

## American Nephrology Nurses Association

Weekly Capitol Hill Update - Monday, July 16, 2018

### Congressional Schedule

#### Senate

- Senate meets at 3 pm, considers nomination of Scott Stump to be asst. secretary for career, technical, and adult education at the Education Department.

#### House

- House meets at noon, with votes around 6:30 pm

### Legislative Update

- **Week in Review**
  - *Senate panel OKs Trump's pick to lead troubled VA.* "A Senate panel voted Tuesday to approve President Donald Trump's nominee to lead Veterans Affairs, a department beset by political infighting and turmoil over providing health care. The Senate Veterans Affairs Committee agreed on voice vote to back Robert Wilkie, currently serving as a Pentagon undersecretary. Independent Sen. Bernie Sanders of Vermont cast a 'no' vote. Wilkie has pledged to 'shake up complacency' at the VA, which has struggled with long waits in providing medical treatment to millions of veterans."
    - Read more: <https://apnews.com/087577a7643a4f3b8f46505614277cf4>
  - *Top Dem demands more details on pricing deal between Pfizer and Trump.* "The top Democrat on the Senate Finance Committee is demanding details on an agreement between President Trump and drug company Pfizer to temporarily hold off on drug price increases. Pfizer announced Tuesday evening it would defer previously announced price increases on 100 drugs following 'an extensive discussion' with Trump to give the administration more time to work on its plan to lower costs. The prices will return to their pre-July 1 levels, and will remain there until the president's blueprint goes into effect or the end of the year, whichever is sooner."
    - Read more: <http://thehill.com/policy/healthcare/396519-top-dem-demands-more-details-on-agreement-between-pfizer-and-trump>
  - *House panel advances bill that would temporarily halt ObamaCare's employer mandate.* "The House Ways and Means Committee on Thursday approved

legislation that would chip away at ObamaCare, including a measure that would temporarily repeal the law's employer mandate. The bill sponsored by GOP Reps. Devin Nunes (Calif.) and Mike Kelly (R-Pa.) would suspend penalties for the employer mandate for 2015 through 2019 and delay implementation of the tax on high-cost employer-sponsored health plans for another year, pushing it back to 2022. Congress repealed the penalty associated with the individual mandate last year, but it doesn't take effect until 2019."

- <http://thehill.com/policy/healthcare/396770-house-panel-passes-bill-that-would-repeal-obamacares-employer-mandate>

- **Week Ahead**

- **HHS Officials to testify on Stark Law.** "HHS Deputy Secretary Eric Hargan and deputy general counsel Kelly Cleary are scheduled to testify at an upcoming House hearing on the physician self-referral regulations known as Stark Law, a person with knowledge of HHS' preparations told Pro's Adam Cancryn. The Ways and Means health subcommittee is hosting the July 17 session, where Hargan and Cleary are likely to discuss their efforts to overhaul regulations that providers say hinders care coordination."
  - Read more: <https://www.politico.com/newsletters/politico-pulse/2018/07/11/under-pressure-pfizer-delays-price-increases-275047>

### Regulatory and Administration Update

- **Hospital-based end-stage renal disease facilities to get 1.8% payment increase.** "The Centers for Medicare and Medicaid Services on Wednesday released proposed payment changes for durable medical equipment prosthetics, orthotics and supplies and the end-stage renal disease programs. Payments for 2019 to end-stage renal disease facilities are expected to increase by 1.7 percent compared to this year. For hospital-based ESRD facilities, CMS projects an increase in total payments of 1.8 percent, while for freestanding facilities, the projected increase in total payments is 1.7 percent."
  - Read more: <https://www.healthcarefinancenews.com/news/hospital-based-end-stage-renal-disease-facilities-get-18-payment-increase>
- **Trump officials again slash funding for ObamaCare outreach groups.** "The Trump administration announced Tuesday that it is significantly cutting funding for outreach groups that help people enroll in ObamaCare coverage. The funding will be cut from \$36 million this year to \$10 million in 2019, the federal Centers for Medicare and Medicaid Services (CMS) said in a statement. The administration's funding for such outreach had already been slashed last year to well below the \$63 million budgeted annually under former President Obama."
  - Read more: <http://thehill.com/policy/healthcare/396379-trump-officials-cut-funding-for-obamacare-outreach-groups>
- **FDA approves freeze-dried blood plasma for troops in combat.** "The Food and Drug Administration (FDA) on Tuesday approved freeze-dried blood plasma for use to treat combat injuries from U.S. troops, after a dispute over whether access would be allowed. House Armed Services Committee Chairman Mac Thornberry (R-Texas) last year

tried to go around the FDA by granting the Department of Defense the ability to allow the freeze-dried plasma use. Eventually, an agreement was reached to prevent that more drastic measure, and the FDA is now approving the use of the freeze-dried plasma from a French company, even though it is not approved for wider use in the United States.”

- Read more: <http://thehill.com/policy/healthcare/396330-fda-approves-freeze-dried-blood-plasma-for-troops-in-combat>
- ***Brett Kavanaugh, Trump's pick for court, has left trail of opinions on health care and pharma issues.*** “Brett Kavanaugh, President Trump’s nominee for the Supreme Court, has left a trail of rulings and opinions concerning the Food and Drug Administration, pharmaceutical companies, and medical device manufacturers in his dozen years on the District of Columbia circuit court. At one point, Kavanaugh urged judges to defer to the FDA and other scientific agencies, largely on the grounds that courts could not compete with the agencies’ expertise. He also sided with the FDA in a case over whether the agency should be forced to provide access to an unapproved drug.”
  - Read more: <https://www.statnews.com/2018/07/10/brett-kavanaugh-cases/>
- ***HHS Secretary: Recent drug price increases ‘creating a tipping point.’*** “Health and Human Services (HHS) Secretary Alex Azar on Monday rebuked drug companies for recent price increases. ‘Change is coming to prescription drug pricing, whether it’s painful or not for pharmaceutical companies,’ Azar said in a speech Monday at a health policy conference. Azar's comments follow Pfizer's decision to raise the list prices of more than 100 prescription drugs. The increases, effective July 1, came despite the administration's recent tough talk on combating rising drug costs.”
  - Read more: <http://thehill.com/policy/healthcare/396162-hhs-secretary-recent-drug-price-increases-creating-a-tipping-point>
- ***Trump admin expected to suspend some ObamaCare risk adjustment payments: report.*** “The Trump administration is planning to suspend some payments to insurance companies, a key provision of the Affordable Care Act, this fall following a federal judge's decision, according to The Wall Street Journal. People familiar with the plans said that the Centers for Medicare and Medicaid Services (CMS) is planning to temporarily suspend some risk-adjustment payments stemming from 2017 business this fall as well as payments next year that would reflect 2018 business. The move comes after a federal judge ruled that the Obama administration's formula calculating the payments was flawed and inadequately justified by regulators, according to the Journal. CMS has made no public statements regarding policy changes for the risk-adjustment payments as of yet. CMS was expected to put out a report at the end of June regarding the payments, but that report has not yet been released.”
  - Read more: <http://thehill.com/policy/healthcare/395937-trump-admin-expected-to-suspend-some-obamacare-risk-adjustment-payments>
- ***Drug shortages prompt FDA to form task force.*** “The US Food and Drug Administration is forming a Drug Shortages Task Force to look into the country's persistent drug shortages and find long-term solutions, according to a statement Thursday from the agency's commissioner, Dr. Scott Gottlieb. ‘We've seen the number of new drug shortages steadily decline since a peak in 2011,’ Gottlieb said. ‘Despite these efforts, we

continue to see ongoing shortages of medically necessary products.' Experts say these shortages aren't just causing the medical community to scramble for solutions -- they're hurting patients."

- Read more: <https://www.cnn.com/2018/07/12/health/fda-drug-shortage-task-force-bn/index.html>
- ***CMS proposes change in the drug payment amount under Medicare Part B.*** "The Centers for Medicare & Medicaid Services on Thursday proposed a change in the payment amount for new drugs under its Part B program, amid the Trump administration's attempts to tackle escalating prices of drugs. Medicare Part B covers medicines patients receive in a doctor's office, such as infusions, CMS said. The move from the agency comes in the same week U.S. President Donald Trump called Pfizer Chief Executive Ian Read to say the company's July 1 price hikes had complicated the administration's drug pricing plans, prompting the company to defer its planned increases."
  - Read more: <https://www.reuters.com/article/us-usa-healthcare-cms/cms-proposes-change-in-the-drug-payment-amount-under-medicare-part-b-idUSKBN1K238X>
- ***CMS proposes new rule to boost telehealth payment.*** "In a move that Centers for Medicare and Medicaid Services Administrator Seema Verma described as among 'the most significant reductions in provider burden undertaken by any administration,' CMS late Thursday proposed a new rule intended to make big strides in telehealth, documentation requirements and interoperability. On the telemedicine side, the proposal would mean CMS will begin paying physicians for 'brief check-ins' via telemedicine as well as remote evaluation of images and videos taken by patients. It also expands the list of Part B services that can be offered by telehealth and adds mobile stroke units, dialysis facilities and the homes of end-stage renal disease patients as valid originating sites for telemedicine visits."
  - Read more: <https://www.healthcareitnews.com/news/cms-proposes-new-rule-boost-telehealth-payments>

### **Articles of Interest**

- ***New York organ collection agency, nation's second-largest, threatened with closure.*** "The government is threatening to close one of the country's largest 'organ procurement organizations' for poor performance, a rare move against a nonprofit group that collects kidneys, livers, hearts and other organs used in transplantation. In a letter last month to LiveOnNY, which recovers organs in the New York City area, the Centers for Medicare and Medicaid Services (CMS) said it 'will not renew its agreement with LiveOnNY' when the contract is set to expire Jan. 31. CMS rejected LiveOnNY's request for reconsideration Monday. It said the organization failed to meet two of the standards used to measure success at collecting organs that are often the last hope for people suffering from life-threatening diseases."
  - Read more: <http://us.lalalay.com/news/us/-164571-new-york-organ-collection-agency-nation-s-second-largest-threatened-with-closure/>

- ***Cheap blood pressure drug might slow diabetes.*** “A cheap and safe blood pressure drug slows the worsening of Type 1 diabetes, researchers reported Monday. It’s the first drug that has been shown to affect the course of the disease, also known as juvenile diabetes, which is caused by the body’s mistaken destruction of the pancreatic cells that make insulin. The blood pressure drug, verapamil, appears to protect some of the pancreatic cells that are damaged, allowing them to continue producing a little insulin. It’s not a cure, but adults with newly diagnosed diabetes who took the drug had better control of their blood sugar over time, the team at the University of Alabama at Birmingham reported.”
  - Read more: [https://www.nbcnews.com/health/health-news/cheap-blood-pressure-drug-might-slow-diabetes-n889836?cid=par-twitter-feed\\_20180709](https://www.nbcnews.com/health/health-news/cheap-blood-pressure-drug-might-slow-diabetes-n889836?cid=par-twitter-feed_20180709)
- ***Tuberculosis vaccine shows potential as low-cost treatment for type 1 diabetes.*** “A tuberculosis vaccine that has been around for a century is being investigated as a potential low-cost, long-term treatment for type 1 diabetes. Researchers published a small study of the Bacillus Calmette-Guerin (BCG) vaccine’s effects in June in the journal *Nature Partner Journal Vaccines*. They found three patients who were injected with two doses of BCG achieved blood sugar reductions of more than 10 percent at three years and sustained those lower A1c levels for another five years. The vaccine costs \$157 per dose in the U.S., according to Kaiser Health News – well below the price of insulin, which has more than doubled in the last decade.”
  - Read more: <https://www.cardiovascularbusiness.com/topics/lipids-metabolic/tuberculosis-vaccine-cost-treatment-type-1-diabetes>
- ***Hepatitis-infected kidneys may be safe new option for transplant.*** “If they’re already infected with hepatitis C virus (HCV), patients in need of a kidney transplant might safely receive an organ from an HCV-infected donor, a new study maintains. Using hepatitis C-infected kidneys for this group of patients would cut costs and waiting times, thereby saving lives, said researchers led by Dr. Mark Eckman. He’s director of general internal medicine at the University of Cincinnati.”
  - Read more: <https://consumer.healthday.com/infectious-disease-information-21/hepatitis-news-373/hepatitis-infected-kidneys-may-be-safe-new-option-for-transplant-735598.html>
- ***BD acquires TVA Medical to advance leadership in solutions for Chronic Kidney Disease.*** “BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced it has completed the acquisition of TVA Medical, Inc., a company that develops minimally invasive vascular access solutions for patients with chronic kidney disease requiring hemodialysis. In the U.S. alone, there are more than 440,000 patients with End-Stage Renal Disease (ESRD) who are surviving on hemodialysis<sup>1</sup>. The addition of TVA Medical enables BD to offer the everlinQ™ endoAVF System, a new endovascular arteriovenous (AV) fistula creation technology that adds to the company's ESRD portfolio of dialysis catheters, drug coated balloons, standard angioplasty balloons and endovascular stent graft products. This technology will further improve BD's ability to serve physicians and their patients by providing a minimally invasive option for creating critical AV fistulas (joining arteries to veins to create a circuit) for hemodialysis procedures.”

- Read more: <http://investors.bd.com/phoenix.zhtml?c=64106&p=irol-newsArticle&ID=2357325>
- ***System for reporting suspicious opioid orders repeatedly failed, report finds.*** “A Senate report released Thursday lays out systematic failures in the reporting system for suspicious opioid orders, faulting some drug distributors and manufacturers for their roles and criticizing the Drug Enforcement Administration for a years-long lull in enforcement actions. The findings, the latest in a series of reports from Sen. Claire McCaskill (D-Mo.), the top Democrat on the Senate’s leading oversight committee, pointed in particular to disparities between two leading drug distributors: McKesson and AmerisourceBergen. The two distributors shipped nearly identical volumes of opioids to Missouri between 2012 and 2017: roughly 650 million doses each.”
  - Read more: <https://www.statnews.com/2018/07/12/senate-report-opioids-distribution/>
- ***Research charity launches \$330M initiative to fund high-risk life sciences projects.*** “One of the world’s largest biomedical research charities is setting up a new \$330 million initiative to fund high-risk projects – an effort it hopes can help researchers challenge the status quo in the life sciences. The Wellcome Trust says that it is establishing what it is calling the Leap Fund – an independently run offshoot that will seek out and provide funding for outside-the-box science. The idea is to support research that is simply not a sure enough bet for more traditional funding bodies, Wellcome’s director, Dr. Jeremy Farrar, told STAT in an interview.”
  - Read more: <https://www.statnews.com/2018/07/09/wellcome-trust-launches-fund-to-boost-high-risk-life-sciences-projects/>
- ***Insurers fall short in catching and reporting Medicaid fraud, inspectors find.*** “Despite receiving billions of dollars in taxpayer money, Medicaid insurers are lax in ferreting out fraud and neglect to tell states about unscrupulous medical providers, according to a federal report released Thursday. The U.S. Health and Human Services’ inspector general’s office said a third of the health plans it examined had referred fewer than 10 cases each of suspected fraud or abuse to state Medicaid officials in 2015 for further investigation. Two insurers in the program, which serves low-income Americans, didn’t identify a single case all year, the report found.”
  - Read more: <https://khn.org/news/insurers-fall-short-in-catching-and-reporting-medicaid-fraud-inspectors-find/>
- ***Drugmakers cancel price hikes after California law takes effect.*** “A handful of the world’s biggest drugmakers are canceling or reducing planned price increases in the U.S., following a new California drug pricing transparency law and continued political pressure over pharmaceutical costs. The California law, which began to take effect earlier this year, requires drugmakers to give insurers, governments and drug purchasers advance notice of large price increases, as a way of publicly pressuring pharmaceutical companies to keep prices down. In the past three weeks, Novartis AG, Gilead Sciences Inc., Roche Holding AG and Novo Nordisk A/S sent notices to California health plans rescinding or reducing previously announced price hikes on at least 10 drugs.”

- Read more: <http://www.latimes.com/business/la-fi-drug-prices-20180710-story.html>
- ***The digest: Doctors repair infants' damaged hearts with experimental procedure.***  
“Doctors at Boston Children’s Hospital have developed a new kind of transplant that is giving infants with damaged hearts a chance to lead a normal, healthy life. These babies aren’t receiving new organs, though. Instead, doctors are transplanting mitochondria from the infant’s own muscle cells right into their failing hearts – and they’re finding the experimental procedure produces remarkable results, according to a new report by *The New York Times*.”
  - Read more: <https://futurism.com/mitochondrial-transplant-damaged-hearts/>
- ***U.S. DoJ will not challenge Aetna-CVS deal: report.*** “Shares of CVS Health Corp (CVS.N) and health insurer Aetna Inc (AET.N) rose more than 2 percent on Thursday after CNBC reported that the U.S. Justice Department will not challenge their planned merger. CNBC said Bloomberg reported the news, citing trade publication Reorg Research. CVS Health Corp and Aetna announced the \$69 billion deal on Dec. 3 last year, arguing it would enable the companies to tackle soaring healthcare spending by offering lower-cost medical services in pharmacies. Aetna and CVS declined to comment.”
  - Read more: <https://www.reuters.com/article/us-aetna-m-a-cvs-health/u-s-doj-will-not-challenge-aetna-cvs-deal-report-idUSKBN1K22S8>