (2) expanding access to treatment and recovery options, including medication-assisted treatment and overdose reversal drugs; (3) expanding law enforcement grants and prescription drug take-back programs; and (4) providing specific opioid abuse prevention, treatment, and recovery resources to veterans, women, and children.

## MILITARY HEALTH CARE NEWS

- **On July 22, 2016, the Defense Department announced Health Net Federal Services and Humana Military would be the contractors to manage the latest generation of its TRICARE health care program.**

The contracts worth \$59 billion collectively over six years. Health Net Federal Services will receive 18 billion to manage health care for the West Region; Humana Military will receive \$41 billion for the East Region.

The vast majority of DoD's spending under the cost-plus-incentive fee contracts will be passed through to the thousands of private-sector health care providers who take part in the TRICARE system during the life of the contract, which will be effective in 2017. Each firm will be allowed a nine-month phase-in period.

The latest round of contracts — dubbed T-2017, the fourth since Congress created the TRICARE system in 1994 — also consolidates the military's health care regions, combining the current North and South contracts into a new East region. The Defense Health Agency merged its own North and South oversight offices into one oversight structure on July 1 in anticipation of the change.

The contracts will be a cost-plus-fixed-fee contract with a nine-month base period (transition-in) and five one-year option periods for health care delivery, plus a transition-out period.

The newly formed East Region includes the District of Columbia, and the states of Alabama, Arkansas, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Iowa (Rock Island Arsenal area only), Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri (St. Louis area only); New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas (excluding areas of Western Texas), Vermont, Virginia, West Virginia, and Wisconsin. There are approximately 6 million TRICARE beneficiaries within this Region.

Four companies submitted proposals for the East Region contract.

Health Net Federal Services, which served as the contractor for what was the North Region, will take over the contract for TRICARE West. The West Region includes the states of Alaska, Arizona, California, Colorado, Hawaii, Idaho, Iowa (except the Rock Island Arsenal area), Kansas, Minnesota, Missouri (except the St. Louis area), Montana, Nebraska, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Texas (areas of Western Texas only), Utah, Washington, and Wyoming. Approximately 3 million TRICARE beneficiaries will be served within this Region.

Three companies submitted proposals for the West Region contract.

## VETERANS AFFAIRS NEWS

- **Veterans Affairs Secretary Robert McDonald promised same-day access to primary care appointments and mental health services at Veterans Affairs facilities during his remarks at the Veterans of Foreign Wars national convention.**

According to McDonald, veterans wait an average of five days for primary care, six days for specialty care and two for mental health services. The VA has completed 5.3 million appointments at VA hospitals and clinics and 730,000 appointments at community care providers since March 2014.

To read the text of the full remarks, please visit:

[http://www.va.gov/opa/speeches/2016/07\\_26\\_2016.asp](http://www.va.gov/opa/speeches/2016/07_26_2016.asp)

## GENERAL HEALTH CARE NEWS

- **The U.S. Department of Health and Human Services (HHS), the Wellcome Trust of London, the AMR Centre of Alderley Park (Cheshire, United Kingdom), and Boston University School of Law will create one of the world's largest public-private partnerships focused on preclinical discovery and development of new antimicrobial products.**

The Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) represents a global innovation project for antibiotic products research and development. CARB-X brings together multiple domestic and international partners and capabilities to find potential antibiotics and move them through preclinical testing to enable safety and efficacy testing in humans and greatly reducing the business risk, which can make advanced development more attractive to private sector investment.

The Biomedical Advanced Research and Development Authority (BARDA), and the National Institutes of Health's National Institute of Allergy and Infectious Diseases (NIAID) will join the Wellcome Trust and the AMR Centre in joint oversight of the project.

Two U.S. non-profit life science accelerators — Massachusetts Biotechnology Council in Cambridge, Massachusetts (MassBio), and the California Life Sciences Institute (CLSI) of South San Francisco, California, will provide support for early-stage antibiotic development projects.

- BARDA will provide \$30 million during the project's first year and up to \$250 million during the five-year project.
- The AMR Centre, a public-private initiative formed in February 2016 to drive the development of new antibiotics and diagnostics, aims to provide \$14 million to support CARB-X projects in year one and up to \$100 million over five years. The Wellcome Trust, a global charitable foundation focused on biomedical research, will contribute further funding and its expertise in overseeing projects of this kind.
- NIAID, which leads the U.S. government in biomedical research on infectious and immune-mediated diseases and developing better means of preventing, diagnosing and treating these illnesses, will provide in-kind research support, including preclinical research expertise, to projects that CARB-X supports. NIAID will also provide technical support related to early-stage antibiotic drug discovery and product development.

The end goal of CARB-X is to move promising antibiotic candidates through early stages of research and development, so that they merit private or public investment for advanced development and earn approval by the FDA and/or the Medicines and Healthcare products Regulatory Agency of the United Kingdom.

CARB-X will be headquartered at the Boston University School of Law in Boston, Massachusetts, where the CARB-X executive team will be led by Kevin Outterson, a health law researcher and collaborator in global projects to address antibiotic resistance. The executive team will be comprised of experts with decades of experience in drug development, including in the area of antibacterial drugs.

Starting in September 2016, CARB-X will review applications for sub-awards to determine the most promising products to support. The agencies and organizations providing funding to CARB-X, namely BARDA, will have a final say in which projects are supported under the cooperative agreement.

Interested companies can visit the CARB-X page on [www.phe.gov](http://www.phe.gov) or [www.carb-x.org](http://www.carb-x.org) for more information.

- **The U.S. Food and Drug Administration approved Adlyxin (lixisenatide), a once-daily injection to improve glycemic control (blood sugar levels), along with diet and exercise, in adults with type 2 diabetes.**

Type 2 diabetes affects more than 29 million people and accounts for more than 90 percent of diabetes cases diagnosed in the United States. Over time, high blood sugar levels can increase the risk for serious complications, including heart disease, blindness and nerve and kidney damage.

Adlyxin is a glucagon-like peptide-1 (GLP-1) receptor agonist, a hormone that helps normalize blood sugar levels. The drug's safety and effectiveness were evaluated in 10 clinical trials that enrolled 5,400 patients with type 2 diabetes. In these trials, Adlyxin was evaluated both as a standalone therapy and in combination with other FDA-approved diabetic medications, including metformin, sulfonylureas, pioglitazone and basal insulin. Use of Adlyxin improved hemoglobin A1c levels (a measure of blood sugar levels) in these trials.

In addition, more than 6,000 patients with type 2 diabetes at risk for atherosclerotic cardiovascular disease were treated with either Adlyxin or a placebo in a cardiovascular outcomes trial. Use of Adlyxin did not increase the risk of cardiovascular adverse events in these patients.

Adlyxin should not be used to treat people with type 1 diabetes or patients with increased ketones in their blood or urine (diabetic ketoacidosis).

Adlyxin is manufactured by Sanofi-Aventis U.S. LLC, of Bridgewater, New Jersey.

## REPORTS/POLICIES

- There were no relevant reports published this week.

## HILL HEARINGS

- There are no hearings next week.

## LEGISLATION

- There was no legislation introduced this week.

## 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/>

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