

American Nephrology Nurses Association

Weekly Capitol Hill Update - Tuesday, August 23, 2016

Congressional Schedule

House and Senate

- “Washington has been quiet lately with Congress in recess (until after Labor Day), but researchers trying to develop a Zika virus vaccine have been busy despite wrangling over how to fund their work.” (CQ)

Legislative Updates

- ***EpiPen Price Rise Sparks Concern for Allergy Sufferers.*** “A steep increase in the price of the EpiPen, a lifesaving injection device for people with severe allergies, has sparked outrage among consumers and lawmakers who worry that parents won’t be able to afford the pens for children heading back to school... The price hike has caught the attention of Washington lawmakers. Senator Amy Klobuchar, Democrat of Minnesota, who has a daughter who carries an EpiPen, has called on the Senate Judiciary Committee and the Federal Trade Commission to review whether the price hikes violate any anti-competition rules. Last year, the drug maker Sanofi recalled a competing product, Auvi-Q, because it may not have been delivering the correct amount of epinephrine, leaving the EpiPen as the primary emergency treatment for severe allergic reactions... Senator Chuck Grassley of Iowa called on Mylan to explain the price hikes, noting that they impose a burden on both parents and school districts, who often keep supplies of the pen at the ready.”
 - For the full article, please see the following link:
<http://well.blogs.nytimes.com/2016/08/22/epipen-price-rise-sparks-concern-for-allergy-sufferers/?hp&action=click&pgtype=Homepage&clickSource=story-heading&module=first-column-region®ion=top-news&WT.nav=top-news&r=1>
- ***Zika Funding Held Back By Politics.*** “To date, nearly 2,000 Zika cases have been reported in the United States. In Miami alone, roughly 30 people have contracted Zika after being bitten by mosquitos, including a tourist who took the virus back with him to Texas. The Centers for Disease Control and Prevention (CDC) has taken the unprecedented action of issuing a travel warning for a community in the United States. Sadly, Congress has yet to act. As physicians we are appalled that politics has prevented our government from funding a response to Zika that will protect women and their

families. We are especially alarmed that elected officials – in Florida, and in Washington – continue to try to tie Zika funding to legislation that would limit women’s access to reproductive and preventive care. If we’re serious about addressing the Zika threat, we must fully fund comprehensive reproductive healthcare – so that all at-risk women who would like to avoid or delay their pregnancy may do so. Florida is, in many ways, is a cautionary tale. While the state is ground-zero for the Zika crisis in the United States, some politicians in the state are putting their own ideology above women’s health by blocking access to preventive care. Just earlier this year Florida Governor Rick Scott signed a law that would block access to birth control, health education, and other screenings – the same services that are critical to combat Zika.”

- For the full article, please see the following link: <http://bit.ly/2bdGT2v>

Regulatory Updates

- ***ESRD QIP Call: Reviewing Your Facility's PY 2017 Performance Data Call.***
An audio recording and transcript are available for the August 2 Centers for Medicare and Medicaid Services (CMS) call on “End-Stage Renal Disease (ESRD) Quality Improvement Program (QIP): Reviewing Your Facility's Payment Year (PY) 2017 Performance Data.”
 - For more information, please see the following link:
<http://go.cms.gov/2bBcYAS>
- ***NIH Publishes Comment Opportunity on Collection Project Related to Nurse Coaches.***
“To provide opportunity for public comment on proposed data collection projects, the National Institutes of Health Clinical Center (CC) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.”
 - *Proposed Collection: Title:* A National Survey of Nurse Coaches, 0925– National Institutes of Health Clinical Center (CC), National Institutes of Health (NIH).
 - *Need and Use of Information Collection:* The purpose of this survey is to describe the role of Certified Nurse Coaches in order to gain insight into their clinical practice including: The settings in which they work, the types of clients/health conditions they see, the types of client records maintained and outcomes followed, as well as the personal benefits experienced by nurse coaches as a result of becoming a nurse coach. It provides information regarding two areas of interest to the CC Department of Nursing Research and Translational Science: The collection of patient-reported outcomes in novel clinical practice areas and the physical and psychosocial benefits of an intervention in nurses, a professional caregiver population.
 - For more information, please see the federal register notice:
<https://www.federalregister.gov/articles/2016/08/22/2016-19823/proposed-collection-60-day-comment-request-a-national-survey-of-nurse-coaches-cc>

- ***Coming Soon? Part D Covered Drug Moves to Part B.*** “We may soon see a provision in the 2015 final rule addressing the utilization of ESRD-related drugs and biologics come into action in the next few months. Specifically, the oral-only drug Sensipar may transition to bundled payment and become reclassified as a Medicare Part B covered drug should a non-oral form be approved by the Food and Drug Administration (FDA). Prescribers and dispensers should be aware that a transition is possible and will likely impact reimbursement for this product. The drug Sensipar is currently considered an oral-only drug product. However, in 2015, a biopharmaceutical company submitted a new drug application for a calcimimetic agent that can be administered intravenously. Under the final rule, approval of this product would likely reclassify the oral-only form as a non-oral-only product and subject it to inclusion in a bundled payment. In other words, if an IV form is approved by the FDA, it will be in a transition period for two years while CMS evaluates the utilization of both the oral and IV forms. If the oral form remains with no FDA-approved IV form, the oral will continue to be paid separately under Medicare Part D. FDA approval of the IV form is anticipated prior to the end of 2016.”

 - For the full article, please see the following link:
http://www.healthlawupdate.com/2016/08/coming-soon-part-d-covered-drug-moves-to-part-b/?utm_source=BakerHostetler+-+Health+Law+Update&utm_campaign=812a817f8c-RSS_EMAIL_CAMPAIGN&utm_medium=email&utm_term=0_d8aec2cb3a-812a817f8c-70691829

- ***Provider Network Comparison Tool Will be Limited to Six States.*** On August 19, 2016, the Centers for Medicare and Medicaid Services (CMS) announced it will be introducing a tool that allows individuals to compare the provider networks in marketplace health plans for 2017, but only in six HealthCare.gov states. Earlier this year, CMS indicated that people in all HealthCare.gov states would be able to compare a health plan's provider network to other options in the same county. CMS has not specified the six states that will pilot the new consumer tool.

 - Guidance issued August 19, 2016:
<https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Network-Classification-Pilot-Guidance-81916.pdf>
 - Guidance issued February 2016:
<https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf>

- ***NIH's Fauci: Gulf Coast States Most Vulnerable to Zika.*** “An NIH official said Sunday that the Zika virus could ‘hang around’ the U.S. for a year or two. Dr. Anthony Fauci told ABC's "This Week" that other Gulf Coast states, besides Florida, are most vulnerable to the spread of the disease. “I would not be surprised if we see cases in Texas and Louisiana, particularly now where you have the situation with flooding in Louisiana,” said Fauci, director of the National Institute of Allergy and Infectious Diseases. “There are going to be a lot of problems getting rid of standing water.” Mosquito-borne Zika cases have been found in two neighborhoods of Miami-Dade County – the Wynwood neighborhood and Miami Beach. They are the first areas on the U.S. mainland where

health officials determined mosquitoes were transmitting Zika, which has spread through Latin American and the Caribbean.”

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

http://www.modernhealthcare.com/article/20160821/NEWS/308219998?utm_source=natnewsletter&utm_medium=email&utm_content=national&utm_campaign=WashingtonDC_20160822_0808

- ***Public Meeting on Patients Who Have Received an Organ Transplant.*** “On September 27, 2016, FDA is conducting a public meeting on Patients Who Have Received an Organ Transplant. FDA is interested in obtaining patient input on the impact of receiving an organ transplant on daily life and patients’ views on currently available therapies to manage organ transplantation.”

- For more information, please see the following link:

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm495933.htm>

- ***CMS Examines Inappropriate Steering of People Eligible for Medicare or Medicaid into Marketplace Plans.*** “CMS said on Thursday it is investigating whether some providers or affiliated groups have improperly steered people who would be eligible for Medicare or Medicaid toward individual market plans. The agency has concerns that such actions are resulting on issues on the federal exchanges. Providers would steer patients toward individual marketplaces, either on or off the exchanges, to obtain higher reimbursement rates, the CMS release suggests. “Ensuring access to high quality patient care is a top priority for us. We are concerned about reports that some organizations may be engaging in enrollment activities that put their profit margins ahead of their patients’ needs,” Andy Slavitt, acting administrator of CMS said in a statement. “These actions can limit benefits for those who need them, potentially result in greater costs to patients, and ultimately increase the cost of Marketplace coverage for everyone.” The agency released a request for public comment and sent letters to all Medicare-enrolled dialysis facilities and centers to inform them of the investigation. “Our goal is to protect patients from being unduly influenced in their decisions about their health insurance options, and to protect the integrity of all the programs we oversee,” Shantanu Agrawal, CMS’s deputy administrator and director of the Center for Program Integrity, said.”

- ***National Kidney Foundation Statement on CMS Announcement to Examine Inappropriate Steering of Patients Eligible for Medicare or Medicaid into Marketplace Plans.*** “The National Kidney Foundation is concerned about allegations of dialysis patients potentially being steered into health insurance options that primarily benefit the provider; but may not necessarily be in the best interests of the patient. We agree with CMS that '[E]nrollment decisions should be made, without influence, by the individual based on their specific circumstances, and health and financial needs.' While the National Kidney Foundation does not provide premium assistance to help kidney patients pay for health insurance coverage nor do we counsel patients on the type of coverage they should choose, we do provide factual information and tools to help patients learn about their options and make informed decisions that best serve their unique needs. Most people with ESRD or kidney failure are eligible for Medicare coverage, regardless of their age; however they are not required to enroll. ESRD

patients who have group health coverage or individual coverage at the time they develop ESRD can choose to forgo Medicare enrollment, but may pay a late penalty for enrollment. While most ESRD patients choose to enroll in Medicare, there are some patients for whom Medicare may not meet their health and financial needs. As a result patients should retain the option to choose private health insurance coverage. Over the past few years insurance companies have developed policies, including refusal to accept third-party premium assistance, to avoid having to cover dialysis patients because of the high costs associated with their care. The Affordable Care Act was intended to protect patients with pre-existing conditions and offer them the option to maintain or enroll in private health coverage regardless of their health status. NKF supports extending this same protection to individuals with kidney failure. In addition, many dialysis patients rely on third-party premium assistance to help pay for their choice in insurance coverage, whether it be for private health insurance coverage or supplemental Medicare insurance known as Medigap. This assistance is offered by some nonprofits focused on kidney disease, however not by the National Kidney Foundation. Access to this assistance is critical for many dialysis patients and should be continued..."

- For the full statement, please see the following link:
<http://www.publicnow.com/view/EDC3D479B994688439CB898678DE35C2C360B72C?2016-08-19-03:01:18+01:00-xxx8417>
- For the full article, please see the following link:
<https://morningconsult.com/alert/cms-investigating-providers-steered-patients-away-public-insurance-programs/>
- For CMS' press release, please see the following link:
<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-08-18-2.html>

Articles of Interest

- ***CDC: Pregnant Women Should Avoid Part of Miami Beach Affected by Zika.*** "Pregnant women should now avoid a popular section of this tourist district where Zika is spreading, in addition to a smaller area north of downtown Miami, the Centers for Disease Control and Prevention (CDC) announced Friday. Pregnant women and their sexual partners who are concerned about the virus could also consider avoiding 'nonessential travel' to all of Miami-Dade County, according to the CDC. Although Zika mostly spreads through mosquito bites, both men and women can transmit the virus sexually. Florida health officials, who have been grappling with a Zika outbreak in Miami's Wynwood neighborhood, confirmed Friday that five people also have been infected in South Beach, the vibrant community that's located across Biscayne Bay from the rest of Miami and known for its pastel-colored buildings and art deco architecture. The new cases bring the total number of infections spread by local mosquitoes to 36, Gov. Rick Scott said. The five latest patients were infected within a 1.5 square mile area of Miami Beach, said Scott, whose state is the first to experience a Zika outbreak from native mosquitoes. The bulk of the USA's more than 2,200 cases of the virus are related to travel."
 - For the full article, please see the following link: <http://usat.ly/2buHudC>

- ***Study Finds Obamacare Increased Prescription Drug Use, Reduced Spending.*** “A new study suggests that because Obamacare has increased access to care, it has also increased prescription drug use while reducing out-of-pocket spending for consumers. It’s unclear how this affects health care spending in other sectors. The study, conducted by the RAND Corporation and appearing in *Health Affairs*, examined prescription transaction data among 6.7 million prescription drug users to track changes in coverage, usage and spending between 2013 and 2014. The *Affordable Care Act’s* Medicaid expansion and individual insurance exchanges were both implemented in 2014. The study found that during the first year of Obamacare’s coverage expansion, the proportion of uninsured prescription drug users decreased by 30 percent. Uninsured people who gained private coverage between 2013 and 2014 also filled 28 percent more prescriptions and paid 29 percent less out-of-pocket per prescription in 2014 compared to the prior year. Those who gained coverage under Medicaid filled 79 percent more prescriptions and had a 58 percent reduction in per-prescription out-of-pocket spending. People with at least one of the chronic conditions the study looked at also saw larger decreases in out-of-pocket spending than those who did not have any. “People who gained coverage had more drug spending paid for by health plans and less out-of-pocket spending after gaining coverage,” the study’s authors wrote. “The increase in plan drug spending is linked to higher utilization rates and reflects these patients’ improved access to health care.” Insurers, the study found, picked up the tab for consumers’ increased usage and decreased costs.”

 - For the full article, please see the following link: <https://morningconsult.com/2016/08/17/study-finds-obamacare-increased-prescription-drug-use-reduced-spending/>

- ***Licensing Logjam for California Nurses.*** “Ivana Russo submitted her application for a California nursing license on April 22, nearly a month before she graduated from a nursing program at Brightwood College in San Diego. She expected it to take 10 to 12 weeks for the state to process her paperwork and authorize her to take the licensing exam. As of early August, 15 weeks later, the licensing board still had not reviewed her file and could not tell her when it would. Russo called the agency, often, to ask about the status of her application. It was hard to get a staff member on the phone. When she did, she said, “Every time I got a different story.” State officials claim that hiring new nurses is a crucial workforce concern for California, yet at least 2,000 recent nursing graduates like Russo remain in licensing limbo, with their applications taking as long as 24 weeks for the Board of Registered Nursing to process. Experienced nurses from other states who apply for California licenses also wait months for the go-ahead to work. Even as labor experts worry the U.S. won’t have enough nurses to care for an aging population, license delays have plagued nursing boards across the nation in recent years – in Georgia, Maryland and, more recently, Ohio, where thousands were reportedly waiting on backlogged license applications as of early August. The current delay in California comes on the heels of a related slowdown in 2014 and is a major inconvenience for the nurses who want jobs and a hassle for the hospitals that want to hire them.”

 - For the full article, please see the following link: <http://khn.org/news/licensing-logjam-for-california-nurses/>

- ***Preventive Care, Specialists Key To Controlling Kidney Failure Treatment Costs.*** “Kidney failure costs Medicare close to \$30 billion per year, and the disease is only expected to become more common. But new research suggests a path forward that could save money while also improving patients’ health. The findings, published Monday in JAMA Internal Medicine, suggest that focusing on modifiable factors for patients with chronic kidney disease, such as promoting early access to nephrologists, could improve overall care, prevent complications and cut health spending. Adult patients experiencing end-stage renal disease, who generally are eligible for Medicare, were as much as four-to-six times more likely to need emergency treatment than the average Medicare beneficiary. But many of those expensive visits, the researchers suggest, could have been avoided.”
 - For the full article, please see the following link:
<http://khn.org/news/preventive-care-specialists-key-to-controlling-kidney-failure-treatment-costs/>

- ***Fallout From Obamacare Probe As Shares Of Dialysis Firms Drop.*** “Dialysis services firms are under pressure, after federal health care officials launched an investigation into complaints some providers may be steering patients into Obamacare plans, in order to obtain higher reimbursement fees. Shares of dialysis DaVita Healthcare fell more than 4 percent, Fresenius Medical Care fell nearly 4 percent, while American Renal Associates shares plunged as much as 18 percent, well below its April IPO price of \$22. ARA shares later recovered some losses and ended the day down more than 10 percent. Regulators from the Centers for Medicare and Medicaid Services issued a request for information seeking public comment into the prevalence of the practice late Thursday, after health insurers raised concerns about the issue. Aetna, Anthem and UnitedHealthcare group all remarked on a trend of higher dialysis claims on their Affordable Care Act plans in the second quarter. CMS issued a warning letter to Medicare-enrolled dialysis firms saying that agency is considering changes to enrollment provisions that now allow some charitable groups to pay for Obamacare plan premiums, and potential penalties for those found to be abusing the system.”
 - For the full article, please see the following link:
<http://www.cnbc.com/2016/08/19/fallout-from-obamacare-probe-as-shares-of-dialysis-firms-drop.html>

- ***A Self-Serve Dialysis Machine May be Coming Home With You.*** “Tablo is a 150-pound, 3-foot-tall, largely automated dialysis machine designed for patients to use by themselves, with a simple step-by-step procedure that makes it easier to operate than existing home machines. Outset was founded as Home Dialysis Plus in 2003 with technology licensed from HP and Oregon State University and developed by co-founder Michael Baker. Outset has raised more than \$100 million, plus \$40 million in debt financing, from investors including Warburg Pincus and Fidelity Investments.”
 - For the full article, please see the following link:
<http://www.bloomberg.com/news/articles/2016-08-17/a-self-serve-dialysis-machine-may-be-coming-home-with-you>