

FEDERAL HEALTH UPDATE

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Produced by Kate Connelly Theroux in collaboration with the Institute of Federal Health Care (IFHC)

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Executive and Congressional News

- **On Sept. 15, 2011, the Senate Appropriations Committee unanimously approved a \$513 billion bill that freezes the Pentagon budget at this year's amount, \$26 billion lower than President Barack Obama's request.**

The legislation provides a 1.6 percent pay raise for military personnel, would trim nearly 600 military programs and would take a significant chunk of \$695 million from the troubled Joint Strike Fighter aircraft program. In addition to the overall bill, the measure also would provide nearly \$118 billion for the wars in Iraq and Afghanistan.

The bill is \$17 billion less than what the House approved and lawmakers will have to work out the difference. With the start of the next fiscal year just 15 days away, Congress is likely to roll the various spending bills into a single, mammoth measure.

- **On Sept. 14, 2011, the House Appropriations Committee introduced a Continuing Resolution (CR) to keep the government operating past the end of the fiscal year on Sept. 30, 2011.**

The CR introduced continues government operations at a rate of \$1.043 trillion – the total amount agreed to by the Congress and the White House in the recent debt-ceiling legislation – and runs until Nov. 18, 2011.

For more details, please visit: <http://appropriations.house.gov/News/DocumentSingle.aspx?DocumentID=260104>.

Military Health Care News

- **The American Pharmacists Association has appointed Stacia Spridgen as director of its federal pharmacy program.**

Spridgen, a retired Army lieutenant colonel, would be responsible for all aspects of the APhA's federal pharmacy programs, including coordination of the annual Federal Forum and oversight management of the Department of Defense Joint Forces Pharmacy Seminar, fostering a collaborative alliance between the APhA and the federal pharmacy sector and developing relationships in the pharmaceutical industry.

Spridgen most recently served as director of the Department of Defense Pharmacoeconomic Center at Ft. Sam Houston, Texas, promoting cost-effective drug therapy throughout the Military Health System. Previously, she worked as executive officer for the Office of the Surgeon General and in other healthcare-related positions in the military.

- **TriWest Healthcare Alliance announced that it has resolved a civil lawsuit with the Department of Justice concerning the company's application of "Letters of Agreement" (LOA), and has implemented processes to ensure better handling of LOAs in the future.**

The Justice Department says the settlement resolves a lawsuit filed by four former TriWest employees under the whistleblower provisions of the False Claims Act.

The government and plaintiffs allege that between 2004 and 2010, TriWest failed to give TRICARE the benefit of negotiated discounts with service providers under letters of agreement.

TriWest said it realized no financial gain, though the unrealized discounts did cause a loss to the government. TriWest has agreed to compensate the government.

TriWest plans to voluntarily implement preventive measures including an annual independent third party audit of letters of agreement claims and better claims processing accuracy.

- **TriWest announced that more than 200,000 TRICARE beneficiaries have chosen to receive their health care statements in paperless form.**

By providing electronic solutions, TriWest is ensuring military families receive prompt, accurate delivery of their healthcare information.

TriWest's "Go Green" program started in fall 2009 and has since branched out to include paperless options for referrals and authorizations, and fee statements. All told, more than 1 million health care statements have been delivered electronically, which represents nearly 10 percent of all TriWest health care statements generated are now paperless.

TRICARE beneficiaries can [register for a TriWest.com account](#), pick paperless and be on their way to getting electronic notifications for their healthcare needs.

In addition, TriWest recently unveiled a mobile application for smartphones and mobile devices, a mobile website (m.TriWest.com) and text alerts.

Learn more about TriWest mobile capabilities at TriWest.com/GoMobile.

- **Inogen has won a service contract to provide supplemental oxygen therapy services and devices to patients in TRICARE's 21-state western service region.**

Through this contract, the Inogen One portable oxygen concentrator to active-duty military members, retired personnel and their families. The Inogen One also is covered by Medicare, so TriWest primary or Medicare supplement policyholders may be eligible to obtain an Inogen One oxygen concentrator for little to no additional cost compared to traditional oxygen therapy devices.

For patients, a portable oxygen concentrator means their oxygen supply will never run out. With the Inogen One, there's no need to carry oxygen tanks or let oxygen therapy affect travel plans and outings. The Inogen One makes its own oxygen with five flow settings to ensure a majority of active oxygen therapy patients' needs are covered. All Inogen patients on service through TRICARE will also receive a backup oxygen supply and will have access to Inogen's 24-hour emergency support service throughout the USA.

Weighing in at seven pounds, the Inogen One is a lightweight, portable oxygen concentrator that is designed for use at home, at night and on the go. Inogen is an award-winning manufacturer and nationally-accredited homecare provider that develops unique solutions and provides in-home services to help patients achieve their desired freedom and independence. Accredited by the Accreditation Commission for Health Care (ACHC), Inogen currently provides oxygen therapy to thousands of patients throughout the United States.

Veterans Health Care News

- **A small pilot study led by a Department of Veterans Affairs (VA) researcher found that a nasal insulin spray improved memory, thinking skills and functional ability in people with mild cognitive impairment and Alzheimer's disease.**

A VA team with the Geriatric Research, Education and Clinical Center at the VA Puget Sound Health Care System led the trial, which was sponsored in large part by the National Institute on Aging, part of the National Institutes of Health (NIH). The new findings appear in the Sept. 12 [Archives of Neurology](#).

Previous studies found that low brain levels of insulin—the main hormone that turns sugar in the bloodstream into energy for cells—could contribute to Alzheimer's. Based on these findings, VA's Dr. Suzanne Craft has led efforts to test the benefits of restoring normal insulin function in the brain.

The new study tested a nasal spray that delivers insulin quickly and directly to the brain, with no harmful side effects, such as increased insulin levels throughout the whole body. The trial included 104 adults with either amnesiac mild cognitive impairment—in which people have memory loss that may progress to Alzheimer's—or mild to moderate Alzheimer's disease.

Currently, there are no effective treatments to delay or prevent Alzheimer's.

- **Health Net Federal Services is sponsoring the 4th National Veterans Summer Sports Clinic, scheduled to be held in San Diego, Calif., Sept. 18-23, 2011.**

The annual event promotes rehabilitation of body and mind by teaching summer sporting activities to recently injured veterans with significant physical or psychological impairments, such as Post Traumatic Stress Disorder (PTSD) or Traumatic Brain Injury (TBI).

Onsite coaches from MHN will attend the Summer Sports Clinic to offer support, education and life skills for participating veterans and their caregivers. Health Net's goal is to help recently injured veterans, their family members and caregivers apply the tools and skills they learn at the Summer Sports Clinic in their daily lives.

The National Veterans Summer Sports Clinic is sponsored by the Department of Veterans Affairs (VA) and hosted by the VA San Diego Healthcare System. Sporting challenges such as sailing, surfing, kayaking, cycling, and track and field will be offered. For more information, please visit www.summersportsclinic.va.gov.

- **On Aug. 31, 2011, the Department of Veterans Affairs, Dayton VA Medical Center awarded VetFed Resources, Inc. a \$20 million contract to provide an enterprise-wide Real-Time Locating System (RTLS) for the VISN 10 Healthcare Network with an implementation timeline of one year.**

VetFed Resources will be responsible to deliver the application software, licensing, receivers, hardware, tags, installation, training and any additional ancillary equipment for tracking of people, equipment, instruments, or supplies.

For more information, please visit: <http://tinyurl.com/62sfawu>.

Health Care News

- **On Sept. 12, 2011, the Presidential Commission for the Study of Bioethical Issues publicly released the results of its investigation into the U.S. Public Health Service (PHS) studies conducted in Guatemala in the 1940s.**

The PHS research involved intentionally exposing and infecting vulnerable populations to sexually transmitted diseases without the subjects' consent.

"In the Commission's view, the Guatemala experiments involved unconscionable basic violations of ethics, even as judged against the researchers' own recognition of the requirements of the medical ethics of the day," Commission Chair Amy Gutmann, Ph.D., said. "The individuals who approved, conducted, facilitated and funded these experiments are morally culpable to various degrees for these wrongs."

Following the revelation last fall that the PHS supported research on sexually transmitted diseases in Guatemala from 1946 to 1948, President Obama asked the Bioethics Commission to oversee a thorough fact-finding investigation into the studies.

The full report, *Ethically Impossible: STD Research in Guatemala from 1946-1953*, also includes the Commission's ethical analysis of the case. The report has been posted on the Commission's website, www.bioethics.gov.

Commission staff reviewed more than 125,000 original pages of documents and approximately 550 secondary sources collected from public and private archives around the country. Commission staff also completed a fact finding trip to Guatemala and met with Guatemala's own internal investigation committee.

The Commission concluded that researchers conducted diagnostic tests including blood draws and spinal taps on as many as 5,500 Guatemalan prison inmates, psychiatric patients, soldiers, commercial sex workers, orphans and school children. Of those, researchers deliberately exposed about 1,300 inmates, psychiatric patients, soldiers and commercial sex workers to sexually transmitted diseases syphilis, gonorrhea or chancroid.

Careful examination of thousands of pages of treatment and follow up records indicates that at least 83 subjects died, although the exact relationship between the experimental procedures and the subject deaths remains unclear.

One key to informing the Commission's conclusions about moral culpability was discovering that several of the same researchers had conducted similar experiments that involved intentionally exposing prison inmates to gonorrhea in Terre Haute, Ind., in 1943. In the Terre Haute experiments, the researchers went to some lengths to obtain consent of their subjects: they fully briefed the prisoners who, in turn, volunteered and gave informed consent. A few years later, the same researchers in Guatemala did not seek their subjects' consent.

With the historical investigation concluded, the Commission now turns its attention to its ongoing work in reviewing contemporary standards that protect human research participants.

That report is due to the President in December.

- **Leon Rodriguez has been appointed as director of HHS' Office for Civil Rights (OCR).**

As the department's civil rights and health privacy rights law enforcement agency, OCR investigates complaints filed by the public and provides technical assistance and public education to ensure understanding of and compliance with federal nondiscrimination and health information privacy laws. Rodriguez most recently served as chief of staff and deputy assistant attorney general for the Department of Justice Civil Rights Division.

From May 2007 to January 2010, Rodriguez served as the county attorney for Montgomery County, Md., where he led efforts to provide legal advice and services to county departments, agencies, boards, and commissions, as well as the County Council.

From May 2001 to May 2007, he was a shareholder in the Health Law department of Ober, Kaler, Grimes & Shriver. For 13 years prior to entering private practice, Rodriguez was a federal and state prosecutor in various jurisdictions. From 1997 to 2001, he was an assistant U.S. attorney in Pittsburgh, Pa., assigned to the prosecution of health care fraud cases. Leon served as the first assistant U.S. attorney from 1999-2001, and as the chief of the White Collar Crimes Section from 1998-1999. From 1994 – 1997, he served as a trial attorney in the Criminal Section of the U.S. Department of Justice, Civil Rights Division. Prior to his first DOJ tour, he was an assistant district attorney in Brooklyn, N.Y. for six years.

Leon Rodriguez is a graduate of Brown University and Boston College Law School and is fluent in Spanish and French.

- **The Department of Health and Human Services (HHS), with several key initial partners, launched *Million Hearts*, an initiative that aims to prevent 1 million heart attacks and strokes over the next five years.**

Currently, cardiovascular disease costs \$444 billion every year in medical costs and lost productivity in Americans. Building on work already underway thanks to the Affordable Care Act, Million Hearts will help improve Americans' health and increase productivity.

Million Hearts is focused on two goals:

- **Empowering Americans to make healthy choices** such as preventing tobacco use and reducing sodium and trans fat consumption. This can reduce the number of people who need medical treatment such as blood pressure or cholesterol medications to prevent heart attacks and strokes.
- **Improving care** for people who do need treatment by encouraging a targeted focus on the "ABCS" – Aspirin for people at risk, Blood pressure control, Cholesterol management and Smoking cessation – which address the major risk factors for cardiovascular disease and can help to prevent heart attacks and strokes.

For details, please visit: <http://www.hhs.gov/news/press/2011pres/09/20110913a.html>.

- **The U.S. Food and Drug Administration announced organizational changes within the office responsible for reviewing all drug and biologic applications for cancer therapies.**

The Center for Drug Evaluation and Research's (CDER) Office of Oncology Drug Products has been reorganized and renamed the Office of Hematology and Oncology Products (OHOP).

Richard Pazdur, M.D., who joined the FDA in 1999 and became director of the office in 2005, will continue to serve as the office director. Pazdur will also continue to head the agency-wide oncology program that coordinates oncology activities within the FDA as well as with external stakeholders. This program will remain in OHOP.

The previous structure contained three divisions: Division of Hematology Products (DHP), Division of Drug Oncology Products (DDOP), and Division of Biologic

Oncology Products (DBOP).

The new structure contains four divisions: Division of Hematology Products (DHP), Division of Oncology Products 1 (DOP1), Division of Oncology Products 2 (DOP2), and Division of Hematology Oncology Toxicology (DHOT).

Two unique features of the reorganization include the creation of DOP1 and DOP2, the agency's primary review divisions for cancer solid tumor therapies, and the creation of DHOT, which will review nonclinical information.

DOP1 and DOP2 will have disease-specific therapeutic areas of responsibility regardless of whether the product is a drug or biologic. DHOT is a newly created division that will be dedicated to reviewing nonclinical pharmacology and toxicology aspects of cancer therapies. DHP will continue reviewing hematology therapies, including those for benign disorders and malignancies.

- **The U.S. Census Bureau announced that in 2010, the percentage without health insurance coverage was not statistically different in 2010 than in 2009.**
 - The number of people with health insurance increased to 256.2 million in 2010 from 255.3 million in 2009. The percentage of people with health insurance was not statistically different from 2009.
 - Between 2009 and 2010, the percentage of people covered by private health insurance declined from 64.5 percent to 64.0 percent, while the percentage covered by government health insurance increased from 30.6 percent to 31.0 percent. The percentage covered by employment-based health insurance declined from 56.1 percent to 55.3 percent.
 - In 2010, 9.8 percent of children under 18 (7.3 million) were without health insurance. Neither estimate is significantly different from the corresponding 2009 estimate. The uninsured rate for children in poverty (15.4 percent) was greater than the rate for all children (9.8 percent).

To view the entire report, please visit: http://www.census.gov/newsroom/releases/archives/news_conferences/2011-09-13_ipnews_conf.html.

- **The Department of Health and Human Services (HHS) announced that on average, Medicare Advantage premiums will be four percent lower in 2012 than in 2011.**

HHS also projects enrollment to increase by 10 percent.

In 2012, all beneficiaries will have access to Medicare-covered preventive services without paying a co-pay or deductible, including an Annual Wellness Visit with their physicians. Those who reach the donut hole will enjoy deep discounts on brand name drugs and expanded coverage for generic drugs under provisions of the Affordable Care Act.

This year marks an important change in Medicare's annual open enrollment, the time period during which people can choose to change plans or shift from Medicare Advantage to Traditional Medicare. Open Enrollment starts earlier – on Oct. 15, 2011 – and lasts longer (7 full weeks) to give beneficiaries enough time to review and make changes to their coverage. As a result, however, beneficiaries will need to make their elections for next year's Medicare coverage by Dec. 7, 2011 rather than the usual Dec. 31. The new open enrollment period will better ensure that individuals have their membership cards in hand and receive uninterrupted health care coverage on Jan. 1, 2012.

CMS is encouraging beneficiaries enrolled in Medicare Advantage and Medicare Prescription Drug plans to review their current health and drug plan coverage for any changes their plans may be making for 2012 before the annual open enrollment period begins on October 15. Beneficiaries should receive their 2012 *Medicare & You* handbook as well as a notice from their current plan that describes any changes from 2011 to 2012 by late September.

To find helpful Medicare tools and information, and compare the cost or benefits of 2012 Medicare health plans in your area, please visit: <http://www.cms.gov/center/openenrollment.asp>

Reserve/Guard

- As of Sept. 13, 2011, the total number of Guard and Reserve currently on active duty has declined by 488 to reach 92,266. The totals for each service are Army National Guard and Army 70,751; Navy Reserve, 4,736; Air National Guard and Air Force Reserve, 10,386; Marine Corps Reserve, 5,721, and the Coast Guard Reserve, 672. www.defenselink.mil

Reports/Policies

- **The GAO published "Drug Safety: FDA Faces Challenges Overseeing the Foreign Drug Manufacturing Supply Chain," (GAO-11-936T) on Sept. 14, 2011.** This report examines FDA's inspection of foreign drug manufacturing establishments; the information FDA has on these establishments; and recent FDA initiatives to improve its oversight of the supply chain.
- **The GAO published "Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals," (GAO-11-801) on Sept. 14, 2011.** This report examines the extent to which agencies have collected data on antibiotic use and resistance in animals; actions HHS's Food and Drug Administration (FDA) took to mitigate the risk of antibiotic resistance in humans as a result of use in animals; extent to which agencies have researched alternatives to current use practices and educated producers and veterinarians about appropriate use; and actions the European Union (EU) and an EU member country, Denmark, have taken to regulate use in animals and lessons that have been learned.
- **The Institute of Medicine (IOM) published "State and Local Policy Initiatives To Reduce Health Disparities - Workshop Summary," on Sept. 13, 2011.** In this report, IOM explores the role of state and local policy initiatives in reducing health disparities, such as residential segregation, race and racism, lack of access to health care, lack of community infrastructure, and shorter life spans for future generations. <http://www.iom.edu/Reports/2011/State-and-Local-Policy-Initiatives-To-Reduce-Health-Disparities-Workshop-Summary.aspx>

Legislation

- **H.R.2878** (introduced Sept. 9, 2011): The *Compassionate Visa for Medical Treatment Act* was referred to the House Committee on the Judiciary
Sponsor: Representative Steve Cohen [TN-9]
- **H.R.2883** (introduced Sept. 12, 2011): The *Child and Family Services Improvement and Innovation Act* was referred to the Committee on Ways and Means, and in addition to the Committee on the Budget
Sponsor: Representative Geoff Davis [KY-4]
- **H.R.2884** (introduced Sept. 12, 2011): The *USPS Retiree Health Benefits Prepayment Extension Act of 2011* was referred to the House Committee on Oversight and Government Reform
Sponsor: Representative Elijah E. Cummings [MD-7]
- **S.1553** (introduced Sept. 9, 2011): A bill to amend the Public Health Service Act to facilitate emergency medical services personnel training and certification curriculums for military veterans was referred to the Committee on Health, Education, Labor and Pensions.
Sponsor: Senator Amy Klobuchar [MN]

Hill Hearings

- The House Veterans Affairs Committee will hold a hearing on **Sept. 20, 2011**, to examine the Federal Recovery Coordination Program.
- The House and Senate will hold a joint hearing on **Sept. 21, 2011**, to receive legislative presentation from the American Legion.

Meetings / Conferences

- NHLBI Symposium: Genomics: Gene Discovery and Clinical Applications for Cardiovascular, Lung, and Blood Diseases will be held on **Sept. 12-13, 2011**, in Bethesda Md. <http://www.nhlbi.nih.gov/meetings/Genomics/index.htm>
- 30th Annual Immunohematology & Blood Transfusion Symposium will be held on **Sept. 15, 2011**, in Bethesda Md. <http://www.cc.nih.gov/dtm/research/symposium.html>
- The National Medical Home Summit West will be held on **Sept. 20-22, 2011**, in San Francisco, Calif. <http://www.medicalhomesummit.com/>
- Advances in Neuropsychiatric Treatment Conference will be held on **Sept. 22-23, 2011**, in San Francisco, Calif. http://www.gtcbio.com/index.php?option=com_conference
- NHLBI Symposium on Cardiovascular Regenerative Medicine will be held on **Oct. 4-5, 2011**, in Bethesda, Md. <http://www.nhlbi.nih.gov/meetings/cv-regen11/index.htm>
- The 13th annual World Vaccine Congress will be held **Oct. 10-13, 2011**, in Lyon, France. <http://www.terrapin.com/2011/world-vaccine-congress-lyon/index.stm>
- NIH's 30th Anniversary Celebrating Scientific Discoveries: Disease Cures and Life: A Healthcare Transformation will be held on **Oct. 13, 2011**, in Bethesda, Md.

- NINR's 25th Anniversary Concluding Scientific Symposium: Bringing Science to Life: A Healthier Tomorrow will be held on **Oct. 13, 2011**, in Bethesda Md. <http://www.ninr.nih.gov/NewsAndInformation/25years/healthiertomorrow.htm>
- American Medical Informatics Association (AMIA) 2011 Annual Symposium will be held on **Oct. 22-26, 2011**, in Washington, DC. <https://www.amia.org/amia2011>
- CFHA's 13th Annual Conference: Accelerating Adoption of Collaborative Care: Reaching the Tipping Point on **Oct. 27-29, 2011**, in Philadelphia, Pa. <http://www.cfha.net/pages/Conference/>
- The American Public Health Association Annual Meeting & Exposition will be held on **Oct. 29-Nov. 2, 2011**, in Washington D.C. <http://www.apha.org/meetings/>
- The 117th AMSUS Annual Meeting will be held **Nov. 6-9, 2011**, in San Antonio, Texas. <http://www.amsus.org/index.php/annual-meeting>
- Eighth Annual Interdisciplinary Women's Health Research Symposium will be held on **Nov. 12, 2011**, in Bethesda, Md. <http://www.orwhmeetings.com/symposium.aspx>
- The CDC's 2011 Symposium on Identification, Screening and Surveillance of HCV Infections in the Era of Improved Therapy for Hepatitis C will be held on **Dec. 1-2, 2011**, in Atlanta Ga. <http://www.cdc.gov/hepatitis/hcvsymposium2011/>
- 17th Annual Maternal and Child Health Epidemiology Conference will be held on **Dec. 14-16, 2011**, in New Orleans, La. <http://www.cdc.gov/reproductivehealth/MCHEpi/Conference/AboutConference.htm>
- mHealth Summit will held on **Dec. 5-7, 2011**, in Washington, D.C. <http://www.mhealthsummit.org/>
- The International Conference on Emerging Infectious Diseases 2012 (ICEID) will be held on **March 11-14, 2012**, in Atlanta, Ga. <http://www.cdc.gov/eid/content/16/11/e1.htm>
- The 15th International Congress on Infectious Diseases (ICID) will be held on **June 13-16, 2012**, in Bangkok, Thailand. http://www.isid.org/15th_ICID/

If you need further information on any of the items in the Federal Health Update, please contact Kate Connelly Theroux at (703) 447-3257 or by e-mail at katetheroux@fedhealthinst.org. To subscribe, please visit <http://fedhealthinst.org/subscriber.cfm>. To unsubscribe, please send an email to newsletter@fedhealthinst.org with UNSUBSCRIBE as the subject.

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5185 MacArthur Blvd. NW, Suite 103-656, Washington, DC 20016
(202)271-5814 postmaster@fedhealthinst.org