

American Nephrology Nurses Association

Weekly Capitol Hill Update - Tuesday, November 7, 2017

Congressional Schedule

Senate

- Senate meets at 10am; resumes consideration of John H. Gibson to be deputy chief management officer at DOD.

House

- House Republicans will be working to iron out their differences over a wide-ranging tax bill that among other things would cut corporate taxes, limit mortgage deductions and phase out the estate tax.
- House meets 10am, to consider 11 bills under suspension of rules, including H.R. 3911 that would give the SEC more discretion when conducting annual examinations of credit rating companies; H.R. 2148 that would narrow definition of High Volatility Commercial Real Estate Acquisition, Development, or Construction loan for purposes of determining amount of capital lender must hold in reserve; and a number of VA-related bills.
- 3 pm: House Rules Committee meeting on H.R. 2201, which would exempt small securities offerings sold to limited number of investors from SEC registration requirements and state securities laws; Committee to also consider H.R. 2874, which would amend National Flood Insurance Act of 1968 to change annual limits on premium increases for insurance obtained through National Flood Insurance Program

Legislative Update

- **Week in Review**
 - *Tax reform bill doesn't include repeal of Obamacare mandate, sources say.* "The House GOP's tax reform bill does not include a repeal of Obamacare's individual mandate, despite a demand from President Trump. The mandate requires everyone to have health insurance, and is not included in the bill set to be unveiled Thursday, according to sources familiar with the matter. Trump touted the idea in a tweet on Wednesday, and the concept is still being toyed with in the Senate Republicans' version of tax reform."

- To read more: <http://www.washingtonexaminer.com/tax-reform-bill-doesnt-include-repeal-of-obamacare-mandate-sources-say/article/2639380>.
 - **Blue Dog Dems back bipartisan health bill.** “A group of centrist Democrats on Thursday endorsed the Senate's bipartisan plan to shore up ObamaCare's insurance markets. The Blue Dog Coalition, a group of 18 centrist Democrats, hopes its support could build momentum to create a similar bill in the House. "This endorsement is a call to action in the House to develop a bill that mirrors the Alexander-Murray health care legislation and bring it to the floor for full consideration,” said Rep. Daniel Lipinski (D-Ill.), Blue Dog co-chair for policy.”
 - To read more: <http://thehill.com/policy/healthcare/358384-blue-dog-dems-back-bipartisan-health-bill>.
 - **Trump administration strikes policy that supporters say helped lower drug prices.** “The Trump administration on Thursday boldly reversed an Obama-era policy that supporters said had helped lower prices for some costly drugs. The policy centers on so-called biosimilar drugs, which are highly similar versions of biologic drugs manufactured in living cells or microorganisms. The Obama administration designed certain Medicare payments to encourage more price competition among those biosimilar drugs. Trump’s Centers for Medicare and Medicaid Services will reverse that policy beginning Jan. 1, 2018.”
 - To read more: <https://www.statnews.com/2017/11/02/biosimilars-drug-prices-cms/>
 - **House OKs children’s health funds, but obstacles remain.** “Legislation providing five more years of financing for an expired children’s health program won House approval Friday, but a partisan battle over paying for the extension seemed certain to delay the bill in the Senate. Each side is using the fight to accuse the other of jeopardizing a program that serves more than 8 million low-income children. Fresh federal money for the health insurance program stopped on Oct. 1. States are continuing to use unspent funds, but Arizona, California, Minnesota, Ohio, Oregon and the District of Columbia are among those expected to deplete that money by late December or in January.”
 - To read more: <https://www.statnews.com/2017/11/03/childrens-health-funds-near-house-ok-obstacles-remain/>.
- **Week Ahead**
 - **Trump puts pressure on lawmakers to repeal ObamaCare mandate.** “The GOP debate over how to repeal ObamaCare is poised to heat up once again. Republicans are divided over including a provision to repeal ObamaCare's individual mandate as part of their sweeping tax reform bill, unveiled on Thursday. House Ways and Means Chairman Kevin Brady (R-Texas) said Friday that lawmakers are considering the move, which is being pushed by President Trump and others, but also expressed strong caution.”

- To read more: <http://thehill.com/policy/healthcare/358699-week-ahead-trump-puts-pressure-on-lawmakers-to-repeal-obamacare-mandate>.
- **Ryan: ObamaCare mandate repeal up for consideration in tax bill.** “Speaker Paul Ryan (R-Wis.) said on Sunday that repealing ObamaCare's individual mandate is being discussed in talks surrounding the Republican tax-reform plan. Ryan's comments come after House Republicans unveiled their tax-reform plan last week. The measure is expected to pass through the lower chamber but face a more difficult path in the Senate. Key Republicans and President Trump have called for a repeal of the individual mandate to be included in the legislation.”
 - To read more: <http://thehill.com/homenews/sunday-talk-shows/358846-ryan-obamacare-mandate-repeal-up-for-consideration-in-tax-bill>.
- **Meet the GOP senator quietly pushing an ObamaCare fix.** “When Sen. Lamar Alexander (R-Tenn.) waded into a crowded hallway of reporters outside a closed-door GOP meeting last month and announced a bipartisan ObamaCare deal, Sen. Mike Rounds (R-S.D.) was right at his side. Rounds, a former insurance agent, had been quietly working with Alexander to forge a deal with Sen. Patty Murray (Wash.) and other Democrats aimed at stabilizing ObamaCare markets. Now he’s trying to sell the deal to skeptical colleagues who don’t want to be seen as propping up a law they revile.”
 - To read more: <http://thehill.com/policy/healthcare/358634-meet-the-gop-senator-quietly-pushing-an-obamacare-fix>.

Regulatory and Administration Update

- **CMS Updates to Policies and Payment Rates for End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury.** “On October 27, 2017, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that updates payment policies and rates under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for renal dialysis services furnished to beneficiaries on or after January 1, 2018. In addition, this rule finalizes updates to the acute kidney injury (AKI) dialysis payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI, as well as updates to the ESRD Quality Incentive Program (ESRD QIP), including for payment years (PYs) 2019, 2020, and 2021, under which payment incentives are made to dialysis facilities to improve the quality of care that they provide.”
 - To read more: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-27.html>.
- **Fresenius Kabi Issues Voluntary Nationwide Recall of Midazolam Injection, USP, 2 mg/2 mL Due to Reports of Blister Packages Containing Syringes of Ondansetron Injection, USP, 4 mg/2 mL.** “Fresenius Kabi USA is voluntarily recalling Lot 6400048 of Midazolam Injection, USP, 2 mg/2 mL packaged in a 2 mL prefilled single-use glass syringe to the hospital/user level. The product mislabeled as Midazolam Injection, USP,

2 mg/2 mL contains syringes containing and labeled as Ondansetron Injection, USP, 4 mg/2 mL. A missed dose of midazolam may lead to ineffective sedation and/or anxiety related to patient recall of a surgical or diagnostic procedure. If a selection error occurs, a patient who may have received a pre-operative dose of ondansetron may inadvertently receive an additional dose of ondansetron. Dose-dependent serious cardiac arrhythmias may be observed with higher dosages of ondansetron in those patients with certain pre-existing cardiac conditions. Patients may also be at risk for serotonin syndrome. Serotonin syndrome is associated with increased serotonergic activity in the central nervous system. Most reports of serotonin syndrome have been associated with concomitant use of certain drugs, some commonly used during surgery, such as fentanyl. Some of the reported cases of serotonin syndrome were fatal."

- To read more:
<http://www.businesswire.com/news/home/20171103005226/en/Fresenius-Kabi-Issues-Voluntary-Nationwide-Recall-Midazolam>.
- ***Medicare scraps future pay model for home health companies.*** "The stocks of publicly traded home health companies soared Thursday after the Centers for Medicare & Medicaid Services tossed out a controversial new payment system that would have cut Medicare payments to home health providers by \$1 billion in 2019. Between the lines: This is yet another example of health care's lobbying power. The home health industry hated Medicare's proposed pay system, talked with the right people, and consequently got what it wanted. What happened: CMS said this week in the 2018 final rule that it will not move forward with a new payment system called the "home health groupings model." Home health companies have drawn scorn from independent policymakers for their lofty Medicare profit margins, and the new system was an attempt to reduce payments through shorter episodes of care. But now that groupings model "is dead and unlikely to reappear," Gary Taylor, a J.P. Morgan health care analyst, wrote Thursday."
 - For more information: <https://www.axios.com/medicare-scraps-future-pay-model-for-home-health-companies-2505646316.html>.
- ***Want Drug Regulators To Consider Real-World Evidence? Then Disrupt Their Outdated Regulatory Infrastructure.*** "In a recent speech, Food and Drug Administration (FDA) commissioner Scott Gottlieb asked, "Should a product be marketed based on a data set that speaks to a limited and rigidly constructed circumstance, when the clinical use, and in turn the evidence we might have to evaluate the product, could have been far richer, far more diverse, and more informative?" In other words: Signals from real-world clinical settings about a new drug's effectiveness are vital for prudent clinical decision making and insurance coverage decisions. At the same time, there have also been recent discussions suggesting that the FDA should no longer worry about efficacy at all, basing drug approval only on safety signals while leaving the market to sort out what works and what does not. These two arguments have been bolstered by the new 21st Century Cures Act, which promises to accelerate a shift in how regulators balance the often competing priorities of speed, access, and safety. These arguments also underscore the great potential and significant challenges embedded in the use of real-world evidence in regulatory decision making."
 - For more information:
<http://www.healthaffairs.org/doi/10.1377/hblog20171030.999857/full/>.

- ***United States Renal Data System Annual Report.*** “The 2017 Annual Data Report is divided into two volumes this year. Volume 1: Chronic Kidney Disease in the United States and Volume 2: End-Stage Renal Disease in the United States. The ADR displays analytical results of USRDS data using graphs and maps. In the HTML version, links to all figures and tables open in a popup window. Also included are the following downloadable files: PDFs of each chapter, PowerPoint slides for all figures and tables, and data for all figures and tables in Excel.”
 - To read more: <https://www.usrds.org/adr.aspx>.
- ***HHS Announces Commitment to Launching Kidney Innovation Accelerator.*** “At ASN Kidney Week 2017, Bruce D. Greenstein, U.S. Department of Health and Human Services (HHS), Chief Technology Officer, highlighted the need for innovation in the nephrology space. Each year more than 100,000 Americans start hemodialysis, and sadly nearly 60% of those patients die within 5 years. With an ageing population and rising prevalence of diabetes, more Americans need dialysis than ever before. Mr. Greenstein shared HHS's vision of a world in which kidney disease patients and their care partners can live meaningful, productive lives. A world in which patients no longer even need dialysis. In order to realize this vision, Mr. Greenstein announced HHS' intent to launch a Kidney Innovation Accelerator. The Accelerator will establish a public-private innovation fund capable of seeding and accelerating not just incremental improvements in treating kidney disease, but will foster real breakthroughs in dialysis and other treatments for kidney disease. The Accelerator will also bring together all the key components of HHS, FDA, CMS, and NIH, to ensure that the path to commercialization is straight and clear.”
 - To read more: <https://www.asn-online.org/policy/webdocs/page.aspx?code=accelerator>.

Articles of Interest

- ***The weird way Trump actually lowered Obamacare premiums for millions.*** “About a month ago, President Trump cut off a key Obamacare subsidy program. Weirdly, it appears that this might make Obamacare more affordable than ever for many enrollees. It might make Obamacare work a bit better than last year, which certainly didn't seem to be the president's intention. But here's where things get interesting: Many insurance plans (often at the behest of local regulators) only increased premiums on midlevel plans, called silver plans. And the silver plans are the ones the federal government uses to figure out how much of a premium subsidy Obamacare enrollees get.”
 - To read more: <https://www.vox.com/policy-and-politics/2017/10/31/16586664/voxcare-obamacare-prices-silver-plan>.
- ***Serious Illness in Late Life: The Public's Views and Experiences.*** “The U.S. population is aging, and with that shift comes new challenges in meeting the needs of older adults with serious health needs. In order to better understand the public's expectations about later life and any efforts they've taken to plan for if they become seriously ill, the Kaiser Family Foundation conducted a large scale, nationally representative telephone survey

of 2,040 adults, including 998 interviews with people with recent experience with serious illness in older age, either personally or with a family member. For this survey, those who are seriously ill are older adults who have at least one of several chronic conditions and report functional limitations due to a health or memory problem. This comprehensive survey helps provide insight into the perspectives of the public at large as well as of older adults personally facing serious illness and their family members about how they view care in the U.S., steps they've taken to plan for becoming seriously ill in later life, and their current experiences with care and support for those with serious illness. It is the first in a series of surveys that will measure how these attitudes and experiences change over time."

- To read more: <https://www.kff.org/disparities-policy/report/serious-illness-in-late-life-the-publics-views-and-experiences/>.
- ***A completely biological "off-the-shelf" arteriovenous graft that recellularizes in baboons.*** "Patients undergoing hemodialysis for renal failure often receive an arteriovenous fistula, a connection between a vein and an artery. These surgical connections fail or cannot be attempted in some patients with compromised vasculature, who instead require vein grafts. As an alternative to autologous or synthetic grafts, Syedain et al. used a tissue engineering approach to generate vascular grafts from sacrificial fibrin scaffolds and human fibroblasts. Decellularized grafts were implanted into baboons and tested as hemodialysis access points. Over the course of 6 months, the grafts were recellularized with host cells and maintained sufficient burst pressure without evidence of immune rejection. Pending additional testing, these grafts represent an additional surgical option for hemodialysis access."
 - To read more: <http://stm.sciencemag.org/content/9/414/eaan4209.full>.
- ***Here are the final recommendations of the White House opioid commission.*** "The White House's commission on drug addiction and the opioid crisis on Wednesday released its final report, a list of recommendations that include an expanded drug court system, educational requirements for prescribers, and a media blitz to spread the word about preventive services and treatment availability for substance use disorder. The report includes 56 distinct recommendations, many of which now fall to Congress, a number of federal departments, and local governments to fund and implement. President Trump declared the opioid crisis a public health emergency on Oct. 26. The six-member commission will vote to approve the draft of the final document during its meeting on Thursday afternoon."
 - To read more: <https://www.statnews.com/2017/11/01/opioid-commission-white-house-final-report/>.
- ***How a Republican Idea for Reducing Medicare Costs Could Affect You.*** "Last month, as Republican leaders were preoccupied with another unsuccessful attempt to replace Obamacare, a senior Trump administration official issued a warning about a different major medical program, Medicare. The official, Seema Verma, administrator of the Centers for Medicare and Medicaid Services, wrote in The Wall Street Journal that Medicare was facing a fiscal crisis. She announced that she was asking the agency's innovation center for ideas to address it, and that part of the answer was to give consumers "incentives to be cost-conscious." This has some Democrats worried that

she's trying to move Medicare toward something called premium support, which would be a huge change for consumers."

- To read more: <https://www.nytimes.com/2017/10/30/upshot/how-a-republican-idea-for-reducing-medicare-costs-could-affect-you.html>.
- ***The Dialysis Machine.*** "As many as thirty million Americans have chronic kidney disease. If you're one of them, and you're white, well educated, and middle class or higher, odds are you'll get the kind of medical care that will save your kidneys. You likely have private health insurance and get regular checkups. You probably caught your condition early and are taking medication to slow down the disease's progression. But if you are poor, less educated, and black, the odds are much greater that your disease will run unchecked and your kidneys will eventually fail. According to the National Institutes of Health, black people are nearly four times as likely to suffer kidney failure as whites. Then you will likely end up on dialysis, spending three days a week, four hours at a time, at a place like this one, as your blood is pumped out of your body, filtered, and pumped back in."
 - To read more: <https://washingtonmonthly.com/magazine/novemberdecember-2017/the-dialysis-machine/>