Welcome to Federal Health Update. This newsletter, produced by Kate Connelly Theroux in collaboration with the Institute of Federal Health Care, 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 April 16, 2012.


- First Lady Michelle Obama and Dr. Jill Biden announce a commitment from nurses across the country to serve the unique needs of service members, veterans and their families.

  In a broad, coordinated effort, more than 150 state and national nursing organizations and more than 500 nursing schools have committed to further educate the nation’s 3 million nurses to address the distinct health needs of service members, veterans and their families.

  Led by the American Nurses Association, American Academy of Nurse Practitioners, American Association of Colleges of Nursing, and the National League for Nursing, in coordination with the
departments of Veterans Affairs and Defense, nursing organizations and schools have committed to educating current and future nurses on how to recognize and care for veterans affected by post-traumatic stress disorder, traumatic brain injury, depression, and other combat-related issues, in ways appropriate to each nurse’s practice setting.

Veterans seeking care within the Veterans Affairs (VA) health system are often treated by health care professionals who have received extensive training in mental health issues. But the majority of veterans in the country seek care outside of the VA system, usually visiting their local hospital staffed by nurses and doctors in their communities.

Nursing leaders have also committed to disseminating effective models for care and to sharing the most up-to-date information on these conditions across academic and practice settings. By working to expand the body of clinical knowledge in this arena and by partnering with other health care providers and institutions, nursing leaders across the country will continue to advance high quality treatment for these conditions in every community.

For more details, please visit: http://www.whitehouse.gov/the-press-office/2012/04/11/americas-nurses-join-forces-first-lady-and-dr-biden-support-veterans-and

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**MILITARY HEALTH CARE NEWS**

- **The Army Times** reports that some physicians are upset about a new policy issued by TRICARE South contractor Humana Military Healthcare Services.

  TRICARE South doctors currently can select from any TRICARE network providers in their area. But Humana issued a memo last week to its TRICARE providers stating that a new computer system will select referrals for beneficiaries who need specialty care or follow-on tests and procedures.

  Physicians will be expected to log on to a Humana website that will generate a list of referral providers to choose from.

  TRICARE spokesman Austin Camacho said the change is part of an overall effort to “fashion the delivery of health care services focusing on readiness, population health, experience of care and per-capita cost.

  “We are providing choices of specialists who are accessible and affordable to beneficiaries with a web-based methodology that improves efficiency of the entire process,” Camacho said April 5.

  Camacho said the computer system will include specialists who have an “established relationship with the beneficiary — for example, was seen in the previous six months by the provider.”

  And beneficiaries “always have the option of selecting a different network specialist,” he added.

  In the Humana memo, the company said selecting a provider outside the list “may delay approval of the referral.” It also states that referral requests submitted for a provider other than those offered by the new system “may not be honored.”

  “Humana Military will, instead, direct to one of the optimal choice network providers, unless the request is accompanied by acceptable clinician rationale,” subject to approval by Humana.

  TRICARE allows its regional contractors to oversee referrals.

  The two other Tricare regions have not changed their referral selection process.

- **Government Info Security** reports that Science Applications International Corp. (SAIC) claims it has enough insurance to cover the costs of potential judgments or settlements.
stemming from seven class action lawsuits related to a September 2011 breach incident affecting 4.9 million TRICARE beneficiaries. TRICARE is the military health insurance program.

In its annual 10-K report filing with the Securities and Exchange Commission, SAIC notes the insurance policy has a $10 million deductible. The company states it has already recorded a loss equal to that amount, “representing the low end of the company’s estimated loss.” The statement adds: “The company believes that, if any loss is experienced by the company in excess of its estimate, such a loss would not exceed the company's insurance coverage.”

SAIC is seeking to have seven pending class action lawsuits related to the breach consolidated, and it has filed motions to dismiss in five of the seven cases, it notes in the 10-K report. An eighth class action suit has already been dismissed. The statement, filed March 27, notes the lawsuits seek statutory damages of $1,000 for each individual affected (or $4.9 billion), plus other damages and costs.

The 10-K report acknowledges that the Department of Health and Human Services' Office for Civil Rights is investigating the breach, which stemmed from backup tapes stolen from the parked car of an SAIC employee who was to transport them between federal facilities on behalf of TRICARE. Such investigations, which can take as long as two years, can result in financial penalties and corrective action plans affecting both the covered entity (in this case TRICARE) and a business associate (SAIC).

Based on the total number of individuals affected, the TRICARE breach is the largest so far on the federal tally of major breaches reported since the HIPAA breach notification rule took effect in September 2009.

- TRICARE Management Activity Deputy Director Brig. Gen. W. Bryan Gamble, M.D. posted a column on the growing problem of childhood obesity, suggesting ways parents can help keep their children from becoming obese and keep them healthy.

To read the column, please visit: The Dr. Is In: Fight Childhood Obesity.

VETERANS AFFAIRS NEWS

- Vincent E. Markey has been named director of the Department of Veterans Affairs’ Insurance Center.

VA Insurance Center is the eighth-largest life insurance program in the world covering more than 4 million veterans, active-duty service members and Reserve Component and National Guard members, plus 3.1 million spouses and children.

The VA Insurance Center directly administers six life insurance programs and supervises the Service members' Group Life Insurance (SGLI) and the Veterans' Group Life Insurance (VGLI) programs. These programs provide $1.3 trillion in insurance coverage.

In 2011, VA’s life insurance programs returned $249 million in dividends to 753,000 veterans holding some of these VA life insurance policies, and paid $2.3 billion in death claims to the beneficiaries of 141,000 veterans and service members.

The program has grown to meet the challenges of the current conflict through a new Traumatic Injury Protection program under SGLI that provides coverage to 2.4 million active-duty personnel. Those who suffer certain severe traumatic injuries may receive benefit amounts ranging from $25,000 to $100,000, depending on the loss.

Markey succeeds Tom Lastowka, who retired after serving as director of both the Insurance Center and the co-located regional office since 1990.
• **McKesson Corporation has been selected by the Department of Veterans Affairs (VA) to continue as the VA’s prime pharmaceutical supplier.**

The two-year agreement calls for McKesson to supply all of the VA's medical centers and outpatient clinics, as well as the VA's Consolidated Mail Outpatient Pharmacies (CMOPs).

As part of the contract award, McKesson will continue to supply pharmaceuticals to more than 700 locations, including more than 270 medical centers, as well as the VA's seven CMOPs. The initial two-year contract includes options for up to three, two-year extensions.

• **The Department of Veterans Affairs in May will eliminate co-payments for in-home video telehealth sessions.**

VA published a proposed rule on March 6 to waive co-payments with a 30-day comment period that has expired. “This would remove a barrier that may have previously discouraged veterans from choosing to use in-home video telehealth as a viable medical care option,” according to the rule. “In turn, VA hopes to make the home a preferred place of care, whenever medically appropriate and possible.”

Also on March 6, VA published a “direct final rule” that eliminates the co-payment, effective on May 7 without further notice unless the agency received relevant adverse comments on the proposed rule. A direct final rule can accompany a proposed rule to speed the rulemaking process if an agency anticipates a rule will be non-controversial. If “significant” adverse comments are received, VA will publish in the Federal Register a notice of receipt of the comments and withdraw of the direct final rule.

The proposed rule is available here and the direct final rule is here.

**GENERAL HEALTH CARE NEWS**

• **A new program that will help physicians, hospitals, and other health care providers work together to improve care for people with Medicare is off to a strong start, the Centers for Medicare & Medicaid Services (CMS) announced.**

Under the new Medicare Shared Savings Program (Shared Savings Program), 27 Accountable Care Organizations (ACOs) have entered into agreements with CMS, taking responsibility for the quality of care furnished to people with Medicare in return for the opportunity to share in savings realized through improved care.

The first 27 Shared Savings Program ACOs will serve an estimated 375,000 beneficiaries in 18 states. This brings the total number of organizations participating Medicare shared savings initiatives on April 1 to 65, including the 32 Pioneer Model ACOs that were announced last December, and six Physician Group Practice Transition Demonstration organizations that started in January 2011. In all, as of April 1, more than 1.1 million beneficiaries are receiving care from providers participating in Medicare shared savings initiatives.

Accountable Care Organizations are designed to lift this burden from patients, while improving care and reducing costs. The selected ACOs include more than 10,000 physicians, 10 hospitals, and 13 smaller physician-driven organizations in both urban and rural areas. Their models for coordinating care and improving quality vary in response to the needs of the beneficiaries in the areas they are serving. CMS is reviewing more than 150 applications from ACOs seeking to enter the program in July.

To learn more about the ACOs, visit: [http://www.cms.gov/apps/media/fact_sheets.asp](http://www.cms.gov/apps/media/fact_sheets.asp).
- The U.S. Food and Drug Administration announced that it is taking three steps to protect public health and promote the judicious use of medically important antibiotics in food-producing animals.

Because it is well established that all uses of antimicrobial drugs, in both humans and animals, contribute to the development of antimicrobial resistance, it is important to use these drugs only when medically necessary. Based on a consideration of relevant reports and scientific data, FDA is proposing a voluntary initiative to phase in certain changes to how medically important antimicrobial drugs are labeled and used in food-producing animals. FDA is taking this action to help preserve the effectiveness of medically important antimicrobials for treating disease in humans.

In support of this initiative, the FDA is publishing three documents in the April 13 Federal Register:

- A final guidance for industry, The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals, that recommends phasing out the agricultural production use of medically important drugs and phasing in veterinary oversight of therapeutic uses of these drugs.

- A draft guidance, open for public comment, which will assist drug companies in voluntarily removing production uses of antibiotics from their FDA-approved product labels; adding, where appropriate, scientifically-supported disease prevention, control, and treatment uses; and changing the marketing status to include veterinary oversight.

- A draft proposed Veterinary Feed Directive regulation, open for public comment, that outlines ways that veterinarians can authorize the use of certain animal drugs in feed, which is important to make the needed veterinary oversight feasible and efficient.

- The National Institute of Dental and Craniofacial Research (NIDCR) has awarded a $66.8 million, seven-year grant that consolidates its dental practice-based research network initiative into a unified nationally coordinated effort.

The consolidated initiative, The National Dental Practice-Based Research Network (NDPBRN), is headquartered at the University of Alabama at Birmingham (UAB) School of Dentistry. It serves as a national administrative hub that leads and oversees six smaller regional research sites, or nodes. The nodes are located in Rochester, NY; Gainesville, Fla.; Birmingham; Minneapolis; San Antonio; and Portland, Ore. The NIDCR is part of the National Institutes of Health.

A dental practice-based research network is an investigative union of practicing dentists and academic scientists. The network provides practitioners with an opportunity to propose or participate in research studies that address day-to-day issues in oral healthcare. The studies, conducted in participating dental offices with consenting patients, help to expand the profession’s evidence base and further refine care.

NDPBRN plans to expand the number of participating practitioners to 5,000. Greater participation will allow for an increased number and range of studies, the intention being to produce data that can be better generalized to the U.S. population in all its diversity.

For more information about the NDPBRN, visit: http://www.nidcr.nih.gov/Research/DER/ClinicalResearch/DentalPracticeBasedResearchNetworks.htm
Three products for patients with end stage renal disease (ESRD) have been chosen to participate in the FDA's Innovation Pathway, an evolving system designed to help medical devices reach patients in a safe, timely and collaborative manner.

The FDA selected three from 32 product applications ranging from an artificial kidney to devices that assist kidney function that were submitted in response to a January 2012 request from FDA’s device center.

The three products are:

- An implantable Renal Assist Device (iRAD) being developed by the University of California, San Francisco.
- A Wearable Artificial Kidney (WAK) in development by Blood Purification Technologies Inc. of Beverly Hills, Calif.
- A Hemoaccess Valve System (HVS) that has been designed by Greenville, S.C.-based CreatiVasc Medical.

The majority of the 32 applications came from small, start-up business or academic institutions.

The ESRD products will be the focus of the second version of the Innovation Pathway, first announced in 2011, to shorten the time and cost it takes for the development, assessment and review of medical devices, in particular breakthrough medical devices.

ESRD is the progressive loss in kidney function over a period of months or years. The kidneys play an essential role, filtering and removing waste from the body and producing hormones that are responsible for calcium absorption and red blood cell production.

The FDA chose ESRD because more than half a million Americans suffer from the disease. Management of the disease is largely dependent upon medical device technology, such as hemodialysis (process for removing waste products) equipment. Most dialysis patients spend long hours in specialized outpatient clinics, adversely affecting their quality of life and reducing productivity. Medicare alone covers some 75 percent of ESRD health care costs, which in 2009 topped $29 billion.

Developers who participate in what FDA now calls Innovation Pathway 2.0 have an opportunity to collaboratively discuss their technology with FDA, work with the agency on the development of a benefit-risk profile for their product that will help guide future studies and map out a regulatory path forward for their product.

This approach is intended to deepen collaboration between FDA and innovators early in the process, prior to pre-market submission, with the goal of making the regulatory and product development process more efficient and timely.

Gary H. Gibbons, M.D. has been named the new director of the NIH's National Heart, Lung, and Blood Institute (NHLBI).

Dr. Gibbons is the founder and current director of the Cardiovascular Research Institute, chairperson of the Department of Physiology, and professor of physiology and medicine at the Morehouse School of Medicine in Atlanta. He expects to start his new position in the summer of 2012.

Gibbons' institute at Morehouse is recognized for its discovery science related to cardiovascular health of minority populations. His laboratory is focused on discovering novel mediators of vascular disease. His program involves collaborative efforts to study the functional significance of genomic variation and changes in gene activities due to 'epigenetic' modifications of DNA that do not involve a change in the genetic code, as factors that enhance the susceptibility to cardiovascular disease.

Gibbons will oversee the third largest institute at the NIH, with an annual budget of more than $3
billion and a staff of 917 federal employees. Gibbons will also direct his own lab at the NIH, focusing on predictive health and genomic medicine in minority populations.

GUARD/RESERVE

- As of April 10, 2012, the total number of Guard and Reserve currently on active duty has decreased by 128 to 71,981. The totals for each service are Army National Guard and 51,631; Navy Reserve, 4,635; Air National Guard and Air Force Reserve, 10,292; Marine Corps Reserve, 4,609, and the Coast Guard Reserve, 814. [www.defenselink.mil](http://www.defenselink.mil)

REPORTS/POLICIES


- The Rand Corporation published “How Does Food Environment Contribute to Childhood Obesity?”, in April 2012. This multi-media report includes findings from two studies to examine food availability in schools and in neighborhoods to investigate how the food environment influences the diet and body mass index (BMI) of children and teens. [http://www.rand.org/health/feature/food-environment-obesity.html](http://www.rand.org/health/feature/food-environment-obesity.html)

- The Institute of Medicine (IOM) published “For the Public’s Health: Investing in a Healthier Future,” on April 10, 2012. This report assesses both the sources and adequacy of current government public health funding and identifies approaches to building a sustainable and sufficient public health presence going forward, while recognizing the importance of the other actors in the health system, including clinical care, governmental public health, and others. [http://www.iom.edu/Reports/2012/For-the-Publics-Health-Investing-in-a-Healthier-Future.aspx](http://www.iom.edu/Reports/2012/For-the-Publics-Health-Investing-in-a-Healthier-Future.aspx)

HILL HEARINGS


- The Senate Armed Services Subcommittee on Personnel will hold a hearing on April 25, 2012, to examine the Active, Guard, Reserve, and civilian personnel programs in review of the Defense Authorization request for fiscal year 2013 and the Future Years Defense Program.

LEGISLATION

- There was no legislation proposed this week.
MEETINGS


- The 7th Annual Amygdala, Stress and PTSD Conference will be held on April 24, 2012, in Bethesda Md. [http://www.amygdalaconference.org/](http://www.amygdalaconference.org/)

- The Conference on Vaccine Research will be held on May 7–9, 2012, in Baltimore, Md. [http://immunize.us1.list-manage2.com/track/click?u=69948816469e0f4801f8647ee&id=20e0c08ef8&e=8a0b0385de](http://immunize.us1.list-manage2.com/track/click?u=69948816469e0f4801f8647ee&id=20e0c08ef8&e=8a0b0385de)

- The Weight of the Nation, Moving Forward, Reversing the Trend Conference will be held on May 7-9, 2012, in Washington DC. [http://www.cdc.gov/won/](http://www.cdc.gov/won/)


- The 28th Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) will be held Nov. 1-3, 2012, in Los Angeles, Calif. [http://www.istss.org/Home.htm](http://www.istss.org/Home.htm)

If you need further information on any of the items in the Federal Health Update, please contact Kate Theroux at (703) 447-3257 or by e-mail at dhakat@aol.com.