

American Nephrology Nurses Association

Weekly Capitol Hill Update - Monday, January 22, 2018

Congressional Schedule

Senate

- Senate meets at 10am; resumes consideration of measure that fund government through Feb. 8.
- Senate will hold procedural vote at noon on measure.

House

- House meets at noon; House Majority Leader Kevin McCarthy has advised Republicans that the House will take up whatever stopgap spending bill the Senate sends over, according to a senior House Republican.

Legislative Update

- **Week in Review**
 - *Federal government shuts down after Senate talks fail.* “The federal government entered a partial shutdown Saturday as a key vote fell far short of the support needed to pass the Senate and the midnight deadline came and went without a deal. One year to the day since President Donald Trump took office flanked by a Republican Congress, a stalemate could not be resolved leading most Democrats and a handful of Republicans to vote against the bill late Friday night. The Senate convenes Saturday as talks continue on a way out of the impasse.”
 - To read more:
https://www.nbcnews.com/politics/congress/government-shutdown-likelihood-grows-amid-senate-standoff-n839301?cid=eml_nbn_20180120

- ***Let's remember: 9 million kids' health insurance is at stake in this budget fight.*** "If Congress fails to reach a deal to avert a government shutdown at 12:01 a.m. Saturday, federal workers won't be the only ones worrying. Parents of the 9 million children insured through the Children's Health Insurance Program, known as CHIP, are panicking because funding for the program has nearly run out. Republicans in Congress thought they had a grand solution: They pitched Democrats a deal to do a one-month extension of overall government funding and a six-year extension of CHIP money. But President Trump tweeted Thursday morning that was a bad idea. House Speaker Paul D. Ryan (R-Wis.) says he spoke with Trump and the president is now on board, but confusion abounds in the Capitol."
 - To read more: https://www.washingtonpost.com/news/wonk/wp/2018/01/18/lets-remember-9-million-kids-health-insurance-is-at-stake-in-this-budget-fight/?utm_term=.38a42e3372b3

- ***Congress once again looking to kick health cost control down the road.*** "Congress is once again poised to delay the Affordable Care Act's "Cadillac tax" on high-value employer health plans, and many economists are once again disappointed by the decision... Most employer-based health benefits aren't taxed. But the Cadillac tax is a 40% excise tax on employer-based plans whose value exceeds a certain threshold, which rises over time. It was included in the ACA for two big reasons: to help finance the law, and to help contain rising health care costs."
 - To read more: <https://www.axios.com/congress-once-again-looking-1516214908-647ee11e-83d4-48e9-ae25-c43b3a566465.html>

- ***Senate Panel Advances Trump Health Secretary Pick.*** "A Senate committee has signed off on President Donald Trump's pick for health secretary, clearing the way for final confirmation of Alex Azar. The Finance Committee voted 15-12 on Wednesday to send Azar's nomination to the full Senate."
 - To read more: <https://www.usnews.com/news/politics/articles/2018-01-17/senate-panel-advances-trump-health-secretary-pick>

- ***Federal budgeting is so broken only earmarks might fix it.*** "Congress' spending cycle has reached peak dysfunction, so much so that a return to the era of earmarks looks good. Lawmakers' failure to accomplish the most basic function of funding the government is now spurring talk of "fixing" the budget process and reviving pork-barrel spending outlawed when the GOP took control of Congress... On Wednesday, members will line up before the House Rules Committee to talk about why they might want to again allow the practice of earmarking pet projects in home districts and states. It's doubtful that would happen this year, and no promises are being made, but

the idea has gained speed among the frustrated lawmakers who control spending.”

- To read more: <https://www.politico.com/story/2018/01/17/federal-budgets-earmarks-republicans-pork-barrel-343097>

- **Week Ahead**

- *Live coverage: Federal government on brink of shutdown.* “A shutdown of the federal government is set to start in less than 24 hours with little hope for a deal. Without action by Congress, the government will shut down at midnight Friday.”
 - To read more: <http://thehill.com/homenews/senate/369707-live-coverage-federal-government-on-brink-of-shutdown>
- *Senate to vote Monday on plan to reopen government.* “Party leaders and rank-and-file senators spent all day Sunday haggling over a deal to reopen the government. But Washington's painful shutdown will nonetheless drag into Day Three. Shortly after 9 p.m. Sunday, Senate Majority Leader Mitch McConnell announced that the chamber would vote on a plan at noon Monday to fund the government through Feb. 8. In an attempted concession to Minority Leader Chuck Schumer, McConnell said he would take up legislation to protect some young immigrants from deportation if a deal to address their status is not reached by the time funding expires in early February.”
 - To read more: <https://www.politico.com/story/2018/01/21/government-shutdown-2018-trump-senate-354113>
- *Senate adjourns without deal to end government shutdown; vote postponed until noon Monday.* “The government shutdown headed into its third day as Republicans insulted Democrats for rejecting the latest offer from Senate Majority Leader Mitch McConnell (R-Ky.), who said he would consider allowing a floor debate on immigration issues in mid- to late February if leaders do not strike an agreement before then. As the Senate prepared for a procedural vote at noon, President Trump went on Twitter to argue Democrats are acting at the behest of their “far left base” in demanding protections for young undocumented immigrants in negotiations to reopen the government.”
 - To read more: https://www.washingtonpost.com/powerpost/trump-launches-new-round-of-partisan-attacks-as-government-shutdown-hits-day-2/2018/01/21/0560aece-fe35-11e7-a46b-a3614530bd87_story.html

- *Half of HHS would stop working during a shutdown.* “Half of the Department of Health and Human Services workforce – more than 40,000 people – would be told not to come to work in the event of a shutdown, according to the department’s planning documents. Why it matters: The federal workforce isn’t just paper-pushers in Washington. A shutdown would freeze several major health care programs, including food safety inspections and monitoring flu outbreaks across the country.”
 - To read more: <https://www.axios.com/half-of-hhs-would-stop-working-during-a-shutdown-1516393821-9efff648-4a93-466a-b192-ee6fb8852ebb.html>

- *How The Shutdown Might Affect Your Health.* “A government shutdown will have far-reaching effects for public health, including the nation’s response to the current, difficult flu season. It will also disrupt some federally supported health services, experts said Friday. In all, the Department of Health and Human Services will send home – or furlough – about half of its employees, or nearly 41,000 people, according to an HHS shutdown contingency plan released Friday.”
 - To read more: <https://khn.org/news/in-the-event-of-a-shutdown/>

Regulatory and Administration Update

- *FDA to release more clinical trial information for newly approved drugs.* “The Food and Drug Administration is taking steps to make it easier for doctors, patients and researchers to get access to clinical trial data amassed during the process of approving new drugs, Commissioner Scott Gottlieb said Tuesday. Gottlieb announced the actions just before a speech on FDA transparency at a Washington forum. The meeting, attended by researchers and academics, focused on 18 recommendations for making the agency's decision-making less opaque. The suggestions were part of a report called Blueprint for Transparency.”
 - To read more: <https://www.washingtonpost.com/news/to-your-health/wp/2018/01/16/fda-to-release-more-clinical-trial-information-for-newly-approved-drugs/>

- *FDA kicks the can on off-label marketing.* “The FDA has placed an indefinite hold on implementing new regulations relating to how the agency determines a medical product’s intended use. The decision to press pause on the new rules drew cheers from the medical device and pharmaceutical industries, after companies voiced their concerns last year that the proposed changes were unclear. The FDA’s new language on intended use was meant to update the types of evidence that the agency can use to decide how a manufacturer intended for patients and doctors to use its product.”

- To read more: <https://www.drugdeliverybusiness.com/fda-kicks-can-off-label-marketing/>
- ***CMS updates open payments data.*** “Today, January 17, 2018, the Centers for Medicare & Medicaid Services (CMS) updated the Open Payments dataset to reflect changes to the data that took place since the last publication on June 30, 2017. The refreshed Open Payments Data Set includes: Record Updates, Disputed Records, and Record Deletions.”
 - To read more: <http://www.kidneynews.org/careers/career-development/cms-updates-open-payments-data>
- ***BPCI Advanced.*** “The Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) is announcing a new voluntary episode payment model, Bundled Payments for Care Improvement Advanced (BPCI Advanced or the Model) that will test a new iteration of bundled payments for 32 Clinical Episodes and aim to align incentives among participating health care providers for reducing expenditures and improving quality of care for Medicare beneficiaries. BPCI Advanced will qualify as an Advanced Alternative Payment Model (APM) under the Quality Payment Program.”
 - Renal failure is one of the 29 Inpatient Clinical Episodes.
 - To read more: <https://innovation.cms.gov/initiatives/bpci-advanced/>
- ***Statement from FDA Commissioner Scott Gottlieb, M.D., in response to GAO report regarding FDA’s ongoing commitment to employing a least burdensome approach to device review.*** “To encourage innovation and provide patients with access to the latest safe and effective medical technologies, we continually strive to make the device development and regulatory review process more modern, science-based and efficient. A key feature of these efforts is early and more thorough engagement with innovators to help them meet the FDA’s science-based requirements in a way that allows companies to bring safe, effective modern devices to patients as soon as possible. This approach is one aspect of what we refer to as “least burdensome.””
 - To read more: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592632.htm>
- ***FDA Commissioner Scott Gottlieb, M.D., updates on some ongoing shortages related to IV fluids.*** “Earlier this month, we updated on the FDA’s efforts to mitigate ongoing IV saline shortages that resulted from, or were worsened by, the devastating impact of Hurricane Maria in Puerto Rico. We also provided some additional updates related to our continued efforts to help the island fully recover from this disaster. Based on the information we’re receiving from companies and the actions we’ve taken at FDA, we continue to expect that the shortage of IV fluids will improve in the coming weeks and months. In addition to working with

manufacturers to ensure that their Puerto Rico facilities can operate at full capacity, we've worked with manufacturers such as Baxter and B. Braun to import product into the U.S. from their foreign facilities including most recently from a Baxter facility in Brazil."

- To read more:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592617.htm>

- ***ESCOs reduced hospitalizations, access issues, but no change in QoL, mortality rate.*** "An analysis completed on the first year of the Comprehensive ESRD Care demonstration indicated the 13 physician-provider groups that participated in the project showed improvement in vascular access management and reducing hospitalizations, but no measurable change was seen in patient quality of life or mortality. No significant increase was seen in the use of home dialysis as well."
 - To read more: <https://www.nephrologynews.com/escos-reduced-hospitalizations-access-issues-no-change-qol-mortality-rate/>

Articles of Interest

- ***Angered by high prices and shortages, hospitals will form their own generic drug maker.*** "Angered by rising prices and persistent shortages of generic drugs, four of the nation's largest hospital systems are forming a new, not-for-profit manufacturer. The new company plans to either directly make or subcontract manufacturing to combat "capricious and unfair pricing practices" that are damaging the generic drug market and hurting consumers, according to a statement from the four hospital groups – Intermountain Healthcare, Ascension, SSM Health, and Trinity Health, which together run more than 300 hospitals."
 - To read more: <https://www.statnews.com/pharmalot/2018/01/18/hospitals-generics-high-prices-shortages/>
- ***How a government shutdown could affect drug safety, flu response, and more.*** "Unless Republicans coalesce this week around a short-term spending deal, the federal government will shut down – a scenario that will likely have widespread and long-lasting consequences for public health. The Food and Drug Administration would likely have to forego updating mislabeled medications or conducting routine food safety inspections. The Centers for Disease Control and Prevention would furlough key staff amid one of the most severe flu seasons in recent memory. And the National Institutes of Health might have to stop enrolling hundreds of patients in clinical trials. All of the federal government's health agencies, moreover, would be hamstrung in their efforts to help address and coordinate a response to the ongoing opioid epidemic."

- To read more: <https://www.statnews.com/2018/01/17/government-shutdown-cdc-fda-nih/>
- ***Medical Care Use and Expenditures Associated With Adult Obesity in the United States.*** “Obesity is associated with several costly medical conditions. Based on data from 2010 through 2015, nearly half of obese adults had hypertension compared with 20% of normal-weight adults. Obese adults were 4 times as likely to have diabetes compared with normal-weight adults. From 2001 through 2015, increases in medical expenditures were greater for obese adults than for normal-weight adults. From 2010 through 2015, adults with a body mass index of 40 or higher incurred \$7800 in annual medical expenditures on average, 76% more than normal-weight adults. Relative to adults with normal weight, obese adults were about twice as likely to have been prescribed a cardiovascular or gastrointestinal agent, nearly 70% more likely to have been prescribed a psychotherapeutic agent, and more than 4 times as likely to be prescribed an antidiabetic agent. Nearly 10% of obese adults were hospitalized annually resulting in 125.9 inpatient hospitalizations per 1000 people annually, compared with just 6% of normal weight-adults hospitalized, resulting in 77.9 stays per 1000 people each year. Nearly half of obese adults had at least 3 physician visits per year compared with 35.1% of normal-weight adults.”
 - To read more: <https://jamanetwork.com/journals/jama/fullarticle/2669713>
- ***Burnout in Nephrology.*** “Nephrology training is at a crossroads. Although nephrology programs remain high quality with skilled, dedicated faculty and research mentors, resident interest and entry into the field have declined. The reasons for this are multifactorial (1), but there is one issue that has received little attention: physician burnout.”
 - To read more: <http://cjasn.asnjournals.org/content/early/2018/01/16/CJN.09870917.full>
- ***Flu response will be maintained during shutdown, officials say, contrary to previous plan.*** “The Centers for Disease Control and Prevention may be able to continue its immediate response to seasonal influenza in the event the government shuts down, a senior administration official said Friday night on a call with reporters.”
 - To read more: <https://www.statnews.com/2018/01/19/flu-response-government-shutdown/>
- ***HHS extends Trump's emergency declaration for opioids.*** “The Trump administration has extended the opioid public health emergency issued by President Trump, days before that declaration was set to expire.”
 - To read more: <http://thehill.com/policy/healthcare/369853-hhs-extends-trumps-emergency-declaration-for-opioids>