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

- House Armed Services Committee Chairman Adam Smith (D-WA) announced the names of the Democrat representatives selected to serve on the Committee’s subcommittees in the 116th Congress:
  
  **Military Personnel**
  Rep. Jackie Speier (D-CA), Chairwoman
  Rep. Susan Davis (D-CA)
  Rep. Ruben Gallego (D-AZ)
  Rep. Gil Cisneros (D-CA)
  Rep. Veronica Escobar (D-TX)
  Rep. Deb Haaland (D-NM)
  Rep. Lori Trahan (D-MA)
  Rep. Elaine Luria (D-VA)

- House Appropriations Committee Chairwoman Nita M. Lowey (D-NY) announced vice chairs for the House Appropriations Committee’s 12 subcommittees in the 116th Congress.
  
  Two vice chairs are:
House Veterans Affairs Chairman Mark Takano (CA-41) announced the vice chair and subcommittee assignments for the House Committee on Veterans’ Affairs during the 116th Congress.

House Committee on Veterans' Affairs Vice Chair: Congressman Conor Lamb (PA-17)

Subcommittee on Disability Assistance and Memorial Affairs: Chair: Congresswoman Elaine Luria (VA-02); Members: Congressman Gil Cisneros (CA-39), Congressman Gregorio Kilili Camacho Sablan (At Large – M.P.), Congressman Colin Allred (TX-32), Congresswoman Lauren Underwood (IL-14)

Subcommittee on Economic Opportunity: Chair: Congressman Mike Levin (CA-49); Members: Congresswoman Kathleen Rice (NY-04), Congressman Anthony Brindisi (NY-22), Congressman Chris Pappas (NH-01), Congresswoman Elaine Luria (VA-02), Congresswoman Susie Lee (NV-03), Congressman Joe Cunningham (SC-01)

Subcommittee on Health: Chair: Congresswoman Julia Brownley (CA-26); Members: Congressman Conor Lamb (PA-17), Congressman Mike Levin (CA-49), Congressman Anthony Brindisi (NY-22), Congressman Max Rose (NY-11), Congressman Gil Cisneros (CA-39), Congressman Collin Peterson (MN-07)

Subcommittee on Oversight and Investigations: Chair: Congressman Chris Pappas (NH-01); Members: Congresswoman Kathleen Rice (NY-04), Congressman Max Rose (NY-11), Congressman Gil Cisneros (CA-39), Congressman Collin Peterson (MN-07)

Subcommittee on Technology Modernization: Chair: Congresswoman Susie Lee (NV-03); Members: Congresswoman Julia Brownley (CA-26), Congressman Conor Lamb (PA-17), Congressman Joe Cunningham (SC-01)

MILITARY HEALTH CARE NEWS

A group of 10 Army medical professionals are the first to participate in a new program designed to help them sustain battlefield medicine skills by training at two of the nation’s civilian teaching hospitals.

The program, called Army Military-Civilian Trauma Team Training (AMCT3), is a two-to-three year program at Cooper University Health Care in Camden, New Jersey, and Oregon Health and Sciences University in Portland, Oregon. The goal of the program is to advance military trauma operational readiness for deployment around the globe by partnering with high-volume civilian trauma centers to gain critical teamwork and technical trauma skills.

The program gives Army surgical teams and individual soldiers the opportunity to maintain proficiency and sustain their trauma skills by working alongside civilian counter parts at high-volume Level 1 trauma centers, according to Crosland. Level 1 trauma centers are comprehensive regional facilities capable of providing total care for every aspect of injury.

The AMCT3 program addresses the National Defense Authorization Act for Fiscal Year 2017 directive for the Military Health System to establish partnerships to maintain trauma care competency along with developing standardized combat care instruction to enhance quality of care outcomes for trauma care.

The program is also inspired by national efforts to stop preventable deaths in people with traumatic injuries. Research has shown that deaths and disabilities due to trauma can be
prevented with better training, coordination and streamlined trauma care systems. AMCT3 promotes a two-way exchange of ideas and can help both military and civilian trauma centers improve outcomes for their patients.

The soldiers assigned to the program were selected because they have medical specialties typically used in military forward surgical teams, such as emergency medicine physician, trauma surgeon, nurse anesthetist, and intensive care and emergency care nurses.

Over the next few years the Army Medical Command hopes to establish at least 10 trauma team training partnerships across the country.

- **The Defense Health Agency (DHA), which manages the TRICARE health care benefits, has issued a Request for Information (RFI) regarding inpatient-clinic administered pharmaceuticals formulary management.**

  Responses are due February 5, 2019.

  The RFI seeks commercial best practices in formulary management focusing on inpatient and medical benefit drugs, but also opens the door for responding vendors to describe their capabilities to train a formulary management staff, to develop approaches to formulary management, to compare program results, to maximize acceptance of an implemented program, and to utilize pharmacists in an inpatient setting.

  DHA issued this RFI as part of a larger effort to integrate the Military Health System under its sole administration, in response to Section 702 of the National Defense Authorization Act (NDAA) of 2017, as amended by Section 711 of the 2019 NDAA, which dictates that DHA will assume responsibility for administration of all MTFs by September 30, 2021.

  The DHA set forth its current phased plan for the transition in its 2018 Final Report to Congress, available here. DHA's administration responsibilities will include any drug formulary for inpatient services provided through TRICARE at MTFs. DHA's pharmacy operations currently cover only outpatient prescribed drugs, hence the agency's interest in commercial best practices for inpatient settings.

  Instructions for responding to the RFI, as well as the RFI in full, are available here.

**VETERANS AFFAIRS NEWS**

- **The Department of Veterans Affairs (VA) announced that it has recently formalized two partnerships aimed at preventing veteran suicide.**

  Effective January, the American Foundation for Suicide Prevention (AFSP) began collaborating with VA to advance and improve the quality of life for Veterans to prevent suicides. Through this partnership, VA and AFSP have been exchanging research on suicide and prevention efforts. AFSP has also begun sharing VA suicide-prevention messaging.

  Effective last November, the National Shooting Sports Foundation (NSSF) began working with VA to develop a program that will empower communities to engage in safe firearm-storage practices. The program will include information to help communities create coalitions around promoting and sustaining firearm safety with an emphasis on service members, Veterans and their families.

  These innovative partnerships highlight the shared mission between the VA, nonprofit organizations and local communities to end suicide among those who have served or are currently serving.

  Research shows there is no single cause for suicide: It is the outcome of multiple contributing
factors and events. However, environmental factors, such as access to lethal means, increase the risk for suicide. Firearms are one of the most deadly and common methods for suicide among Americans — particularly for service members and veterans.

Veterans in crisis or having thoughts of suicide, and those who know a veteran in crisis, can call the Veterans Crisis Line for confidential support 24 hours a day, seven days a week, 365 days a year. Call 800-273-8255 and press 1, chat online at VeteransCrisisLine.net/Chat, or text to 838255.

The Department of Veterans Affairs (VA) announced its proposed access standards for community care and urgent care provisions that will take effect in June and guide when veterans can seek care to meet their needs under the MISSION Act – be it with VA or with community providers.

Under the MISSION Act, signed by President Trump in June 2018, there are six different eligibility criteria for community care:

- Services unavailable
- Residence in a state without a full-service VA medical facility
- 40-mile legacy/grandfathered from the Choice program
- Best medical interest
- Needing care from a VA medical service line that VA determines is not providing care that complies with VA's standards for quality
- Access standards

ACCESS STANDARDS

VA is proposing new access standards, effective when the final regulations publish (expected in June 2019), to ensure Veterans have greater choice in receiving care.

Eligibility criteria and final standards as follows were based on VA’s analysis of all of the best practices both in government and in the private sector and tailored to the needs of our Veteran patients:

Access standards will be based on average drive time and appointment wait times.

- For primary care, mental health, and non-institutional extended care services, VA is proposing a 30-minute average drive time standard.
- For specialty care, VA is proposing a 60-minute average drive time standard.
- VA is proposing appointment wait-time standards of 20 days for primary care, mental health care, and non-institutional extended care services, and 28 days for specialty care from the date of request with certain exceptions.
- Eligible veterans who cannot access care within those standards would be able to choose between eligible community providers and care at a VA medical facility.

URGENT CARE

Eligible veterans will have access to urgent (walk-in) care that gives them the choice to receive certain services when and where they need it. To access this new benefit, Veterans will select a provider in VA’s community care network and may be charged a copayment.

VA encourages the public to comment on the proposed access standards and urgent care benefit during the public comment period once these proposed regulations (RIN 2900-AQ46 and RIN 2900-AQ47, respectively) publish in the Federal Register; we look forward to receiving this
The Department of Health and Human Services proposed a rule to lower prescription drug prices and out-of-pocket costs by encouraging manufacturers to pass discounts directly on to patients and bringing new transparency to prescription drug markets.

The HHS proposal would expressly exclude from safe harbor protection under the Anti-Kickback Statute rebates on prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs), Part D plans and Medicaid managed care organizations.

It would create a new safe harbor for prescription drug discounts offered directly to patients, as well as fixed fee service arrangements between drug manufacturers and PBMs. The proposal would also provide a historic new level of transparency to a system that has been shrouded in secrecy for decades.

Under the proposed rule, prescription drug rebates that today amount to, on average, 26 to 30 percent of a drug’s list price may be passed on directly to patients and reflected in what they pay at the pharmacy counter. By encouraging negotiated discounts that are reflected in cost-sharing methods like co-insurance, used for many expensive drugs in Medicare Part D, the proposal is projected to provide the greatest benefits to seniors with high drug costs.

The proposal would also address the most significant incentive drug manufacturers cite in raising their list prices every year, the pressure to provide larger and larger rebates. This rule provides a clear pathway for drug companies instead to compete to have the lower price and out-of-pocket cost to the patient.

Read a fact sheet - PDF on the proposed rule.

Read the proposed rule.

The U.S. Food and Drug Administration approved the first generic of Advair Diskus (fluticasone propionate and salmeterol inhalation powder) for the twice-daily treatment of asthma in patients aged four years and older and maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD).

Mylan obtained approval to market its generic inhaler in three strengths: fluticasone propionate 100 mcg/ salmeterol 50 mcg, fluticasone propionate 250 mcg/ salmeterol 50 mcg and fluticasone propionate 500 mcg/ salmeterol 50 mcg.

According to the National Heart, Lung, and Blood Institute, asthma is a chronic lung disease that inflames and narrows the airways. Asthma causes recurring periods of wheezing (a whistling sound when you breathe), chest tightness, shortness of breath and coughing. The coughing often occurs at night or early in the morning. Asthma affects people of all ages, but it most often starts during childhood. In the United States, more than 26 million people are known to have asthma, about seven million of these people are children. COPD is a progressive lung disease that makes it hard to breathe and may become worse over time. COPD can cause coughing that produces large amounts of mucus, wheezing, shortness of breath, chest tightness and other symptoms.

Inhalers are known as “combination products” because they consist of a drug and a device. The development of generic combination products can be more challenging than, for instance, solid oral dosage forms, like tablets, and the FDA regularly takes steps to help guide industry through
the process. The FDA recognizes the challenges companies face when seeking to develop hard-to-copy complex generics, such as drug-device combination products, including when the drugs are incorporated into inhalation devices.

Under GDUFA II, individual companies can meet with the FDA as part of their pre-ANDA program to support their development of such complex products. The FDA also publishes publicly available guidance documents describing the steps the FDA recommends companies take to submit complete, approvable applications for various types of drug products.

In 2013, the FDA issued a draft product specific guidance for proposed generic drug products referencing Advair Diskus, which, among other things, provides bioequivalence recommendations, as well as formulation and device considerations. Further, as with brand-name drugs, the FDA inspects manufacturing and packaging facilities for generic drugs to ensure that they are capable of consistently producing quality products.

The FDA requires appropriate data and information to demonstrate that complex generic drug-device combination products meet the agency’s rigorous approval standards to ensure quality drug products that are as safe and effective as their brand name counterparts are available to patients.

The FDA continues to advance new policies to promote more generic competition for complex drugs. Recently, the FDA issued 27 guidance documents to help advance the development of generic transdermal and topical delivery systems. The agency also intends to issue an umbrella guidance to help generic drug developers address some of the most challenging regulatory and scientific issues that may be encountered during the development of complex drugs.

REPORTS/POLICIES


HILL HEARINGS

- The Senate Appropriations Subcommittee on Military Construction and Veterans Affairs, and Related Agencies will hold a hearing on Feb. 5, 2019, to examine an implementation update on the Department of Veterans Affairs’ electronic health record modernization.

LEGISLATION

- H.R.908 (introduced Jan. 30, 2019): A bill to amend the Internal Revenue Code of 1986 to allow individuals only enrolled in Medicare Part A to contribute to health savings accounts was referred to the House Committee on Ways and Means. Sponsor: Representative Robert E. Latta [R-OH-5]

MEETINGS A

- HIMSS 2019 Annual Conference will be held on Feb. 11-15, 2019, in Orlando, Fla.
  http://www.himssconference.org/

- The 9th Annual Heroes of Military Medicine Awards Dinner will be held on May 9, 2019, in Washington DC. https://www.hjfcp3.org/heroes-dinner/

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