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

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The Hill reports that Speaker John Boehner (R-Ohio) and House Minority Leader Nancy Pelosi (D-Calif.) met Sept. 17 to discuss a government funding bill to avert a government shutdown.

Boehner is trying to figure out how to avoid a shutdown, as 31 conservative Republican lawmakers have vowed not to vote for any spending bill that includes Planned Parenthood funds.

Pelosi met with President Obama and Senate Minority Leader Harry Reid (D-Nev.) at the White House on Sept. 17. The three want to pass a clean stopgap bill to avert a government shutdown and allow negotiators more time to reach a long-term budget deal.

On Sept. 14, 2015, the Army Chief of Staff, announced the following officer assignments:

Maj. Gen. Jeffrey B. Clark, director, Walter Reed National Military Medical Center, Bethesda, Maryland, to be director, healthcare operations, Defense Health Agency, Falls Church, Va.
On Sept. 17, 2015, Secretary of Defense Ash Carter announced that Navy Rear Adm. Raquel C. Bono has been nominated for appointment to the rank of vice admiral and for assignment as director, Defense Health Agency, Falls Church, Virginia. Bono is currently serving as director, National Capital Region Medical Directorate/chief of the Medical Corps, Walter Reed National Military Medical Center, Bethesda, Maryland.

Air Force Lt. Gen. Douglas Robb, Defense Health Agency (DHA) director, offers his thoughts on full operational capability and the two-year anniversary of DHA. In his remarks, Robb highlights improved delivery of services and savings. According to DHA, the agency has saved $350 million in fiscal year 2014 alone, and is projecting nearly $3.5 billion in savings over the next four years.


VETERANS AFFAIRS NEWS

The Department of Veterans Affairs announced that veterans who fill their prescriptions at a Veterans Affairs Department pharmacy will see no increase in co-payments until at least January 2017.

Under the new policy published in the Federal Register, VA will extend a freeze on co-payment increases until at least Dec. 31, 2016.

Veterans are required to pay a portion of the cost for prescription drugs they receive for non-service-related conditions if their incomes exceed established threshold limits. They pay either $8 or $9 per 30-day prescription, depending on their eligibility status within the VA health system.

According to VA, veterans tend to reduce use of their pharmacy benefits when co-payments rise, which leads to not taking their medications as prescribed.

Patients also are at greater risk for adverse drug interactions if they fill some of their prescriptions at VA and others at civilian pharmacies, VA officials say.

The freeze is designed to continue providing the benefit to veterans at moderate cost.

The Department of Veterans Affairs (VA) is awarding up to $8 million in grants to eligible recipients with experience managing large scale adaptive sports programs for disabled veterans and disabled service members of the Armed Forces.

The grant recipients may use these funds for planning, developing, managing and implementing adaptive sports programs.

The VA is awarding the grants to national governing bodies, which prepare high-level athletes for Paralympic competition; veterans service organizations; city and regional municipalities; and other community groups to provide a wide range of adaptive sports opportunities for eligible veterans and service members. The grants will support sports ranging from rowing, cycling and skiing to golf, fly fishing and equestrian sports.
VA will distribute the grants to 89 national, regional and community programs serving all 50 states, the District of Columbia, Puerto Rico, the Virgin Islands and Guam. Approximately 10,000 veterans and service members are expected to benefit.

Information about the awardees and details of the program may be found at [www.va.gov/adaptive-sports](http://www.va.gov/adaptive-sports).

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**GENERAL HEALTH CARE NEWS**

- **Multiple drugs to combat bioterrorism threats and other life-threatening bacterial infections will be developed under a public-private partnership agreement between the U.S. Department of Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response (ASPR) and AstraZeneca, a global biopharmaceutical company.**

  Traditionally, BARDA supports development of individual products. Supporting development of multiple drug candidates increases the likelihood that one or more will advance to the level at which the company can apply for U.S. Food and Drug Administration approval of the drug. In addition, novel antibiotics developed under the agreement may become available in the commercial marketplace, which diminishes the federal government’s need to stockpile these products for biodefense and reduces long-term costs for taxpayers.

  BARDA and AstraZeneca will manage and fund the portfolio over the next five years. In the cost-sharing arrangement, BARDA initially will provide $50 million toward product development and could provide up to a total of $170 million for development of additional products in the portfolio during the five-year period. During joint annual portfolio reviews, BARDA and AstraZeneca will determine which drug candidates move in or out of the portfolio based on technical and financial considerations and each drug candidate’s development progress.

  The first drug candidate in the portfolio combines two antibiotics, Aztreonam and Avibactam, known together as ATM-AVI. The new drug is being developed to treat Gram-negative infections for which there are currently limited treatment options. Under today’s agreement, the company also will conduct studies evaluating ATM-AVI and other antibiotic candidates for use in treating illnesses caused by deadly bioterrorism threats such as melioidosis, glanders and plague.

  [CDC](https://www.cdc.gov) has estimated that in the U.S. antibiotic-resistant bacteria are responsible for two million infections and 23,000 deaths annually with an estimated annual economic burden of $35 billion on the healthcare system.

- **The Department of Health and Human Services (HHS) hosed a two-day meeting with representatives from all 50 states and Washington, DC, focused on preventing opioid overdose and opioid use disorder.**

  During the meeting, HHS announced it expand access to medication-assisted treatment (MAT) by revising the regulations related to the prescribing of buprenorphine to treat opioid dependence. HHS will also award $1.8 million to rural communities to expand access to naloxone – a drug that reverses an opioid overdose.

  In 2013, overdoses from prescription opioid pain relievers claimed more than 16,200 lives, with more than 145,000 people dying from these overdoses in the last decade. Heroin deaths have also been climbing sharply, more than doubling between 2010 and 2013. The resulting health,
social, and economic consequences for communities across the country are enormous.

The two-day convening will focus specifically on improving opioid prescribing practices, increasing access to naloxone, and expanding the use of medication-assisted treatment (MAT).

Medication-assisted treatment (MAT) is a comprehensive way to address the needs of individuals that combines the use of medication with counseling and behavioral therapies to treat substance use disorders. Nevertheless, existing evidence shows that this lifesaving, evidence-based treatment is under-utilized. A recent HHS report indicates that of the 2.5 million people who currently need treatment for opioid use disorder, fewer than 1 million are receiving it. To help close this gap, the secretary announced today that HHS will move to revise the regulations related to the prescribing of buprenorphine-containing products approved by the FDA for treatment of opioid dependence.

Under current regulations, physicians that are certified to prescribe buprenorphine for MAT are allowed to prescribe up to 30 patients initially and then after 1 year can request authorization to prescribe up to a maximum of 100 patients. This cap on prescribing limits the ability of some physicians to prescribe to patients with opioid use disorder. The HHS revision to the regulation will be developed to provide a balance between expanding the supply of this important treatment, encouraging use of evidence-based MAT, and minimizing the risk of drug diversion.

For more information on the department’s efforts and this initiative, click here.

- New recommendations from the Centers for Disease Control and Prevention (CDC) advise all nursing homes to improve antibiotic prescribing practices and reduce their inappropriate use to protect residents from the consequences of antibiotic-resistant infections, such as C. difficile.

To guide these improvements, CDC released a new resource: Core Elements of Antibiotic Stewardship for Nursing Homes. The Core Elements for Nursing Homes expand upon CDC’s recommendation last year that all acute care hospitals implement an antibiotic stewardship program designed to optimize treatment of infections while reducing adverse events associated with antibiotic use.

Approximately 4.1 million Americans are admitted to or reside in nursing homes each year. Antibiotics are the most frequently prescribed medications in nursing homes. Up to 70 percent of residents receive one or more courses of antibiotics during a year. As much as 75 percent of antibiotics prescribed in nursing homes are given incorrectly, meaning either the drug is unnecessary or the prescription is for the wrong drug, dose, or duration.

The Core Elements provide practical ways for nursing homes to initiate or expand antibiotic stewardship activities. The guide provides examples of how antibiotic use can be monitored and improved by nursing home leadership and staff. CDC recommend that nursing home antibiotic stewardship activities should, at a minimum, include the following:

- **Leadership commitment:** Demonstrate support and commitment to safe and appropriate antibiotic use.
- **Accountability:** Identify leaders who are responsible for promoting and overseeing antibiotic stewardship activities at the nursing home.
- **Drug expertise:** Establish access to experts with experience or training in improving antibiotic use.
- **Action:** Take at least one new action to improve the way antibiotics are used in the facility.
- **Tracking:** Measure how antibiotics are used and the complications (e.g., C. difficile infections) from antibiotics in the facility.
- **Reporting:** Share information with healthcare providers and staff about how
antibiotics are used in the facility.

- **Education:** Provide resources to healthcare providers, nursing staff, residents and families to learn about antibiotic resistance and opportunities for improving antibiotic use.

The Centers for Medicare & Medicaid Services (CMS) recently proposed a rule that would require long-term care facilities to incorporate an antibiotic stewardship program, including antibiotic use protocols and antibiotic monitoring, into their infection prevention and control program. According to CMS, these requirements will decrease unnecessary or inappropriate antibiotic use by ensuring that residents who need antibiotics are prescribed the right drug at the right dose for the right duration.

- The Department of Health and Human Services announced nearly $500 million in Affordable Care Act funding to support health centers nationwide in providing primary care services to those who need them most.

The awards include approximately $350 million for 1,184 health centers to increase access to services such as medical, oral, behavioral, pharmacy, and vision care. Nearly $150 million will be awarded to 160 health centers for facility renovation, expansion, or construction to increase patient or service capacity.

The Health Center Expanded Services funds build on HHS’s investments to expand access to affordable care for the millions of Americans who have become insured thanks to the Affordable Care Act. The next open enrollment for the Health Insurance Marketplace begins on Nov. 1, 2015, and eligible people can enroll in Medicaid year round.

These funds may be used to support these outreach and enrollment activities and help individuals find the health care coverage that best meets their needs and budget. Since 2013, health centers have assisted more than 12 million people with their efforts to become insured. The Health Infrastructure Investment Program awards allow health centers to renovate or acquire new health center clinical space to help health centers meet community needs.

Since the beginning of 2009, health centers have added 6 million patients, and are now serving nearly 23 million people each year. Today, over 1,300 health center grantees operate approximately 9,000 clinic sites in every state and U.S. territory.


**REPORTS/Policies**

- The GAO published “State Health Insurance Marketplaces: CMS Should Improve Oversight of State Information Technology Projects,” (GAO-15-527) on Sept. 16, 2015. The purpose of this study is to determine how states have used federal funds for IT projects to support their marketplaces and the status of the marketplaces; determine CMS’s and states’ roles in overseeing these projects; and describe IT challenges states have encountered and lessons learned. http://www.gao.gov/assets/680/672565.pdf
The GAO published “Medicare Part D: Changes Needed to Improve CMS’s Recovery Audit Program Operations and Contractor Oversight,” (GAO-15-633) Sept. 14, 2015. This report examines how CMS has implemented the Part D RAC program and any challenges it faced during implementation; the extent to which CMS has overseen the RAC’s audit activities; and the results of the RAC’s work to date and any challenges CMS and the RAC faced in identifying and collecting improper payments. http://www.gao.gov/assets/680/671997.pdf

HILL HEARINGS

- The House Veterans Affairs Committee will hold a hearing on Oct. 7, 2015, to examine an independent assessment of the Veterans Health Administration.

LEGISLATION

- **H.R.3494** (introduced Sept. 11, 2015): the Protecting Infants Born Alive Act was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means. Sponsor: Representative Marsha Blackburn [TN-7]
- **H.R.3520** (introduced Sept. 16, 2015): To amend the Public Health Service Act to establish an interagency coordinating committee on pulmonary hypertension, and for other purposes was referred to the House Committee on Energy and Commerce. Sponsor: Representative Kevin Brady [TX-8]
- **H.RES.421** (introduced Sept. 16, 2015): Providing for consideration of the bill (H.R. 3134) to provide for a moratorium on Federal funding to Planned Parenthood Federation of America, Inc.; providing for consideration of the bill (H.R. 3504) to amend title 18, United States Code, to prohibit a health care practitioner from failing to exercise the proper degree of care in the case of a child who survives an abortion or attempted abortion; and for other purposes was passed in the House of Representatives. Sponsor: Representative Virginia Foxx [NC-5]
- **S.2030** (introduced Sept. 15, 2015): Advancing Targeted Therapies for Rare Diseases Act of 2015 was referred to the Committee on Health, Education, Labor, and Pensions. Sponsor: Senator Michael F. Bennet [CO]
- **S.2041** (introduced Sept. 16, 2015): A bill to promote the development of safe drugs for neonates was referred to the Committee on Health, Education, Labor, and Pensions. Sponsor: Senator Robert P. Casey, Jr. [PA]
- **S.2055** (introduced Sept. 17, 2015): A bill to amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to national health security was referred to the Committee on Health, Education, Labor, and Pensions. Sponsor: Senator Richard Burr [NC]
- **S.2060** (introduced Sept. 17, 2015): A bill to amend the Public Health Service Act to reauthorize and extend the Fetal Alcohol Syndrome prevention and services program, and for other purposes was referred to the Committee on Health, Education, Labor, and Pensions. Sponsor: Senator Lisa Murkowski [AK]
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| • The 2015 AHRQ Research Conference, “Producing Evidence and Engaging Partners to Improve Health Care”, will be held **Oct. 4–6, 2015**, in Crystal City, Va.  
| • The AUSA 2015 Annual Meeting & Exposition will be held **Oct. 12-14, 2015**, in Washington DC.  
| • The 31st Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) will be held **Nov.5-7, 2015**, in New Orleans, La.  
  [http://www.istss.org/am15/home.aspx](http://www.istss.org/am15/home.aspx) |
| • The AMIA 2015 Annual Symposium will be held on **Nov. 14-16, 2015**, in San Francisco, Calif.  
| • 2015 AMSUS Annual Continuing Education Meeting will be held **Dec. 1-4, 2015**, in San Antonio, Texas  
  [http://amsusmeetings.org](http://amsusmeetings.org) |

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