

## American Nephrology Nurses Association

Weekly Capitol Hill Update - Tuesday, September 4, 2018

### Congressional Schedule

#### Senate

- Senate meets at 3pm; holds procedural vote on the nomination of Elad Roisman to be an SEC commissioner; also considers nominations of eight district court judges

#### House

- House meets at 2pm; starts process of going to conference with Senate to work out differences on H.R. 6157, the FY19 funding measure covering Pentagon and Labor-HHS-Education

### Legislative Update

- **Week in Review**
  - *Dem introduces measure to overturn Trump expansion of non-Obamacare plans.* “Sen. Tammy Baldwin (D-Wis.) on Wednesday introduced a measure to overturn a Trump administration rule expanding access to non-ObamaCare insurance plans. The move is a step in Senate Democrats’ plan to force a vote on the measure as they seek to argue Republicans are attacking protections for people with pre-existing conditions, a key argument Democrats want to make in the midterm election campaign. Baldwin’s office said she has the support of the 30 senators necessary to force a vote on the measure under the Congressional Review Act.”
    - Read more: <http://thehill.com/policy/healthcare/404148-dem-introduces-measure-to-overturn-trump-expansion-of-non-obamacare-plans>
- **Week Ahead**
  - House returns to session after August recess on September 4.
  - *Senate GOP signs off on opioid package, clearing key milestone before possible vote next week.* “Republican senators have signed off on a legislative package to fight the opioid crisis and now wait for Democrats to weigh in, with GOP Senate leadership hoping for a vote next month. ‘The ball is in their court,’ said Senate

Majority Leader Mitch McConnell, R-Ky., in a press conference Tuesday. ‘We are hoping Democrats will be able to clear those as well and this is something we can reach a consent agreement on to have a vote after Labor Day.’ Sen. Lamar Alexander, R-Tn., who is shepherding the legislation, said that every Republican has approved the legislation. Now Sen. Patty Murray, D-Wash., must do the same for the Senate’s Democrats.”

- Read more: <https://www.washingtonexaminer.com/policy/healthcare/senate-gop-signs-off-on-opioid-package-clearing-key-milestone-before-possible-vote-next-week>
- ***Washington’s fall agenda: Pre-existing conditions fight takes center stage in midterms.*** “Health care is one of the issues taking center stage in this November’s midterm elections as Democrats press Republicans on preserving protections for pre-existing conditions under ObamaCare. But there is also plenty of unfinished work for Congress and the administration this fall, from passing opioid legislation to tackling drug costs.”
  - Read more: <http://thehill.com/policy/healthcare/404263-washingtons-fall-agenda-pre-existing-conditions-fight-takes-center-stage-in>
- ***GOP eyes another shot at Obamacare repeal after McCain’s death.*** “Senate Republicans say they would like Arizona Gov. Doug Ducey (R) to appoint a successor to the late Sen. John McCain (R-Ariz.) who, unlike McCain, would support GOP legislation to repeal ObamaCare. Republican lawmakers say they won’t have time to hold another vote to repeal the law in 2018 but vow to try again next year if they manage to keep their Senate and House majorities.”
  - Read more: <http://thehill.com/homenews/senate/404089-gop-eyes-another-shot-at-obamacare-repeal-after-mccains-death>
- ***The Senate could soon pass an opioids package. But a new law is still a long way away.*** “The Senate is likely to pass a comprehensive bill to address the opioid crisis in the coming weeks. The House did so in June. But the finish line on that long-discussed priority remains a long way off. Lawmakers have left untouched many of the bill’s most contentious issues, like debates over patient privacy and expensive changes to Medicaid payments for addiction treatment. There’s no sign yet they’ll iron out those issues before the Senate votes.”
  - Read more: <https://www.statnews.com/2018/08/30/senate-opioids-legislation/>
- ***Supreme Court nominee Brett Kavanaugh’s highly anticipated confirmation hearing, explained.*** “Supreme Court nominee Brett Kavanaugh heads to the Senate Judiciary Committee on Tuesday, where lawmakers will be able to publicly press the controversial pick on a wide-ranging set of issues — including abortion rights and executive power. The confirmation hearing, which is expected to go all week, is an important opportunity to shed more light on Kavanaugh’s record and legal reasoning. It’s historically served as a vital step in vetting contenders for the high court. It’s also a last-ditch chance for Democrats

to make their case against the nominee before he gets a Senate vote. And they aren't planning to hold back."

- Read more: <https://www.vox.com/2018/9/4/17796546/brett-kavanaugh-confirmation-hearing>
- ***#SubHealth to review bills to improve patient care, reduce health care fraud.***  
"The Health Subcommittee, chaired by Rep. Michael C. Burgess, M.D. (R-TX), announced a hearing for Wednesday, September 5, 2018, at 10 a.m. in room 2123 of the Rayburn House Office Building. The hearing is entitled, 'Opportunities to Improve Health Care.' Next week, #SubHealth will review five bills to improve health care in a variety of ways."
  - Read more: <https://energycommerce.house.gov/news/press-release/subhealth-to-review-bills-to-improve-patient-care-reduce-health-care-fraud/>
- ***Examining federal efforts to ensure quality of care and resident safety in nursing homes.*** Hearing to be held at 10:15 am on Thursday, September 6, in 2322 Rayburn House Office Building. Witnesses include Mr. John Dicken, Director of Health Care at the U.S. Government Accountability Office, and Ms. Ruth Ann Dorrill, Regional Inspector General in the Office of the Inspector General at the U.S. Department of Health and Human Services.
  - Read more: <https://energycommerce.house.gov/hearings/examining-federal-efforts-to-ensure-quality-of-care-and-resident-safety-in-nursing-homes/>
- ***A Texas lawsuit being heard this week could mean life or death for the ACA.***  
"Wednesday is looking like yet another pivotal day in the life-or-death saga that has marked the history of the Affordable Care Act. In a Texas courtroom, a group of Republican attorneys general, led by Texas' Ken Paxton, are set to face off against a group of Democratic attorneys general, led by California's Xavier Becerra, in a lawsuit aimed at striking down the federal health law. The Republicans say that when Congress eliminated the penalty for not having health insurance as part of last year's tax bill, lawmakers rendered the entire health law unconstitutional. The Democrats argue that's not the case."
  - Read more: <https://khn.org/news/democratic-gop-attorneys-general-square-off-in-texas-showdown-over-health-law/>

### **Regulatory and Administration Update**

- ***CMS provides new flexibility to increase prescription drug choices and strengthen negotiation for Medicare enrollees.*** "The Centers for Medicare & Medicaid Services (CMS) issued a memo today to Medicare Part D plans, which cover prescription drugs that beneficiaries pick up at a pharmacy, offering plans new tools and flexibility to expand choices and lower drug prices for patients. Currently, if a Part D plan includes a particular drug on its formulary, the plan must cover that drug for every FDA-approved indication, or patient condition, even if the plan would otherwise instead cover a different drug for a particular indication. The requirement to cover drugs in this manner

can discourage Part D plans from including more drugs on their formularies and limit their power to negotiate discounts. Today's memo explains that starting in 2020, plans will have new flexibility to tailor their formularies so that different drugs can be included for different indications. This policy, known as 'indication-based formulary design,' is used in the private sector and will enable Part D plans to negotiate lower prices for patients. Targeted formulary coverage based on indication will also provide Part D beneficiaries with more drug choices and will empower beneficiaries to select a plan that is designed to meet their unique health needs."

- Read more: <https://www.cms.gov/newsroom/press-releases/cms-provides-new-flexibility-increase-prescription-drug-choices-and-strengthen-negotiation-medicare>
- **Physician groups say CMS' change to drug formularies shifts decisions from doctors' hands to insurers.** "Physician and patient advocacy groups are not happy with the latest effort by the Trump Administration to lower drug costs, saying it takes decisions out of doctors' hands and will limit treatments for patients. The administration's change to the way Part D plans construct drug formularies, offering more flexibility for sponsors to add or exclude drugs based on a particular indication, will take decisions out of the hands of doctors and put insurance companies in control of patient treatment plans, said the American College of Rheumatology (ACR) in a statement."
  - Read more: <https://www.fiercehealthcare.com/practices/physician-groups-say-cms-change-to-drug-formularies-bad-news-for-doctors-and-patients>
- **NIH comes out swinging on opioid abuse with anticipated \$40.4 million to research chronic pain.** "The NIH is pulling out all the stops to make President Donald Trump's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand a reality. And older Americans are likely to benefit every bit as much as young people. *Learning about fatal opioid overdoses changes prescribing behavior.* That was the headline on an announcement today from the National Institutes of Health (NIH) outlining a study the nation's medical research agency did to see if putting an individual face on the opioid epidemic could alter prescribers' behavior. As it turns out, it did just that."
  - Read more: <https://www.forbes.com/sites/robinseatonjefferson/2018/08/28/nih-comes-out-swinging-on-opioid-abuse-with-anticipated-40-4-million-to-research-chronic-pain/#119569996aea>
- **FDA warns of serious genital infection linked to certain diabetes drugs.** "The U.S. Food and Drug Administration (FDA) said on Wednesday a serious genital infection has been reported in patients taking a certain class of diabetes drugs, with one death and 11 others hospitalized. The warning pertains to a class of medicines called SGLT2 inhibitors, first approved in 2013 to lower blood sugar in adults with type 2 diabetes. Patients are at risk of the infection known as Fournier's gangrene, an extremely rare but life-threatening infection of the tissue under the skin that surrounds the genital area, the FDA said in a statement."

- Read more: <https://www.reuters.com/article/us-diabetesdrugs-fda/fda-warns-of-serious-genital-infection-linked-to-certain-diabetes-drugs-idUSKCN1LE2PQ>
- ***FDA widening probe into heart drugs linked to cancer.*** “After learning an ingredient used to make a widely prescribed heart drug contained a substance linked to cancer, the Food and Drug Administration is now testing all drugs in that class for traces of the toxic material. The probe into angiotensin II receptor blockers is part of a widening investigation into a mystery over an impurity known as NDMA, which was found last month in generic valsartan blood pressure pills made by Zhejiang Huahai Pharmaceutical. NDMA, which is considered a possible carcinogen by the Environmental Protection Agency, is an organic chemical once used to make rocket fuel and is an unintended by-product of certain chemical reactions.”
  - Read more: <https://www.statnews.com/pharmalot/2018/08/30/fda-heart-drugs-cancer-link/>
- ***Health and Human Services Department; National Institutes of Health; National Institute of Nursing Research.*** Health and Human Services Department; National Institutes of Health; National Institute of Nursing Research holds a meeting of the National Advisory Council for Nursing Research to discuss program policies and issues. September 4, 1:00 P.M.; NIH, Building 31, 31 Center Drive, Sixth Floor, C Wing, Room 6, Bethesda, Md.
  - Read more: <https://www.federalregister.gov/documents/2018/08/08/2018-16978/national-institute-of-nursing-research-notice-of-meeting>
- ***CMS extends deadline for MIPS targeted review to October 1, 2018.*** “If you participate in the Merit-based Incentive Payment System (MIPS), you should have reviewed your 2017 performance feedback by now. The 2017 MIPS performance feedback, reflecting activities in performance year one of the QPP (2017), indicates if you will receive a negative, neutral, or positive payment adjustment in 2019. If you believe an error has been made in your 2019 MIPS payment adjustment calculation, you can request a targeted review until October 1, 2018.”
  - Read more: <https://www.kidneynews.org/policy-advocacy/leading-edge/cms-extends-deadline-for-mips-targeted-review-to-october-1-2018>
- ***Proposed 2019 Medicare reimbursement changes may negatively impact nephrologists and dialysis vascular access providers.*** “The Centers for Medicare and Medicaid Services (CMS) released the Calendar Year (CY) 2019 Proposed Rule for the Medicare Physician Fee Schedule (MPFS) on July 12, 2018 (the Proposed Rule), and the CY 2019 proposed rule to update the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System on July 25, 2018. As evidence of the shift to “site-neutral” payment policies, proposed reimbursement changes continue to place significant financial pressure on physicians and organizations that provide dialysis vascular access services in an office-based (POS-11) setting, while at the same time significantly decreasing the differences in reimbursement for providing such services in a Medicare-certified ASC.”
  - Read more: <https://www.jdsupra.com/legalnews/proposed-2019-medicare-reimbursement-71545/>

### Articles of Interest

- ***Outset Medical has created a 37-inch dialysis clinic on wheels for the home.*** “A company called Outset Medical has been working on an upgrade so that someday soon patients will be able to get lifesaving treatment at home rather than at the hospital. Outset's technology works through a combination of software and sensors that automate the manual steps that are typically required to get a machine up and running. It also purifies water and produces dialysate (one of the fluids used in dialysis) in real time, and it takes a patient's blood pressure. To get it started, the system only needs an electrical outlet and access to water.”
  - Read more: <https://www.cnbc.com/2018/08/28/outset-medical-raises-132-million-more-to-bring-dialysis-to-the-home.html>
- ***Insulin's high cost leads to lethal rationing.*** “The price of insulin in the U.S. has more than doubled since 2012. That has put the life-saving hormone out of reach for some people with diabetes. It has left others scrambling for solutions to afford the one thing they need to live. Today, the list price for a single vial of insulin is more than \$250. Most patients use two to four vials per month. Without insurance or other forms of medical assistance, those prices can get out of hand quickly. Rationing insulin is a dangerous solution. Still, 1 in 4 people with diabetes admits to having done it.”
  - Read more: <https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing>
- ***Watchdog group calls for NIG to halt 'dangerous' study of sepsis treatment.*** “A medical watchdog group is calling on the National Institutes of Health to immediately stop the enrollment of patients in a clinical trial of sepsis treatment and launch an investigation of how the study received approval, arguing that it puts patients at risk of serious harm, including death. The group, Public Citizen, says in a letter dated Tuesday that the study's protocol is also so 'fundamentally flawed' that it will not produce reliable findings. The basis for the central criticism is twofold. First, Carome told STAT, patients are being put at risk because one of the two sepsis treatments in the study could, depending on how seriously ill the patients are, allow their blood pressure to remain dangerously low for hours. In addition, he said, everyone will receive what he called an experimental treatment, rather than some patients receiving the standard of care, as clinical trials generally do to enable researchers to compare results for patients treated with experimental and standard treatments.”
  - Read more: <https://www.statnews.com/2018/08/28/nih-sepsis-study-public-citizen/>
- ***U.S. deaths from self-injury surpass those from diabetes.*** “More people in the U.S. are dying from self-inflicted harm, including suicide and drug overdose, than from diabetes, a new study suggests. In 2016, for every 100,000 people, 29 deaths were due to self-injury and 25 were due to diabetes, researchers found when they looked at data from the Centers for Disease Control and Prevention. Until 2015, diabetes was the seventh most common killer of people in the U.S., the authors note in Injury Prevention.”

- Read more: <https://www.reuters.com/article/us-health-selfinjury-mortality/us-deaths-from-self-injury-surpass-those-from-diabetes-idUSKCN1LE25W>
- ***Healthcare consumers in a digital transition.*** “Every year we deploy a 4K-person survey of the US adult population to shed light on how consumers are engaging with technology-driven healthcare innovation. 2017 was the third year we deployed this survey, giving us three-year trend data for the first time. Not surprisingly, chronically ill seniors have the greatest demand for healthcare services – 86% visited a doctor at least twice in the past year and 97% are managing at least one prescription. Yet they are the least likely to leverage digital health technologies, with extremely low rates of live video telemedicine use, digital health goal tracking, and wearable use.”
  - Read more: <https://rockhealth.com/reports/healthcare-consumers-in-a-digital-transition/>
- ***How Medicare wastes \$4.6 billion a year on long-term care hospitals.*** “A new study, published by the National Bureau of Economic Research, finds that in 2014, Medicare paid LTCHs three-times what it paid SNFs, or about \$33,000 more, for each discharge. And there is no evidence, according to the research, that mortality is any lower than for nursing facility patients. Overall, according to the authors, Medicare could save \$4.6 billion annually by reimbursing LTCHs like SNFs – with no harm to patients.”
  - Read more: <https://www.forbes.com/sites/howardgleckman/2018/08/29/how-medicare-wastes-4-6-billion-a-year-on-long-term-care-hospitals/#640ce89f4ec8>
- ***Judge tosses lawsuit against California drug price law.*** “A federal judge has dismissed a lawsuit seeking to block a California law requiring pharmaceutical companies to give advance notice before big price increases. U.S. District Judge Morrison England Jr., ruled Thursday in Sacramento that the Pharmaceutical Research and Manufacturers of America failed to show that the court has jurisdiction to hear the case. He gave PhRMA 30 days to refile. The law requires 60 days’ notice to raise national wholesale prices above a certain threshold.”
  - Read more: <https://apnews.com/88a87b4e56cb4148a60ea1e7d9bda343>
- ***Facing shortfall, Kentucky mulls ending Medicaid expansion.*** “Warning of a nearly \$300 million potential shortfall in Kentucky’s Medicaid program, officials say they could eliminate health coverage for more than 480,000 people to balance the state’s budget. Kentucky’s Medicaid program spends about \$11.5 billion every year, but most of that money comes from the federal government. Cabinet for Health and Family Services Secretary Adam Meier told state lawmakers Thursday that Kentucky’s share of that budget will be \$296 million short by 2020 – money that must come from the cash-strapped state.”
  - Read more: <https://apnews.com/195ef904d3fb4d93844fe13697992ea8/Facing-shortfall,-Kentucky-mulls-ending-Medicaid-expansion>
- ***Analysts predict health care marketplace premiums will stabilize for 2019 coverage.*** “Consumers who buy insurance through the Affordable Care Act markets may be pleasantly surprised this fall as average premiums are forecast to rise much less than in

recent years. The price of a 2019 policy sold on the ACA exchanges will increase less than 4 percent, according to an analysis of preliminary filings from insurers in all 50 states by ACASignups.net, a website and blog run by analyst Charles Gaba that tracks ACA enrollment and insurer participation. And those insurers are expanding their offerings.”

- Read more: <https://www.npr.org/sections/health-shots/2018/09/03/643457582/analysts-predict-health-care-marketplace-premiums-will-stabilize-in-2019>
- ***How a California bill could upend the dialysis industry.*** “This week is make or break for a California bill that has the potential to sap hundreds of millions of dollars in profits from dialysis providers in the state. California's Legislature has until this Friday to pass SB 1156, a union-backed bill that would cap commercial dialysis payments at lower Medicare rates and force charities to disclose donors of third-party payments. If it passes, Gov. Jerry Brown has until the end of September to sign it into law. This essentially would become single-payer for dialysis services in California. But even if this bill falls short, it could pop up again in other states where the Service Employees International Union wants to take on big dialysis providers like DaVita and Fresenius.”
  - Read more: <https://www.axios.com/california-dialysis-bill-davita-fresenius-dd80358f-f102-40e1-a174-96c7bf0e6617.html>