American Nephrology Nurses Association

Weekly Capitol Hill Update – Tuesday, September 6, 2016

Congressional Schedule

House
- Convenes at 2 p.m. for legislative business and will consider 13 bills under suspension of the rules. Roll call votes will be held at 6:30 p.m. (CQ)
- **Week Ahead:** On Wednesday, the House meets at noon and will consider five bills under suspension of the rules. (CQ)

Senate
- Convenes at 3 p.m. and will vote at 5:30 p.m. on procedural measures related to the Defense (H.R. 5293) and Military Construction-VA and Zika (H.R. 2577) spending bills. (CQ)

Legislative Updates

- **9 Senate Seats Most Likely to Flip.** “The race for the Senate is heading into the homestretch as Republicans seek to maintain their grip on their slim majority. Democrats must net four seats and retain the White House to regain control of the upper chamber. They are defending 10 seats while Republicans face a more challenging path, needing to defend 24 seats.” The seats most likely to flip include those in Illinois, Wisconsin, New Hampshire, Pennsylvania, Indiana, Nevada, North Carolina, Ohio, and Florida.”
  - For the article, please see the following link: [http://thehill.com/homenews/campaign/294372-senate-seats-most-likely-to-flip-in-2016](http://thehill.com/homenews/campaign/294372-senate-seats-most-likely-to-flip-in-2016)

- **No 6-Month Stopgap for Democrats, Reid Insists.** “Senate Minority Leader Harry Reid confirmed Thursday that Democrats this month will oppose any stopgap spending bill that would punt current government funding and policies into 2017, a strategy favored by conservative Republicans who don't want a lame-duck session. “Everyone should be alerted today to this: We are not going to agree to a long-term CR,” the Nevada Democrat told reporters on a conference call, referring to a continuing resolution. “We are not doing anything into next year. The Republicans should be made aware of that right now.” Lawmakers have until Sept. 30 to pass a continuing resolution to avoid a government shutdown when fiscal 2016 funding expires. Reid’s comments on the length
of a stopgap, his most forceful to date, came after he apparently discussed the matter privately with President Barack Obama on Wednesday. Reid added that Democrats would likely accept a measure that continues funding into December, “up to Christmas,” but nothing longer.”

- For the full article, please see the following link:

- **Senators Push for Pre-Claim Delay After ‘Complete Mess’ in Illinois.** “Two U.S. Senators have called for a controversial home health pre-claim review demonstration program to be delayed in Florida, and they reiterated concerns over how pre-claim threatens providers and patients. And their concerns appear well-founded, considering reports from providers in Illinois, where pre-claim already has been implemented. “We remain concerned this demonstration may restrict beneficiary access to timely services, divert clinical resources to paperwork management, and incur high administrative costs,” wrote Florida Sens. Ben Nelson (D) and Marco Rubio (R) in a letter to Andy Slavitt, Acting Administrator of the Centers for Medicare & Medicaid Services (CMS). “We urge CMS to delay expansion of PCRD into Florida and the other states until CMS, stakeholders, and Congress have the opportunity to evaluate and understand the impact of the demonstration in Illinois.” Since its implementation at the beginning of August, the impacts of pre-claim appear to be highly negative in Illinois. The National Association for Home Care & Hospice (NAHC) has received reports from members that the demonstration is rife with problems.”

- For the full article, please see the following link:

- **Juan Williams: GOP Leaders Must Pick a Poison on Shutdown.** “Here is the latest chapter in bang-your-head-on-the-wall, stupid, frustrating Congressional politics. When the House and Senate get back to work tomorrow, the GOP majorities on both sides of Capitol Hill will be up against a September 30 deadline to pass a spending bill to keep the federal government open. That means funding the military, keeping Social Security checks going out and assuring global investors that the world’s leading economic power is not about to grind to a halt. If Congress fails to act, there will be a government shutdown weeks before a presidential election. In fact, early voting will be underway in several states. In terms of the presidential race and the fight over control of the Senate, history tells us a government shutdown is a loser for Republicans. In 2013, a majority of voters — 53 percent according to a Washington Post poll — blamed Republicans for the shutdown while only 29 percent blamed President Obama and the Democrats. The same was true in a 1996 shutdown — the majority of voters blamed the GOP-led Congress, not President Clinton. But hardline conservatives in the House Freedom Caucus don’t care about history. They are willing to hold the federal government and fellow Republicans running for election hostage until GOP congressional leaders, Obama and the Democrats agree to more spending cuts.”
**Regulatory Updates**

- **CMS Extends End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) Preview Period for Payment Year (PY) 2017 through 5 pm ET on Friday, September 30, 2016.** “The Preview Period is an opportunity for outpatient dialysis facilities to review their scores before they are finalized. Facilities with PY 2017 ESRD QIP scores that fail to meet or exceed the minimum Total Performance Score face reimbursement reductions of up to 2 percent for dialysis treatments that will be rendered during 2017.
  - For more information, visit the ESRD QIP website, review the materials from the August 2 MLN Connects® Call, or contact CMS at: ESRDQIP@cms.hhs.gov.”

- **The Medicare Payment Advisory Commission (MedPAC) will be meeting from September 8 – 9, 2016 in Washington, DC.** “The Commission meets publicly in Washington, DC to discuss Medicare issues and policy questions and to develop and approve reports and recommendations to the Congress. At these meetings, staff present research and policy options for the Commissioners to discuss. Meeting agendas and briefs are usually posted one week before the meeting. Transcripts and presentation slides are available 3 to 5 days after the meeting. All Commission meetings include several opportunities for public comment. These times are noted on the meeting agenda. We also accept comments on our meeting agendas through email, beginning approximately one week before the meeting and for one week thereafter. Due to the volume of comments we receive, we cannot acknowledge individual comments.”
  - For the agenda, please see the following link: [http://www.medpac.gov/-public-meetings-](http://www.medpac.gov/-public-meetings-)

- **Opioid Update.** “The Obama administration says it will distribute $53 million to 44 states in an effort to curb opioid abuse. HHS Secretary Burwell says the funding will focus on reducing over-prescribing of pain killers, increasing access to treatment and making sure the antidote naloxone is widely available. The administration is also calling on Congress to provide $1.1 billion in new money, saying legislation recently signed into law didn't do enough to expand treatment. That bill authorized $181 million in new spending. Steve Williams, the mayor of Huntington, West Virginia, said in a conference call announcing the funding that opioid abuse is so common he carries an overdose reversal kit with him. He says federal funding is urgently needed so people seeking treatment don't have to wait months.”
  - For the full article, please see the following link: [http://www.modernhealthcare.com/article/20160831/NEWS/308319997?utm_source=modernhealthcare&utm_medium=email&utm_content=20160831-NEWS-308319997&utm_campaign=am](http://www.modernhealthcare.com/article/20160831/NEWS/308319997?utm_source=modernhealthcare&utm_medium=email&utm_content=20160831-NEWS-308319997&utm_campaign=am)
FDA Bans 19 Chemicals Used In Antibacterial Soaps. “Consumers don't need to use antibacterial soaps, and some of them may even be dangerous, the Food and Drug Administration says. On Friday, the FDA issued a rule banning the use of triclosan, triclocarban and 17 other chemicals in hand and body washes which are marketed as being more effective than simple soap. Companies have a year to take these ingredients out of their products or remove the products from the market, the agency said. "If the product makes antibacterial claims, chances are pretty good that it contains one of these ingredients," Theresa Michele, director of the FDA's Division of Nonprescription Drug Products, said Friday in a conference call with reporters. The ban applies only to consumer products, not to antibacterial soaps used in hospitals and food service settings.”
  o For the full article, please see the following link: http://n.pr/2c9UQiG

Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Public Hearing; Request for Comments. “The Food and Drug Administration (FDA or Agency) is announcing a 2-day public hearing to obtain input on issues related to communications by manufacturers, packers, and distributors, including their representatives (collectively “firms”), regarding FDA-regulated drugs and medical devices for humans, including those that are licensed as biological products, and animal drugs (collectively, “medical products”). FDA is engaged in a comprehensive review of its regulations and policies governing firms' communications about unapproved uses of approved/cleared medical products, and the input from this meeting will inform FDA's policy development in this area.”
  o For the full federal register notice, please see the following link: https://www.federalregister.gov/articles/2016/09/01/2016-21062/manufacturer-communications-regarding-unapproved-uses-of-approved-or-cleared-medical-products-public

Articles of Interest

Charitable Assistance: The New ‘Pre-Existing Condition.’ “For years, health insurance companies systematically denied coverage to Americans with pre-existing medical conditions. As a result, those who needed coverage the most—people with severe and chronic conditions—were unable to buy insurance or were charged exorbitant premiums that were equivalent to a denial of insurance. Today, insurers can no longer deny coverage to sick people and cannot place a cap on benefits paid to treat their illnesses. For many patients, this access to insurance and treatment is crucial to their wellbeing and, often, their lives. But now insurers are engaging in a different kind of effort to avoid covering people with expensive illnesses by refusing to accept premium payments from third-party charities that help low-income patients pay their premiums. In other words, charitable assistance is insurers’ new “pre-existing condition.” Insurance industry lobbyists are working hard to exclude the sickest and most vulnerable patients from having a choice in their insurance. Patients with end-stage renal disease (ESRD) are a case in point. Nearly half a million people in the United States depend on dialysis to survive. Most are unable to work because dialysis is both physically taxing and life-consuming. These patients have two options to cover the expense of the treatments that keep them alive: private insurance or enrollment in Medicare or Medicaid.”
• Gaps In Care Persist During Transition From Hospital To Home. “For elderly patients like Rodgers, leaving the hospital is fraught with risk. Most are sent home or to nursing facilities after just a few days, still reeling from acute illnesses — not to mention the chronic conditions they are also confronting. “Just because they have had four days in a hospital doesn’t mean they are better,” said Mary Naylor, a gerontology professor at the University of Pennsylvania School of Nursing. It’s during that critical time when problems can occur. Patients may get sicker because they don’t have access to medications, transportation, food or crucial equipment such as oxygen tanks. And many don’t have relatives or caregivers to help with the daily tasks that they were able to perform unassisted before being hospitalized. “There are gaps in care, there are gaps in communication, there are gaps in adequate preparation for patients and families,” said Naylor, who designed a transitions model to address these problems. In recent years, federal health officials have begun penalizing hospitals for high rates of readmission and sponsoring pilot projects — like the one that sent a social worker and nurse to see Rodgers — to help ensure smoother discharges. Hospitals and community groups are experimenting with different methods to improve the transition of elderly patients from the hospital.”

• EpiPen Controversy Fuels Concerns Over Generic Drug Approval Backlog. “Consumers and Congress members pushing for cheaper alternatives to the EpiPen and other high-priced drugs are seeking answers about a stubborn backlog of generic drug applications at the Food and Drug Administration that still stretches almost four years. As of July 1, the FDA had 4,036 generic drug applications awaiting approval, and the median time it takes for the FDA to approve a generic is now 47 months, according to the Generic Pharmaceutical Association, or GPhA. The FDA has approved more generics the past few years, but a flood of new applications has steadily added to the demand. By comparison, the European Medicines Agency (EMA), Europe’s version of the FDA, has just 24 generics or biologically-based “biosimilars” awaiting approval. (The FDA’s count does not include biosimilars.) And the EMA along with the European Commission, which handles approval of marketing materials, are approving generics and brand name drugs in about a year on average, according to the EMA. Critics say getting generic alternatives to the U.S. market for products like EpiPen is still taking far too long.”

• Experts Say Stepped-Up Monitoring Is Crucial as Zika’s Threat Lasts Beyond A Baby’s Birth. “As the Zika virus spreads both at home and abroad, new information is bringing to light how children — even those who at birth do not show obvious signs of impairment — are likely at a greater risk than previously believed. This possibility, experts say, is highlighting a need to better track the development and well-being of babies who may have been exposed to the virus in utero. The development: Scientists in Brazil reported last week on an infant, whose mother contracted the virus late in pregnancy, which has typically been considered a less vulnerable time. The infant didn’t
show signs of developmental problems but still had Zika in his urine, saliva and serum two months after being born. By six months, the child had begun showing signs of brain impairment — suggesting the virus can linger longer in babies’ systems and cause health problems later than previously believed. The report only describes one case, which limits what scientists can reasonably conclude. But it underscores a need for better counseling, more thorough monitoring of children who were potentially exposed and increased research on how Zika may affect children, doctors said.”

- For the full article, please see the following link: [http://bit.ly/2cdlusB](http://bit.ly/2cdlusB)

- **4,800 Nurses Strike at 5 Hospitals Amid Union Dispute with Allina.** “Nearly 5,000 nurses took to the picket lines on Monday — Labor Day — as they began an open-ended strike at five Twin Cities hospitals operated by the Allina Health system. The strike follows a 22-hour negotiation session that stretched from Friday into Saturday morning but failed to produce an agreement between the Minnesota Nurses Association and Minneapolis-based Allina. “We should be at a Labor Day picnic, and here we are at a Labor Day picket instead,” MNA executive director Rose Roach said at a Monday news conference outside Abbot Northwestern Hospital in Minneapolis. MNA and Allina continue to disagree on nurses’ health insurance, which has been a central point of conflict since contract negotiations began in February. Allina’s latest health insurance proposal still shifts too many costs onto nurses and doesn’t recognize concessions already made by the union, Roach said.”

- For the full article, please see the following link: [http://bit.ly/2cDw3G5](http://bit.ly/2cDw3G5)

- **Senator Kirk Partners with National Kidney Foundation to Provide Free Kidney Disease Screening in Maywood.** “U.S. Senator Mark Kirk (R-Ill.) recently joined Rock of Ages Baptist Church and St. Eulalia Parish in Maywood to present a free kidney disease screening. The free screenings were provided by the National Kidney Foundation, the leading organization in the U.S. dedicated to the awareness, prevention and treatment of kidney disease. “Kidney disease is a silent killer that can easily go undetected, so I am partnering with the National Kidney Foundation to ensure everyone in the Chicagoland area has access to free kidney screenings,” said Senator Kirk. “Early detection is key to preventing the disease from advancing and saving your life.” Senator Kirk has been a longtime advocate to prevent kidney disease. In 2002, Senator Kirk founded the Congressional Kidney Caucus with Rep. Jim McDermott (D-Wa.). Kidney disease has virtually no symptoms and can be deadly, which makes regular screenings and early detection crucial for saving lives. One in nine Americans are already suffering from the disease and are unaware that they have it.”


- **Older Patients Feel They Have Little Say in Choosing Dialysis, Study Says.** “Starting dialysis treatment for end-stage renal disease (ESRD) should be a shared decision made by an informed patient based on discussions with a physician and family members. However, many older dialysis patients say they feel voiceless in the decision-making process and are unaware of more conservative management approaches that could help them avoid initiating a treatment that reduces their quality of life, according to a study
led by Tufts University researchers. The study, published online in Nephrology Dialysis Transplantation in advance of print, also found that patients who perceived they did not have a choice in starting dialysis reported low satisfaction with the treatment, despite acknowledging its life-extending benefits. The research coincides with the recent increase of attention to poor end-of-life care in the United States. The study's link between the process of decision-making and satisfaction with treatment choices affirms the need to prioritize better understanding of shared decision-making in the older patient population.”

For the full article, please see the following link:

• **How Should Undocumented Immigrants Get Free Dialysis?** “Thanks to a rare quirk in the U.S. health system, citizens with advanced kidney disease don't have to worry about whether they will be able to receive routine dialysis treatment. For more than four decades, the federal government has paid for dialysis to ensure that people with a potentially deadly disease have access to life-saving treatment. But the legislation that opened the door to seemingly universal dialysis in 1972 left out one group of patients: undocumented immigrants. These individuals often find themselves forced to rely on what many experts say is substandard care to stay alive. They often must wait until their situation deteriorates to the point they must seek emergency room care — a situation many experts say is not only dangerous for the patient but increases taxpayer costs.”

For the full article, please see the following link:

• **Are Promises Made to Living Donors Being Upheld?** “A new study finds some shortcomings by the transplant community in providing prompt access to transplantation for living kidney donors who later develop kidney disease and need a transplant. Donors are told that they will have priority for transplantation if they ever need a kidney, so any delays in providing this access must be addressed. The study's results appear in an upcoming issue of the Clinical Journal of the American Society of Nephrology (CJASN). Jennifer Wainright, PhD (United Network for Organ Sharing, or UNOS) and her colleagues examined how consistently living donors get transplant priority in a timely fashion, using information from the Organ Procurement and Transplantation Network (OPTN), which includes data on all donors, wait-listed candidates, and transplant recipients in the United States. UNOS is the private, non-profit organization that manages the nation's organ transplant system under contract with the federal government.”

For the full article, please see the following link:

**Upcoming Hearings**

**Wednesday, September 7th**

• **House Ways and Means Human Resources Subcommittee - Hearing on “Unemployment Insurance: An Overview of the Challenges and Strengths of Today’s System”**
  - 10:00 am @ 1100 Longworth House Office Building
• **House Ways and Means Health Subcommittee** - *Hearing on Incentivizing Quality Outcomes in Medicare Part A*
  o 2:00 pm @ 1100 Longworth House Office Building

**Thursday, September 8th**

• **House Energy and Commerce Health Subcommittee** - *Examining Legislation to Improve Public Health*
  o 10:00 am @ 2322 Rayburn House Office Building

• **House Energy and Commerce Health Subcommittee** - *An Examination of Federal Mental Health Parity Laws and Regulations*
  o 9:00 am @ 2322 Rayburn House Office Building