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

The Update will not be published on Aug 24 and 31, 2018.

EXECUTIVE AND CONGRESSIONAL NEWS

- The House will be in recess in October.

- The House passed H R 6157, the conference report for the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019. The legislation provides $684 billion provides more than $606 billion in base defense spending and nearly $68 billion more in overseas contingency funds. The measure funds a 2.6 percent pay raise for troops starting next January and a boost in military end strength of 16,400 spread across the active-duty and reserve forces. Operation and maintenance spending totals $243.2 billion of the defense total, and research and development efforts another $96.1 billion. Defense health and military family programs would receive $34.4 billion. The Senate passed the bill last week. President Donald Trump has promised to sign the bill, eliminating the chance for a government shutdown.

MILITARY HEALTH CARE NEWS

- The White House announced that former Army Staff Sgt. Ronald J. Shurer II, a medic with the 3rd Special Forces Group (Airborne), will receive the Medal of Honor on Oct. 1, 2018.
Shurer went above and beyond the call of duty April 6, 2008, while assigned to Special Operations Task Force 33 in Afghanistan during Operation Enduring Freedom. In April 2008, Shurer was assigned to support Special Forces operators working to take out high-value targets of the Hezab Islami al Gulbadin in Shok Valley. As the team navigated through the valley, a firefight quickly erupted, and a series of insurgent sniper fire, rocket-propelled grenades, and small arms and machine gun fire forced the unit into a defensive fighting position.

Around that time, Shurer received word that their forward assault element was also pinned down at another location, and the forward team had suffered multiple casualties.

With disregard for his safety, Shurer moved quickly through a hail of bullets toward the base of the mountain to reach the pinned-down forward element. While on the move, Shurer stopped to treat a wounded teammate's neck injury caused by shrapnel from a recent RPG blast.

After providing aid, Shurer spent the next hour fighting across several hundred meters and killing multiple insurgents. Eventually, Shurer arrived to support the pinned down element and immediately rendered aid to four critically wounded U.S. units and 10 injured commandos until teammates arrived.

Soon after their arrival, Shurer and his team sergeant were shot at the same time. The medic ran 15 meters through a barrage of gunfire to help his sergeant. Despite a bullet hitting his helmet and a gunshot wound to his arm, Shurer pulled his teammate to cover and rendered care.

Moments later, Shurer moved back through heavy gunfire to help sustain another teammate who had suffered a traumatic amputation of his right leg.

For the next several hours, Shurer helped keep the large insurgent force at bay while simultaneously providing care to his wounded teammates. Shurer's actions helped save the lives of all wounded casualties under his care.

Shurer also helped evacuate three critically wounded, teammates down a nearly vertical 60-foot cliff, all while avoiding rounds of enemy gunfire and falling debris caused by numerous airstrikes.

Further, Shurer found a run of nylon webbing and used it to lower casualties while he physically shielded them from falling debris.

Shurer's Medal of Honor was upgraded from a Silver Star upon review.

**According to Military.com, there is a shortage of providers in TRICARE's western region and the provider directory is inaccurate and incomplete. In the east region, Defense Health Agency (DHA) reports of slow claim processing.**

In a briefing, DHA reports Health Net, the managed care contractor for the western region, is short 503 primary-care providers and specialists in 12 regional areas, as of August 2018. In addition, the provider directory is correct for only 25 percent correct of the western region. In some cases, no providers are listed for their area when some actually are available.

In the eastern region, DHA reported that Humana is under the standard, or "red," in four of the eight categories used to measure claims processing through, including processing times and accuracy. Humana is currently meeting that 130-day benchmark in only about 70 percent of cases.

Humana says it has made changes in to its subcontracting to erase the remaining claims backlog by the end of the month.

The new contracts went into effect on January 1, 2018.
The Department of Veterans Affairs (VA) released national and state-level findings from its most recent analysis of veteran suicide data, from 2005 to 2016.

The new data show that veterans accounted for 14 percent of suicides nationwide though they make up only 8 percent of the U.S. population. The suicide rate for female veterans is 1.8 times higher than their civilian counterparts.

The report yields several important insights:

- From 2015 to 2016, the overall current and former service member suicide count decreased from 7,663 to 7,298 deaths (decrease of 365).
- From 2015 to 2016, the veteran specific suicide count decreased from 6,281 to 6,079 deaths (decrease of 202).
- Overall, the fact remains that on average about 20 current or former service members die each day, six have been in VA health care and 14 were not.
- Rates of suicide were highest among younger veterans (ages 18-34) and lowest among older veterans (ages 55 and older). However, because the older veteran population is the largest, this group accounted for 58.1 percent of Veteran suicide deaths in 2016.
- The rate of suicide among 18-34-year-old veterans continues to increase.
- The use of firearms as a method of suicide remains high. The percentage of suicide deaths that involved firearms was 67.0 percent in 2015 and 69.4 percent in 2016.

The 2016 VA National Suicide Data Report follows a new format, designed to be easier to understand and consume. This report does not highlight the average number of suicides per day, a measure that is commonly misinterpreted as a rate. Unlike a rate, the count per day does not account for changes in population size. VA’s goal is to present complex suicide data in the most actionable format and to convey the key findings in the clearest terms. The “VA National Suicide Data Report 2005–2016,” and the accompanying state data sheets are available at: [https://www.mentalhealth.va.gov/suicide_prevention/Suicide-Prevention-Data.asp](https://www.mentalhealth.va.gov/suicide_prevention/Suicide-Prevention-Data.asp)

Veterans who are in crisis or having thoughts of suicide, and those who know a Veteran in crisis, can call the Veterans Crisis Line for confidential crisis intervention and support 24 hours a day, seven days a week, 365 days a year. Call 800-273-8255 and press 1; send a text message to 838255 or chat online at [VeteransCrisisLine.net/Chat](https://VeteransCrisisLine.net/Chat).

Department of Veterans Affairs (VA) scientists at the VA Ann Arbor Healthcare System in Michigan recently announced that they are working to create a 3D-printed artificial lung that could potentially revolutionize treatment of Veterans affected by lung disease.

Though still in its infancy, VA researchers hope to build what they call the first artificial lung that closely replicates the natural lung, resulting in compatibility with living cells and a very small size for portable or wearable short- and long-term respiratory support.

In the near term, the device could be used as a temporary measure — a bridge to help patients waiting lung transplant or an aid for veterans with recovering lungs. According to researchers, future versions could have longer-term applications.

Exposure to burn pits, sand, diesel exhaust and chemicals are some of the most commonly cited factors that lead to lung problems for active-duty military. About 20 percent of patients with severe traumatic brain injury also have acute lung injury.

One lung disorder VA researchers hope to tackle someday with the 3D-printed artificial lung is chronic obstructive pulmonary disease (COPD), regarded as one of the most prevalent and costliest ailments in the Veteran population.
COPD affects 5 percent of American adults and 16 percent of the veteran population. Most people with COPD have emphysema, in which the air sacs of the lung are damaged and enlarged, and chronic bronchitis, a long-lasting cough caused by chronic inflammation of the bronchial tubes. The disease is characterized by an airflow limitation that is often linked to an abnormal response of the lungs to noxious particles or gases, such as those in cigarette smoke.


GENERAL HEALTH CARE NEWS

- **The Biomedical Advanced Research and Development Authority (BARDA) will sponsor the advanced development of the new testing technology under an 18-month, approximately $9.3 million contract with SeLux Diagnostic, Inc of Charlestown, Massachusetts.**

  SeLux is developing a phenotypic test; it identifies bacteria based on observable physical or biochemical characteristics of the bacteria. Based on the characteristics, the test identifies the class of bacteria and which antibiotics are best for treating that particular bacterial infection.

  Faster information to select the best antibiotic can speed a patient’s recovery, which means fewer days spent in a hospital and better outcomes for patients. The ability to match bacteria more precisely to the drugs that will combat the infection also could curb antibiotic resistant infections.

  “Antibiotic resistance is a growing threat to public health and to the health security of the United States,” said BARDA Director Rick Bright, Ph.D. “In a bioterrorism incident, antibiotic resistant infections could be devastating. We will need innovative tools for precision medicine to save lives.”

  BARDA is sponsoring the development of two test systems from SeLux. The company’s first-generation test system may be able to provide results using bacteria isolated from patient samples 24 hours faster than current state-of-the-art methods and may be able to provide results from blood samples three days faster than the current methods. The company’s second-generation test system may be able to provide results the same day that the test is started.

  The tests are designed to be used in hospital and commercial laboratories. Rapid information on bacteria and how susceptible they are to antibiotics would help doctors make earlier, better-informed decisions about how best to treat infections.

  BARDA funding will support necessary work for the company to apply for U.S. Food and Drug Administration (FDA) approval. The agreement can be extended to fund additional work up to a total of approximately $36 million through 2023.

- **The Department of Health and Human Services (HHS) has awarded three new grants to combat opioid addiction and improve access to mental health services for youth and young adults.**

  The grants funding by HHS’s Substance Abuse and Mental Health Services Administration (SAMHSA) were awarded to Fairbanks Native Association and Tanana Chiefs Conference, Inc., are expected to total over $6.2 million over the next few years.

  Over the next five years, Tanana Chiefs Conference, Inc., is expected to receive just under $5 million for a Healthy Transitions Grant. The grant will be used to provide developmentally
appropriate, culturally and linguistically competent services and supports to address serious mental disorders among youth and young adults 16 – 25 years of age. The goal is maximize their potential to assume adult roles and responsibilities and lead full productive lives.

Both Tanana Chiefs Conference and Fairbanks Native Association were awarded a Tribal Opioid Response Grant. Over the next two years, Tanana Chiefs Conference is expected to receive just over $700,000 and Fairbanks Native Associations is expected to receive just over $500,000 to increase access to culturally appropriate and evidence-based treatment, including medication-assisted treatment (MAT), for opioid use disorders.

These grants add to the more than $1 billion announced last week for opioid-specific grants for states to address the crisis affecting the country. To learn more about HHS’s recent actions to combat the opioid epidemic visit https://www.hhs.gov/about/news/2018/09/19/hhs-awards-over-1-billion-combat-opioid-crisis.html.

For additional information on these and other SAMHSA grant awards please visit www.SAMHSA.gov/grants.

- The U.S. Food and Drug Administration has awarded 12 new clinical trial research grants totaling more than $18 million over the next four years to enhance the development of medical products for patients with rare diseases.

These new grants were awarded to principal investigators from academia and industry across the country.

The FDA awarded the grants through the Orphan Products Clinical Trials Grants Program. This program is funded by Congressional appropriations and encourages clinical development of drugs, biologics, medical devices or medical foods for use in rare diseases. The grants are intended for clinical studies evaluating the safety and effectiveness of products that could either result in, or substantially contribute to, the FDA approval of products targeted to the treatment of rare diseases. Grant applications were reviewed and evaluated for scientific and technical merit by more than 100 rare disease experts, which included representatives from academia, the National Institutes of Health and the FDA.

The grant recipients, principal investigators and approximate funding amounts are:

- Alkeus Pharmaceuticals, Inc. (Cambridge, Massachusetts), Leonide Saad, phase 2 study of ALK-001 for the treatment of Stargardt disease – $1.75 million over four years
- Arizona State University-Tempe Campus (Tempe, Arizona), Keith Lindor, phase 2 study of oral vancomycin for the treatment of primary sclerosing cholangitis – $2 million over four years
- Cedars-Sinai Medical Center (Los Angeles), Shlomo Melmed, phase 2 study of seliciclib for the treatment of Cushing disease – $2 million over four years
- Columbia University of New York (New York), Yvonne Saenger, phase 1 study of talimogene laherparepvec for the treatment for advanced pancreatic cancer – $750,000 over three years
- Emory University (Atlanta), Eric Sorscher, phase 1/2 study of Ad/PNP fludarabine for the treatment of head and neck squamous cell carcinoma – $1.5 million over three years
- Fibrocell Technologies, Inc. (Exton, Pennsylvania), John Maslowski, phase 1/2 study of gene-modified ex-vivo autologous fibroblasts for the treatment of dystrophic epidermolysis bullosa – $1.5 million over four years
- Johns Hopkins University (Baltimore), Amy Dezern, phase 1/2 study of CD8-reduced T
cells for the treatment of myelodysplastic syndrome or acute myeloid leukemia – $750,000 over three years

- Oncolimmune, Inc. (Rockville, Maryland) Yang Liu, phase 2b study of CD24Fc for the prevention of graft versus host disease – $2 million over four years

- Patagonia Pharmaceuticals, LLC (Woodcliff Lake, New Jersey), Zachary Rome, phase 2 study of PAT-001 (isotretinoin) for the treatment of congenital ichthyosis – $1.5 million over three years

- The General Hospital Corporation (Boston), Stephanie Seminara, phase 2 study of kisspeptin for the treatment of dopamine agonist intolerant hyperprolactinemia – $1.4 million over four years

- University of Minnesota (Minneapolis), Kyriakie Sarafoglou, phase 2a study of subcutaneous hydrocortisone infusion pump for the treatment of congenital adrenal hyperplasia – $1.4 million over three years

- University of North Carolina at Chapel Hill (Chapel Hill, North Carolina), Matthew Laughon, phase 2 study of sildenafil for the prevention of bronchopulmonary dysplasia – $2 million over four years

One-third (33 percent) of the new awards aim to accelerate cancer research by enrolling patients with rare forms of cancer, including advanced pancreatic cancer, head and neck squamous cell carcinoma, myelodysplastic syndrome and acute myeloid leukemia. Another 25 percent of the new awards fund studies evaluating drug products for rare endocrine disorders, including Cushing disease, dopamine agonist intolerant hyperprolactinemia and congenital adrenal hyperplasia. Another study addresses an unmet need in primary sclerosing cholangitis, a rare, chronic and potentially serious bile duct disease.

About 42 percent of the grants fund studies which enroll children and adolescents, targeting a variety of rare diseases in children such as Stargardt disease, a juvenile genetic eye disorder that causes progressive vision loss; dystrophic epidermolysis bullosa, a genetic condition that causes the skin to be fragile resulting in painful blisters; and bronchopulmonary dysplasia, a serious lung condition that affects infants.

To date, the program’s grants have supported research that led to the marketing approval of more than 60 orphan products. Among the recent product approvals which were supported by studies funded by this grants program are a marketing approval for a much-needed treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults with multidrug resistant HIV-1 infection and another approval to reduce the acute complications of sickle cell disease in adult and pediatric patients.

Since its creation in 1983, the Orphan Products Grants Program has provided more than $400 million to fund more than 600 new clinical studies.

REPORTS/POLICIES

- The National Academies of Sciences, Engineering and Medicine published “Exploring Tax Policy to Advance Population Health, Health Equity, and Economic Prosperity—Proceedings of a Workshop,” on Sept. 20, 2018. This report explores tax policy focusing on taxes, credits, policy design considerations and redirecting resources to support population health interventions. It examines how tax policies have been used to channel resources and shape economic incentives in support of population health goals, and to equip participants with basic knowledge of tax policy and ways to engage in dialogue about it with community members and stakeholders. http://nationalacademies.org/hmd/reports/2018/explore-tax-policy-advance-population-health-health-equity-economic-prosperity-proceedings.aspx
**HILL HEARINGS**

- The Senate Health, Education, Labor, and Pensions Subcommittee on Children and Families will hold a hearing on **Oct. 3, 2018**, to examine rare diseases, focusing on expediting treatments for patients.

**LEGISLATION**

- **S.3501** (introduced Sept. 26, 2018): A bill to require the Secretary of Veterans Affairs to enter into a contract or other agreement with a third party to review appointees in the Veterans Health Administration who had a license terminated for cause by a State licensing board for care or services rendered at a non-Veterans Health Administration facility and providing individuals treated by such an appointee with notice if it is determined that an episode of care or services to which they received was below the standard of care, and for other purposes was referred to the Committee on Veterans’ Affairs. Sponsor: Senator Joni Ernst [R-IA]

- **S.3482** (introduced Sept. 26, 2018): A bill to amend the Public Health Service Act to reauthorize the Emergency Medical Services for Children program was referred to the Committee on Health, Education, Labor, and Pension. Sponsor: Senator Robert P. Casey Jr. [D-PA]

- **S.3485** (introduced Sept. 24, 2018): A bill to allow States to expand basic health programs to cover more low-income individuals at lower cost was referred to the Committee on Health, Education, Labor, and Pensions. Sponsor: Senator Maria Cantwell [D-WA]

- **H.R.6898** (introduced Sept. 26, 2018): To amend the Health Insurance Portability and Accountability Act to ensure coverage for individuals with preexisting conditions, and for other purposes was referred to the Committees on Energy and Commerce, Ways and Means, and Education and the Workforce. Sponsor: Representative Stephen Knight [R-CA-25]

- **S.3500** (introduced Sept. 26, 2018): A bill to authorize the Secretary of Health and Human Services to conduct programs to address the usage of illicit drugs, particularly fentanyl, and for other purposes was referred to the Committee on Health, Education, Labor, and Pensions. Sponsor: Senator Elizabeth Warren [D-MA]

- **S.3496** (introduced Sept. 25, 2018): A bill to direct the Secretary of Health and Human Services to conduct a study and submit a report on the effects of the inclusion of quality increases in the determination of blended benchmark amounts under part C of the Medicare program was referred to the Committee on Finance. Sponsor: Senator Steve Daines [R-MT]

**MEETINGS**


- The 2018 AMSUS Annual Continuing Education Meeting will be held on **Nov. 26-30, 2018**, at the Gaylord National Harbor, Md. [http://www.amsusmeetings.org/home-2/](http://www.amsusmeetings.org/home-2/)
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.