

## American Nephrology Nurses Association

Weekly Capitol Hill Update - Monday, December 3, 2018

### Congressional Schedule

#### Senate

- Senate in session, convenes at 3pm Monday.

#### House

- House in session, beginning Tuesday.

### Legislative Update

- **Week in Review**
  - *Democrats back Nancy Pelosi as next House speaker despite calls for fresh leadership.* "Nancy Pelosi won support from a majority of Democrats on Wednesday to be House speaker, marking an important milestone in her quest to lead the House when her party takes majority control of the chamber in January. The Democratic caucus vote in favor of Pelosi, who served as the first woman speaker from 2007 to 2011, brings her a step closer to the gavel that many expect her to regain."
    - Read more: <https://www.usatoday.com/story/news/politics/2018/11/28/nancy-pelosi-faces-test-vote-bid-speaker/2123786002/>
  - *GOP lawmakers air concerns with Trump drug pricing move in meeting with health chief.* "Republican lawmakers who worked as doctors expressed their concerns about President Trump's controversial proposal to lower drug prices with the president's health chief Thursday. The lawmakers in the GOP Doctors Caucus questioned Secretary of Health and Human Services Alex Azar in the meeting about a proposal Trump put forward in October to lower certain Medicare drug prices by tying them to lower prices paid in other countries."
    - Read more: <https://thehill.com/policy/healthcare/419026-gop-lawmakers-air-concerns-with-trump-drug-pricing-move-in-meeting-with>
  - *Dem senator Murray calls for trying again on bipartisan ObamaCare fix.* "Sen. Patty Murray (D-Wash.) on Wednesday called for reviving bipartisan efforts to

reach a deal to fix ObamaCare after an agreement she was part of collapsed last year. The deal last year, which came to be known as Alexander-Murray, sought to lower premiums and stabilize the ObamaCare markets, but was stalled for months amid the bitter partisan divide over the health law and a dispute about including abortion restrictions on the funding in the bill. Alexander on Wednesday expressed skepticism about the ability to reach a new agreement, but said he is willing to try if Murray wants to.”

- Read more: <https://thehill.com/policy/healthcare/418689-dem-senator-murray-calls-for-trying-again-on-bipartisan-obamacare-fix>

- **Week Ahead**

- *Senators urge vote on health insurance tax delay during lame duck.* “A small bipartisan group of senators are urging leadership to extend a delay of ObamaCare’s health insurance tax before the end of the lame duck session. The health insurance tax has been criticized by Republicans and some Democrats for driving up premiums. Sens. John Barrasso (R-Wyo.), Cory Gardner (R-Colo.), Jeanne Shaheen (D-N.H.) and Doug Jones (D-Ala.) wrote in a letter to Senate leadership that they want that moratorium extended.”
  - Read more: <https://thehill.com/policy/healthcare/419136-senators-urge-vote-on-health-insurance-tax-delay-during-lame-duck>
- *Dem single-payer fight set to shift to battle over Medicare ‘buy-in’.* “Momentum is building among House Democrats for a more moderate alternative to single-payer health-care legislation. The legislation, which would allow people aged 50 to 65 to buy Medicare, is being championed by Rep. Brian Higgins (D-N.Y.), who supported House Minority Nancy Pelosi (D-Calif.) for Speaker in exchange for a commitment to work on his bill when Democrats take control of the House early next year.”
  - Read more: <https://thehill.com/policy/healthcare/418812-dem-single-payer-fight-set-to-shift-to-battle-over-medicare-buy-in>

### **Regulatory and Administration Update**

- *The KidneyX team will be answering questions about the KidneyX prize challenge ‘Redesign Dialysis’.* “Learn more about the #KidneyX prize challenge: Redesign Dialysis during this webinar on December 6, 2018 from 1:00 PM- 2:00 PM EST. We will have Sandeep Patel, PhD, U.S. Department of Health and Human Services KidneyX Program Director, available for questions as well as representatives from the American Society of Nephrology, the Centers for Medicare and Medicaid Services, the National Institutes of Health and the Food and Drug Administration.”
  - Read more: <https://www.eventbrite.com/e/kidneyx-webinar-tickets-52526131072>
- *Contract Year (CY) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P).* “The Centers for Medicare & Medicaid Services (CMS) is committed to implementing President Trump’s blueprint to lower drug costs and reduce out-of-pocket costs for patients. In line with the policies discussed in the President’s blueprint,

CMS issued a proposed rule on November 26, 2018 that solicits public comments on potential policies that would remove administrative hurdles to offer lower cost options to seniors and provide support for private sector partners by providing them the tools to lower the cost of prescription drugs.”

- Read more: <https://www.cms.gov/newsroom/fact-sheets/contract-year-cy-2020-medicare-advantage-and-part-d-drug-pricing-proposed-rule-cms-4180-p>
- ***Trump administration proposes letting private Medicare plans exclude new types of drugs.*** “The Trump administration wants to give private Medicare plans the flexibility to exclude from their formularies certain drugs, including some like antidepressants and AIDS medications, in hopes the increased negotiating power will help the plans bring down drug costs for patients and for the Medicare program itself. It was the first in a series of changes that the Trump administration put forth in a new regulation late on Monday, all of which largely nibble around the edges of the underlying problem of high drug prices. Each of the policies are nonetheless likely to inflame drug companies and allied patient advocates who have said similar policy proposals could limit patient access to medicines.”
  - Read more: <https://www.statnews.com/2018/11/26/trump-administration-proposes-letting-private-medicare-plans-exclude-new-types-of-drugs/>
- ***Strategy on reducing burden relating to the use of health IT and EHRs: Draft released for public comment.*** “In the 21st Century Cures Act, Congress identified the importance of easing regulatory and administrative burdens associated with the use of electronic health records (EHRs) and health information technology. Specifically, Congress directed the Department of Health and Human Services (HHS) to establish a goal, develop a strategy, and provide recommendations to reduce EHR-related burdens that affect care delivery. This draft *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs* reflects input HHS has received through several wide-reaching listening sessions, written input, and stakeholder outreach. Now, we are encouraging you to give us your comments on this draft strategy. The deadline for comment submission is 11:59pm ET on January 28, 2019.”
  - Read more: <https://www.healthit.gov/topic/usability-and-provider-burden/strategy-reducing-burden-relating-use-health-it-and-ehrs>
- ***340B Final rule will launch on January 1, 2019.*** “After several delays, hundreds of public comments, a lawsuit, and an eight-year-old Congressional mandate, the federal government on Thursday bumped up the starting date of its 340B drug pricing final rule by six months. In a notice published this week in the Federal Register, the Department of Health and Human Services said the final rule – which is designed to protect hospitals from being overcharged by drug manufacturers – would take effect on January 1, 2019, instead of July 1, 2019.”
  - Read more: <https://www.healthleadersmedia.com/340b-final-rule-will-launch-january-1-2019>
- ***FDA plans overhaul of decades-old medical device system.*** “U.S. health officials said Monday they plan to overhaul the nation’s decades-old system for approving most medical devices, which has long been criticized by experts for failing to catch problems

with risky implants and medical instruments. The Food and Drug Administration announced plans aimed at making sure new medical devices reflect up-to-date safety and effectiveness features. The system targeted by the actions generally allows manufacturers to launch new products based on similarities to decades-old products, not new clinical testing in patients.”

- Read more: <https://www.statnews.com/2018/11/26/fda-plans-overhaul-medical-device-system/>
- ***Trump administration allows states to loosen ObamaCare coverage requirements.*** “The Trump administration on Thursday told states it will allow them to use ObamaCare insurance subsidies to help people pay for plans that don’t meet the law’s coverage requirements. The new use of subsidies is part of a larger push toward giving states more flexibility to waive ObamaCare requirements and pursue conservative health care policies that were previously not allowed under the Obama administration. Currently, states can apply for waivers from certain ObamaCare policies in order to help shore up individual insurance markets.”
  - Read more: <https://thehill.com/policy/healthcare/418964-trump-administration-allows-states-to-loosen-obamacare-coverage>
- ***Trump health chief ‘looking closely’ at thousands who lost Medicaid from work requirements.*** “A top Trump administration health-care official on Tuesday said she is ‘looking closely’ at why thousands of people have lost Medicaid coverage in Arkansas due to the state’s new work requirements, but indicated the administration would not slow down in implementing the new rules. Asked if those people losing coverage is a weakness in the administration’s plan, Centers for Medicare and Medicaid Services Administrator Seema Verma told reporters Tuesday that her agency is still trying to understand why those people left the Medicaid program.”
  - Read more: <https://thehill.com/policy/healthcare/418405-trump-health-chief-looking-closely-at-thousands-who-lost-medicaid-from-work>

#### **Articles of Interest**

- ***Insulin pumps have most reported problems in FDA database.*** “When it comes to medical devices, none have had more reported problems over the last decade than insulin pumps, a product that's used by hundreds of thousands of diabetics around the world, many of them children. Collectively, insulin pumps and their components are responsible for the highest overall number of malfunction, injury and death reports in the U.S. Food and Drug Administration's medical device database, according to an Associated Press analysis of reports since 2008. In terms of injuries alone, insulin pumps were second only to metal hip replacements.”
  - Read more: <https://abcnews.go.com/Health/wireStory/ap-investigation-insulin-pumps-high-number-injuries-59445209>
- ***‘I shouldn’t have to beg’: a protest over insulin prices is seen as a fight for life.*** “Some were faced with the choice of paying their rent or paying for insulin. A few saw their children die after they rationed the lifesaving medication. They were all part of a group

of protesters stationed outside the Cambridge, Mass., office of insulin maker Sanofi on a recent morning, rallying against the rising price of the drug.”

- Read more: <https://www.statnews.com/2018/11/27/insulin-prices-protest-sanofi/>
- **Scientists call for oversight after Chinese researcher claims first gene-edited baby.** “More than 100 scientists signed a petition calling for greater oversight of gene editing following a Chinese researcher's claim Monday that he helped create the first genetically edited babies. Southern University of Science and Technology of China's He Jiankui said he altered the DNA of twin girls born earlier this month in order to help them resist future infection from AIDS, The Associated Press reports.”
  - Read more: <https://thehill.com/policy/healthcare/418291-scientists-petition-for-oversight-after-chinese-scientist-claims-creating>
- **Number of uninsured children increases for first time in a decade.** “The number of uninsured children in the U.S. increased for the first time in a decade, according to a new report that puts much of the blame on policies spearheaded by Republicans. An estimated 3.9 million children did not have health insurance in 2017, an increase of 276,000 compared to the previous year, according to the Georgetown University Center for Children and Families.”
  - Read more: <https://thehill.com/policy/healthcare/418884-number-of-uninsured-children-increased-for-first-time-in-a-decade-during>
- **U.S. life expectancy falls, driven by suicides and drug overdoses.** “U.S. life expectancy declined in 2017 as more Americans died of drug overdoses and suicides, furthering a troubling trend of declining lifespans not seen in a century, the Centers for Disease Control and Prevention found in a report released Thursday. Life expectancy was 78.6 years in 2017, down from 78.7 years in 2016, the CDC said. Life expectancy also declined in 2015 and stayed flat in 2016, making this the first three-year period of general decline since the late 1910s. That decline took place during World War I and a sweeping flu epidemic – and before dozens of medical advances.”
  - Read more: <https://thehill.com/policy/healthcare/418851-us-life-expectancy-falls-driven-by-suicides-and-drug-overdoses>
- **Babies of the opioid crisis seek their day in court.** “Lawyers representing babies born with opioid dependency are trying to break away from the massive national litigation around the addiction epidemic, arguing that these particularly vulnerable victims need a legal pathway all their own. A federal judge in Cleveland overseeing the complex lawsuit against opioid makers and distributors is encouraging hundreds of local governments, Native American tribes, hospitals and patients who filed separate lawsuits to soon reach a single settlement worth potentially hundreds of billions of dollars from companies that pushed out the powerful painkillers while downplaying their risks.”
  - Read more: <https://www.politico.com/story/2018/11/29/opioid-epidemic-class-action-lawsuit-babies-1026071>
- **Two more blood pressure drugs recalled for potential cancer risk.** “Teva Pharmaceuticals has launched a voluntary recall into two drugs used to treat high blood pressure as yet

more medications face concerns over a possible cancer risk. In a statement from Teva posted by the Food and Drug Administration, the recall affects all lots of combination tablets featuring the drugs amlodipine and valsartan and another combo drug featuring amlodipine, valsartan, and hydrochlorothiazide. The drugs could contain an impurity called N-nitroso-diethylamine (NDEA), which has been classified as a possible human carcinogen, the FDA said."

- Read more:

<https://www.usatoday.com/story/news/health/2018/11/30/blood-pressure-drugs-two-more-medications-recalled-cancer-risk/2159850002/>

- ***Democrats taking key leadership jobs have received millions from pharma.*** "On Wednesday, House Democrats selected Rep. Steny Hoyer of Maryland to serve as the next majority leader and Rep. James Clyburn of South Carolina as majority whip, making them the No. 2 and No. 3 most powerful Democrats as their party regains control of the House in January. Both lawmakers have received more than \$1 million from pharmaceutical company political action committees in the past decade. Just four members of Congress hold that distinction, including Rep. Kevin McCarthy of California, whom Republicans chose as the next House minority leader earlier this month."
  - Read more: <https://californiahealthline.org/news/democrats-taking-key-leadership-jobs-have-pocketed-millions-from-pharma/>
- ***Another drug crisis: Methamphetamine use by pregnant women.*** "A study published Thursday in the *American Journal of Public Health* confirms the rise in meth use among pregnant women and provides new data illustrating the scope of the problem. The research, which analyzed hospital discharge records between 2004 and 2015, found that as opioid use among pregnant women has grown in recent years, so has their use of amphetamines, and particularly methamphetamine. Though that class of drugs includes prescription medicines like Adderall and Dexedrine that are sometimes used to treat attention deficit hyperactivity disorder, 'we think our findings nearly entirely represent illicit methamphetamine use,' says Dr. Lindsay Admon, an assistant professor of obstetrics and gynecology at the University of Michigan and the lead author of the study."
  - Read more: <https://www.npr.org/sections/health-shots/2018/11/29/668487475/another-drug-crisis-methamphetamine-use-by-pregnant-women>
- ***Top Dems blame 'sabotage' as ObamaCare enrollment slows.*** "Top House Democrats are blaming President Trump for ObamaCare signup numbers that so far are lower than last year. The Trump administration announced earlier Wednesday that 500,437 people signed up for ObamaCare coverage in the fourth week of the sign-up period, which ends Dec. 15. Compared to this point last year, sign-ups are running about 11 percent lower, according to ObamaCare numbers analyst Charles Gaba. The full picture will not be clear until after Dec. 15."
  - Read more: <https://thehill.com/policy/healthcare/418747-top-dems-blame-sabotage-as-obamacare-enrollment-slows>

- Conservative groups write letter opposing Trump move to lower drug prices.** “A coalition of 55 conservative groups has written a letter calling on the Trump administration to withdraw a proposal to lower drug prices, warning of creating ‘price controls.’ The letter from the groups represents a break between President Trump and conservative allies over the drug pricing proposal unveiled in October, which departs from the traditional Republican position on drug prices. The letter warns that the administration’s proposal ‘imports foreign price controls into the U.S.’ It was signed by leaders of prominent conservative groups such as Americans for Tax Reform, FreedomWorks and the American Conservative Union.”

  - Read more: <https://thehill.com/policy/healthcare/418667-conservative-groups-write-letter-opposing-trump-move-to-lower-drug-prices>
- Advocacy groups push back against CMS protected drugs claims.** “An advocacy group is skeptical of the CMS claim that insurers have few tools to lower the cost of prescription drug prices for drugs that are in protected classes. A report conducted by Avalere Health and commissioned by the Partnership for Part D Access shows Part D plan sponsors are already using a variety of techniques to limit access to expensive medications in protected classes. The report found that nearly 75% of all drugs in the six protected classes are placed on a non-preferred or specialty tier – in other words the most difficult drugs to access. It also found there is very low use of these drugs, which are typically the most expensive. ‘Only 1% of all the prescriptions filled for drugs across the protected classes were for products that are always placed on high tiers,’ according to the report. More than 90% of the prescriptions filled across the protected classes were for generic medications, even though just 35% of the drugs covered are generics, the report found.”

  - Read more: <https://www.healthcaredive.com/news/advocacy-groups-push-back-against-cms-protected-drugs-claims/543248/>
- Majority of voters back national health plan – unless it’s called ‘single payer.’** “With the 2020 primary elections just within sight and congressional Democrats preparing to take the House majority in January, some Democratic lawmakers, such as Rep. Pramila Jayapal (D-Wash.), are seizing the opportunity to act on a long-time goal of progressives: a federally run health care system for all Americans. As they deliberate messaging tactics, a new Morning Consult/Politico survey suggests that while describing the controversial health policy as ‘Medicare for all’ is a crowd pleaser, Democrats should avoid calling it a ‘single-payer’ plan.”

  - Read more: <https://morningconsult.com/2018/11/29/majority-of-voters-back-national-health-plan-unless-its-called-single-payer/>
- Lyft just hired a hotshot exec from McKesson to run its growing business transporting patients to medical appointments.** “Lyft is looking to build out its health care business unit, which helps patients get rides to non-emergency medical appointments. It has hired Megan Callahan, chief strategy officer for McKesson's Change Healthcare. Right now, the focus is on non-emergency medical transportation, meaning to get patients to their medical visits on time.”

  - Read more: <https://www.cnn.com/2018/11/28/lyft-hiresmegan-callahan-from-mckesson-to-run-health-business.html>

- ***Study highlights discrepancy in hospital rankings.*** “A retrospective study in JAMA Cardiology suggests online hospital rankings may not be reliable in helping people choose where they get care. Researchers from Harvard Medical School and affiliated hospitals reviewed U.S. News & World Report's 2017-2108 rankings on cardiology and heart surgery at 3,552 U.S. hospitals and compared them with nonranked hospitals. The main outcomes studied were 30-day risk-standardized mortality and readmission for acute myocardial infarction, heart failure and coronary artery bypass grafting. They also looked at patient satisfaction. While top-ranked hospitals outperformed nonranked hospitals on 30-day mortality for all three conditions, 30-day readmission rates were similar for AMI and CABG and were actually higher for heart failure. On patient satisfaction, top-ranked hospitals did better than their nonranked peers.”

  - Read more: <https://www.healthcarediver.com/news/study-highlights-discrepancy-in-hospital-rankings/543199/>
  
- ***Grassley's move to finance committee could bolster drug price efforts.*** “Sen. Charles E. Grassley's return to the helm of the Finance Committee could put him in a position to address high prescription prices, although former aides say his biggest initial contribution to the drug debate will be his zeal for accountability. Mark Hayes, a former Finance chief health counsel under Grassley, said the Iowa Republican's well-earned reputation for oversight can be a catalyst for action.”

  - Read more: <http://www.rollcall.com/news/politics/grassleys-move-bolster-drug-price-efforts>
  
- ***3 reasons to care about balance billing legislation.*** “As the national conversation about surprise medical bills gets louder, the Senate is taking notice, introducing two new bills over the past several months that aim to limit surprise charges from out-of-network providers. Here are three things to consider: 1. Action could be imminent on the state level, 2. Hospitals may soon need to speak up, 3. The bottom line may be affected.”

  - Read more: <https://www.healthleadersmedia.com/finance/3-reasons-care-about-balance-billing-legislation>
  
- ***'A loss for the rest of us': An FDA approval is a boon for a drug maker, but could come at a major cost for patients.*** “A Florida-based drug maker now has the ability to charge a premium on a drug that has come free or dirt cheap for many patients for decades.”

  - Read more: <https://www.statnews.com/2018/11/30/fda-approval-lems-drug-costs/>