

Federal Health Update

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

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Best Wishes for a Happy Labor Day!

EXECUTIVE AND CONGRESSIONAL NEWS

- **Congress returns next week.**

MILITARY HEALTH CARE NEWS

- **Defense Secretary Jim Mattis released the following statement on Aug. 29 regarding the military service by transgender individuals.**

In his statement, he indicated that the current policy for transgender service members would remain unchanged until a study has been completed and a panel of experts from DoD and HHS has offered its recommendations.

“The Department of Defense has received the Presidential Memorandum, dated August 25, 2017, entitled “Military Service by Transgender Individuals.”

“The department will carry out the president’s policy direction, in consultation with the Department of Homeland Security. As directed, we will develop a study and implementation plan, which will contain the steps that will promote military readiness, lethality, and unit cohesion,

with due regard for budgetary constraints and consistent with applicable law. The soon arriving senior civilian leadership of DOD will play an important role in this effort. The implementation plan will address accessions of transgender individuals and transgender individuals currently serving in the United States military.

“Our focus must always be on what is best for the military’s combat effectiveness leading to victory on the battlefield. To that end, I will establish a panel of experts serving within the Departments of Defense and Homeland Security to provide advice and recommendations on the implementation of the president’s direction. Panel members will bring mature experience, most notably in combat and deployed operations, and seasoned judgment to this task. The panel will assemble and thoroughly analyze all pertinent data, quantifiable and non-quantifiable. Further information on the panel will be forthcoming.

“Once the panel reports its recommendations and following my consultation with the secretary of Homeland Security, I will provide my advice to the president concerning implementation of his policy direction. In the interim, current policy with respect to currently serving members will remain in place. I expect to issue interim guidance to the force concerning the president’s direction, including any necessary interim adjustments to procedures, to ensure the continued combat readiness of the force until our final policy on this subject is issued.”

▪ **The governors of Louisiana and Texas have declared a State of Emergency due to Hurricane Harvey.**

TRICARE announced that emergency refill procedures are in place from Aug. 23 - Sept. 15, 2017 for the following counties:

Texas: Aransas, Atascosa, Austin, Bastrop, Bee, Bexar, Brazoria, Brazos, Burleson, Caldwell, Calhoun, Cameron, Chambers, Colorado, Comal, DeWitt, Fayette, Fort Bend, Galveston, Goliad, Gonzales, Grimes, Guadalupe, Hardin, Harris, Jackson, Jasper, Jefferson, Jim Wells, Karnes, Kerr, Kleberg, Lavaca, Lee, Leon, Liberty, Live Oak, Madison, Matagorda, Montgomery, Newton, Nueces, Polk, Refugio, San Jacinto, San Patricio, Tyler, Victoria, Waller, Walker, Washington, Wharton, Wilson and Willacy.

Louisiana: All counties

To get an emergency refill, take your prescription bottle to any TRICARE retail network pharmacy. To find a network pharmacy, call Express Scripts at 1-877-363-1303 or use the [network pharmacy locator](#). If possible, visit the pharmacy where the prescription was filled.

- If you use a retail chain, you can fill your prescription at another store in that chain.
- If your provider is available, he or she may call in a new prescription to any network pharmacy.
- You can request assistance at another pharmacy, but it's at that pharmacy's discretion to help you.

For beneficiaries in the affected areas, TRICARE has waived the referral requirement. This includes the following locations:

Texas: Aransas, Austin, Bastrop, Bee, Brazos, Burleson, Calhoun, Chambers, Colorado, Brazoria, DeWitt, Fayette, Fort Bend, Galveston, Goliad, Gonzales, Grimes, Hardin, Harris, Jackson, Jasper, Jefferson, Jim Wells, Karnes, Kleberg, Lavaca, Lee, Leon, Liberty, Live Oak, Madison, Matagorda, Montgomery, Newton, Nueces, Polk, Refugio, San Jacinto, San Patricio, Tyler, Victoria, Waller, Walker, Washington, Wharton, and Wilson.

Effective Dates: Aug. 24 – Sept. 5, 2017

VETERANS AFFAIRS NEWS

- **The Department of Veterans Affairs (VA) announced a new partnership to increase access to lung screening for veterans.**

Sponsored by the Bristol-Myers Squibb Foundation, the project brings together experts from within and outside VA to develop the VA-PALS Implementation Network (VA-Partnership to increase Access to Lung Screening). Its goal is to develop early-detection programs for lung cancer, a malignancy with an 80 percent cure rate when caught early.

This new project will launch lung-screening services at the Phoenix VA Health Care System by December 2017, and then extend these services to nine additional VA medical facilities starting in 2018. Once fully implemented, the project has the potential to become even more widely available throughout VA.

The VA-PALS initiative builds upon lessons learned from currently available screening programs, including those of VA's Office of Rural Health, which is supporting the project's goal to reach Veterans living in rural areas. It also adds to a portfolio of other major VA lung cancer initiatives, which include the VALOR Trial (Veterans Affairs Lung Cancer Or Stereotactic Radiotherapy) and the APOLLO Network (Applied Proteogenomics Organizational Learning and Outcomes).

- **Veterans Affairs (VA) Secretary Dr. David J. Shulkin announced that VA plans to propose changes to regulations for its State Veterans Home Construction Grant Program to make it easier to for states to receive VA funding to construct Veterans homes in rural areas.**

State Veterans Homes provide veterans with nursing home, domiciliary or adult day health care and are owned, operated and managed by state governments.

Currently, the construction grant regulations focus on veteran demographics as well as nursing home and domiciliary bed need within a State, when determining priority group placement based on projected demand for assistance. Unfortunately, this makes it difficult for some rural areas to compete for VA State Home Construction Grants.

In highly rural areas, there could be a 500-mile distance from one State Veterans Home to the next, which gives family members limited options when searching for a conveniently located facility for a veteran family member.

By incorporating a consideration for the need of veterans in rural areas into the ranking priorities for grant applications in the regulations, rural states may find it easier to compete for the limited VA construction grant funding that is available.

"We want to remove the red tape," said Secretary Shulkin. "Veterans in rural areas need to be able to get nursing home care when it's needed as close as possible to their homes, families and friends. Changes in VA regulations can save families from having to travel long distances to visit a loved one in a facility far from home."

VA anticipates that the revision of these regulations will be completed by the end of this calendar year (2017). The updated regulations will be available for public comment. VA is working to ensure that the updated regulations go into effect as soon as possible.

For more information about State Veterans Homes, visit https://www.va.gov/GERIATRICS/Guide/LongTermCare/State_Veterans_Homes.asp.

GENERAL HEALTH CARE NEWS

- **U.S. Department of Health and Human Services (HHS) established a 250-bed Federal Medical Station for those sheltering at the George R. Brown Convention Center in Houston.**

HHS also is helping evacuate hospital patients to healthcare facilities outside the impacted area.

The Federal Medical Station at the convention center will be staffed by members of HHS' National Disaster Medical System and U.S. Public Health Service Commissioned Corps.

HHS has additional Federal Medical Stations available for patient care in Texas, and has positioned two 250-bed Federal Medical Stations in Baton Rouge ready to be deployed in Louisiana should state officials determine they are needed.

HHS has more than 500 personnel on the ground to assist those affected by Hurricane Harvey and 1,300 more on standby.

HHS also has helped local public health officials address the needs of those who rely upon electricity-dependent medical equipment. Using its emPOWER tool, HHS has provided information to local public health officials about the number of Medicare beneficiaries in each impacted area who rely on 14 types of life-maintaining and assistive equipment, ranging from oxygen concentrators to electric wheelchairs, as well as data on the number of people who rely on dialysis, oxygen, and home health services. These citizens are among the most vulnerable in their communities and most likely to need life-saving assistance in prolonged power outages.

HHS has activated its Disaster Distress Helpline, a toll-free call center, that is available at 1-800-985-5990 to aid people in coping with the behavioral health effects of the storm and help people in impacted areas connect with local behavioral health professionals.

In addition to full-scale coordination across the federal Cabinet agencies, HHS remains in regular contact with Texas and Louisiana health officials to maintain awareness of the local situation and stands ready to augment support to the states as the situation unfolds.

HHS' NDMS consists of approximately 5,000 medical, public health, and emergency management professionals from communities nationwide and serve as Federal government employees when activated as part of a coordinated federal response.

- **The Centers for Disease Control and Prevention released findings from its latest obesity study.**

According to the study, all 50 states had more than 1 in 5 adults (20 percent) with obesity. The state with lowest rate of obesity was Colorado (22.3 percent); the state with the highest rate of obesity is West Virginia (37.7 percent).

The South had the highest prevalence of obesity (32.0 percent), followed by the Midwest (31.4 percent), the Northeast (26.9 percent), and the West (26.0 percent). Five states (Alabama, Arkansas, Louisiana, Mississippi, and West Virginia) now have more than 35 percent of adults with obesity.

Adults with more education were less likely to report being obese. Adults without a high school education had the highest self-reported obesity (35.5 percent), followed by high school graduates (32.3 percent), adults with some college (31 percent), and college graduates (22.2 percent).

Obese American adults are more at risk for serious chronic diseases and health conditions. These include:

- Type 2 diabetes

- Cardiovascular disease
- Stroke
- Certain cancers
- Poorer mental health.
- Infertility and problems with pregnancy.

Obesity negatively affects worker productivity, health care costs, and the ability to serve in the military.

Preventing and reducing obesity in the United States will require action by many parts of society. State and community leaders, employers, government agencies, healthcare providers, and many others can help make it easier for adults and their families to move more and eat healthier to reduce the risk of obesity.

Find out more at <https://www.cdc.gov/obesity/strategies/index.htmls>.

- **On Aug. 30, 2017, the U.S. Food and Drug Administration approved the first gene therapy available in the United States, ushering in a new approach to the treatment of cancer and other serious and life-threatening diseases.**

The FDA approved Kymriah (tisagenlecleucel) for certain pediatric and young adult patients with a form of acute lymphoblastic leukemia (ALL).

Kymriah, a cell-based gene therapy, is approved in the United States for the treatment of patients up to 25 years of age with B-cell precursor ALL that is refractory or in second or later relapse.

Kymriah is a genetically-modified autologous T-cell immunotherapy. Each dose of Kymriah is a customized treatment created using an individual patient's own T-cells, a type of white blood cell known as a lymphocyte. The patient's T-cells are collected and sent to a manufacturing center where they are genetically modified to include a new gene that contains a specific protein (a chimeric antigen receptor or CAR) that directs the T-cells to target and kill leukemia cells that have a specific antigen (CD19) on the surface. Once the cells are modified, they are infused back into the patient to kill the cancer cells.

ALL is a cancer of the bone marrow and blood, in which the body makes abnormal lymphocytes. The disease progresses quickly and is the most common childhood cancer in the U.S. The National Cancer Institute estimates that approximately 3,100 patients aged 20 and younger are diagnosed with ALL each year. ALL can be of either T- or B-cell origin, with B-cell the most common. Kymriah is approved for use in pediatric and young adult patients with B-cell ALL and is intended for patients whose cancer has not responded to or has returned after initial treatment, which occurs in an estimated 15-20 percent of patients.

The safety and efficacy of Kymriah were demonstrated in one multicenter clinical trial of 63 pediatric and young adult patients with relapsed or refractory B-cell precursor ALL. The overall remission rate within three months of treatment was 83 percent.

The FDA also expanded the approval of Actemra (tocilizumab) to treat CAR T-cell-induced severe or life-threatening CRS in patients 2 years of age or older. In clinical trials in patients treated with CAR-T cells, 69 percent of patients had complete resolution of CRS within two weeks following one or two doses of Actemra.

Because of the risk of CRS and neurological events, Kymriah is being approved with a risk evaluation and mitigation strategy (REMS), which includes elements to assure safe use (ETASU). The FDA is requiring that hospitals and their associated clinics that dispense Kymriah be specially certified. As part of that certification, staff involved in the prescribing, dispensing, or

administering of Kymriah are required to be trained to recognize and manage CRS and neurological events. Additionally, the certified health care settings are required to have protocols in place to ensure that Kymriah is only given to patients after verifying that tocilizumab is available for immediate administration. The REMS program specifies that patients be informed of the signs and symptoms of CRS and neurological toxicities following infusion – and of the importance of promptly returning to the treatment site if they develop fever or other adverse reactions after receiving treatment with Kymriah.

To further evaluate the long-term safety, Novartis is also required to conduct a post-marketing observational study involving patients treated with Kymriah.

The FDA granted Kymriah [Priority Review](#) and [Breakthrough Therapy](#) designations. The Kymriah application was reviewed using a coordinated, cross-agency approach. The clinical review was coordinated by the FDA's Oncology Center of Excellence, while CBER conducted all other aspects of review and made the final product approval determination.

The FDA granted approval of Kymriah to Novartis Pharmaceuticals Corp. The FDA granted the expanded approval of Actemra to Genentech Inc.

REPORTS/POLICIES

- There were no relevant reports published this week.

HILL HEARINGS

- There are no relevant hearings scheduled until September.

LEGISLATION

- There was no legislation proposed while Congress is in recess.

MEETINGS

- The AUSA 2017 Annual Meeting & Exposition will be held **Oct. 9-11, 2017**, in Washington DC. <http://ausameetings.org/2017annualmeeting/>
- 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/>

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.