American Nephrology Nurses Association

Weekly Capitol Hill Update – Monday, August 29, 2016

Congressional Schedule

House and Senate

- "Not in session. Lawmakers will return after Labor Day." (CQ)

Legislative Updates

- ***ICYMI.*** On July 7, 2016, Reps. Diane Black (R-TN) and Earl Blumenauer (D-OR), introduced the Access to Better Care Act of 2016 (H.R. 5652), legislation that would allow eligible high deductible health plans with health savings accounts (HSAs) the option of providing pre-deductible coverage for medical management of chronic conditions or diseases.
    - To view the press release: https://black.house.gov/press-release/black-blumenauer-introduce-access-better-care-act-2016

- ***EpiPen Price Increase.*** On Friday, Senator Susan Collins (R-ME) released a statement on the EpiPen price increase. "While patient assistance programs help some consumers afford the skyrocketing prices of drugs like the EpiPen, they do not assist anyone who participates in government healthcare programs like the Children's Health Insurance Program (CHIP,) Medicaid, Medicare, and other federal health insurance programs. That means that millions of patients will not benefit from the actions Mylan is taking in issuing patient assistance cards. In addition, private insurers will continue to bear the full cost of their share of the drug, which in turn contributes to higher premiums paid by consumers."
    - To view the full press release, please see the following link: https://wabi.tv/2016/08/26/senator-collins-releases-statement-on-epipen-price-increase/

    - ***Mylan Boosts EpiPen Patient Programs, Doesn't Budge on Price.*** "The maker of EpiPens offered patients more help to pay for its costly emergency allergy shots but didn't budge Thursday on the $608 price. The announcement from Mylan N.V. triggered a new round of condemnation from politicians and consumer groups, who accuse the company of price-gouging on a potentially life-saving treatment. Critics stressed that insurers, employers and taxpayers will still foot most of the cost for EpiPens. Over

time, that drives up insurance premiums and the country's burgeoning health care tab. 'Everybody suffers, except the Mylan investors,' said Sabrina Corlette of Georgetown University's Health Policy Institute. This week, Mylan joined other drugmakers such as Valeant Pharmaceuticals International Inc. and Turing Pharmaceuticals, who've been blasted for mammoth price increases. Mylan CEO Heather Bresch defended her company's price hikes Thursday, telling CNBC that lowering the price was not an option. Bresch said the company only receives $274 of the $608 for a twin-package of EpiPens. She said insurers, pharmacies, prescription benefit managers and distributors divvy up the rest."

- To read the full article, please see the following link: http://krqe.com/2016/08/26/mylan-boosts-epipen-patient-programs-doesnt-budge-on-price/

Regulatory Updates

- ***CMS Releases Proposed Notice of Benefit and Payment Parameters for 2018.*** "The proposed HHS Notice of Benefit and Payment Parameters for 2018 released today proposes standards for issuers and each Health Insurance Marketplace, generally for plan years that begin on or after January 1, 2018… The proposals in this proposed rule include improvements to the risk adjustment program that will strengthen its ability to protect consumers' access to high-quality, affordable options in the individual and small group markets, as well as other changes that will streamline the Marketplace consumer experience and the individual and small group markets as a whole. The actions in this proposed rule build on other actions CMS has taken to strengthen the Marketplace in recent months, including a recent request for information (RFI) seeking public comment on concerns that some health care providers and provider-affiliated organizations may be steering Medicare or Medicaid enrolled or eligible people into a Marketplace qualified health plan (QHP) to obtain higher reimbursement rates; the announcement of a new outreach strategy targeting young adults; and beginning implementation of the special enrollment confirmation process to ensure eligible individuals have access to coverage while preventing misuse of the system."
  - To read more: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-29.html

- ***CMS Releases Updated Prescriber-Level Medicare Data.*** "The Centers for Medicare & Medicaid Services (CMS) has made available its second annual release of data that details information on the prescription drugs that were prescribed by individual physicians and other health care providers and paid for under the Medicare Part D Prescription Drug Program. The new 2014 dataset describes the specific medications paid for under the Medicare Part D program and statistics on their utilization and costs for 38 million beneficiaries enrolled in a Medicare Part D plan, who represent 70 percent of all Medicare beneficiaries. It provides data on more than one million distinct health care providers who collectively prescribed $121 billion in prescription drugs under the Part D program. New in the 2014 data are distinct beneficiary counts, prescription drug event counts and total drug costs aggregated by drug category for opioids, antibiotics, antipsychotics, and high-risk medications among the elderly. In addition, a prescriber

enrollment status field has been added to indicate whether the prescriber is enrolled, not enrolled or opted out of the Medicare program. The data are posted on the CMS website at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/PartD2014.html."

- To read more, please visit: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-18.html

- ***CMS Releases Inappropriate Steering of Individuals Request for Information.*** "On August 18, 2016, CMS issued a request for information seeking public comment on concerns that some health care providers and provider-affiliated organizations may be steering people eligible for, or receiving, Medicare and/or Medicaid benefits into Affordable Care Act-compliant individual market plans, including Health Insurance Marketplace plans, for the purpose of obtaining higher reimbursement rates. CMS also sent letters to all Medicare-enrolled dialysis facilities and centers informing them of this announcement. The request for information and letters to providers focus on situations where patients may be steered away from Medicare or Medicaid benefits, which can among other concerns, result in beneficiaries experiencing a disruption in the continuity and coordination of their care as a result of changes to their network of providers. These actions reflect ongoing efforts by the CMS Center for Program Integrity to address possible issues in the Marketplace that could affect the integrity of the programs for both consumers and issuers, and the costs of the individual insurance market, while at the same time help ensure patients are enrolled in the right plan for them…"
  - To view the press release: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-08-18-2.html
  - To view the request for information: https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-20034.pdf
  - To view the letter to Medicare-enrolled dialysis facilities: https://www.cms.gov/about-cms/components/cpi/downloads/rfi-medicare-dialysis.pdf

- ***FDA Hits Amgen With Rejection for Next-Gen Kidney Med.*** "The FDA has slapped a complete response letter onto Amgen ($AMGN) for its experimental med to treat a hormonal imbalance in dialysis patients, dashing its hopes of a 2016 approval. The NDA Amgen was seeking was for its candidate Parsabiv (etelcalcetide) in patients with secondary hyperparathyroidism (sHPT) with chronic kidney disease on hemodialysis. In a very brief update, Amgen said the FDA has rejected it application in its current form, but gave no details as to whether this was due to concerns over safety, manufacturing of efficacy. The nature of the letter, and especially if it required additional clinical trials, could seriously delay any approval of the med. Amgen said in a statement that it was "reviewing the Complete Response Letter, and we anticipate a post-action meeting with the FDA later this year to discuss the Complete Response." The FDA does not have to publicly declare the reason for its rejection, and companies can wait to make this information available. It filed the drug for U.S. review back in September, and in the same month with the EMA. Amgen added that this wouldn't affect other regulatory

submissions, but this may well depend on the issue or issues the FDA has found, and whether that will impact the drug's other reviews."

- For the full article, please see the following link: http://www.fiercebiotech.com/biotech/fda-hits-amgen-rejection-for-next-gen-kidney-med

- ***NQF's Renal Draft Report Comment Period Closes September 6th.*** The National Quality Foundation's Renal 2015-2017 project is accepting comments on its draft report through Tuesday, September 6 at 6:00 pm EST. This project seeks to identify and endorse performance measures for accountability and quality improvement that specifically address conditions, treatments, interventions, or procedures relating to kidney disease.
  - The Renal Standing Committee does not recommend:
    - NQF 0260: Assessment of Health-Related Quality of Life in Dialysis Patients (Witten and Associates, LLC)
    - NQF 0369: Dialysis Facility Risk-Adjusted Standardized Mortality Ratio (CMS)
  - The Renal Standing Committee recommends:
    - NQF 1463: Standardized Hospitalization Ratio for Admissions (CMS)
    - NQF 2977: Vascular Access—Standardized Fistula Rate (CMS)
    - NQF 2978: Vascular Access—Long-Term Catheter Rate (CMS)
    - NQF 2989: Standardized Transfusion Ratio for Dialysis Facilities (CMS)
  - The draft report, additional information on the measures, and the comment portal can be accessed at: http://www.qualityforum.org/Renal_2015-2017.aspx

- ***Health Resources and Service Administration Requests Comment on National Health Service Corps Loan Repayment Program.*** "HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden."
  - To view the full announcement, please see the following link: https://www.federalregister.gov/articles/2016/08/29/2016-20584/agency-information-collection-activities-proposed-collection-public-comment-request-the-national

- ***CMS Announces Accountable Care Organizations' Performance for 2015.*** Last week, "the Centers for Medicare and Medicaid Services (CMS) announced the 2015 performance year results for the Medicare Shared Savings Program and the Pioneer Accountable Care Organization Model that show physicians, hospitals, and health care providers participating in Accountable Care Organizations continue to make significant improvements in the quality of care for Medicare beneficiaries, while achieving cost savings. Collectively, Medicare Accountable Care Organizations have generated more than $1.29 billion in total Medicare savings since 2012. "The coordinated, physician-led care provided by Accountable Care Organizations resulted in better care for over 7.7 million Medicare beneficiaries while also reducing costs," said CMS Acting Administrator Andy Slavitt. "I congratulate these leaders and look forward to

significant growth in the program in the coming year." In 2015, Medicare Accountable Care Organizations had combined total program savings of $466 million, which includes all Accountable Care Organizations' experiences, for 392 Medicare Shared Savings Program participants and 12 Pioneer Accountable Care Organization Model participants. The results show that more Accountable Care Organizations shared savings in 2015 compared to 2014 and those with more experience tend to perform better over time."

- For more information, please see the following link: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-08-25.html

- ***Upcoming Special Open Door Forum: The IMPACT Act and Improving Care Coordination***. "The purpose of this Special Open Door Forum (SODF) is to provide information and solicit feedback pertaining to the *Improving Medicare Post-Acute Care Transformation Act of 2014* (IMPACT Act). This SODF will offer discussion on the goals of the IMPACT Act, the expected outcomes of the Act, and potential roles post-acute care providers can play in improving coordinated care. This SODF will serve as a platform to update providers, consumers, stakeholders, researchers, and advocates alike on the work around the IMPACT Act and to solicit input on the ways the IMPACT Act can help you improve care coordination."
  - The conference call will take place on Thursday, September 15, 2016 from 2:00 - 3:00 pm Eastern Time.
  - Visit the following link for more information: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html

Articles of Interest

- ***Dialysis in the United States: How Do We Compare With Other Countries?*** "A fantastic and fascinating study recently came out in the Lancet, which is publishing a series of articles about dialysis. The first author is Bruce Robinson (a former fellow here at the University of Pennsylvania), with coauthors from Japan, Australia, and The Netherlands. They studied practices and outcomes of hemodialysis around the world in more than 50 countries and regions. They compared and contrasted various outcomes, mortality rates, incidence and prevalence, and dialysis practices. Today I am going to focus on the practices around the world. In terms of treatment modalities for end-stage renal disease (ESRD), some of the findings were very interesting. For instance, about 30% of patients with ESRD in the United States are transplanted over the course of their lives, whereas in Norway and Iceland, it's more than 60%. In some Asian and Eastern European countries, it's less than 5%-10%. Wide differences in access to, availability of, or use of transplant are seen around the world. The reasons for this are not entirely clear. The authors suggested that in some of the countries with a very low incidence of ESRD, such as Norway and Iceland, it may be possible to get more of their ESRD patients transplanted. Of interest, preemptive transplant was used in only 1%-2% of patients in the United States compared with up to 40% in the United Kingdom, some Scandinavian

countries, and The Netherlands. It is a striking difference, and certainly an area for improvement here in the United States."

- For the full article, please see the following link: http://www.medscape.com/viewarticle/867412

- ***In Iran, Unique System Allows Payments for Kidney Donors.*** "Iran's kidney program stands apart from other organ donation systems around the world by openly allowing payments, typically of several thousand dollars. It has helped effectively eliminate the country's kidney transplant waiting list since 1999, the government says, in contrast to Western nations like the United States, where tens of thousands hope for an organ and thousands die waiting each year. Critics warn the system can prey on the poor in Iran's long-sanctioned economy, with ads promising cash for kidneys. The World Health Organization and other groups oppose "commercializing" organ transplants. Some argue such a paid system in the U.S. or elsewhere could put those who cannot afford to pay at a disadvantage in securing a kidney if they need one. But as black-market organ sales continue in countries like India, the Philippines and Pakistan and many die each year waiting for kidneys, some doctors and other experts have urged America and other nations to consider adopting aspects of Iran's system to save lives."
  - For the full article, please see the following link: http://bigstory.ap.org/article/bf5b96efde5b4ec89469ee8700312105/iran-unique-system-allows-payments-kidney-donors

- ***FDA: All Blood Donations Should Be Tested For Zika.*** "The Food and Drug Administration (FDA) is now recommending that all blood donations in the U.S. undergo testing for the Zika virus amid mounting concerns about how the disease is spread. The agency's sweeping recommendation Friday underscores concerns within the medical community about the still relatively unknown virus, which has spread rapidly by travel throughout the U.S. this summer. Zika-carrying mosquitoes have also arrived in parts of southern Florida this month. "There's tremendous uncertainty," Dr. Peter Marks, head of the FDA's Center for Biologics Evaluation and Research, said in a call with reporters. Several local blood banks, including in Tampa, Atlanta and Houston, have already implemented Zika screening procedures. Those screenings have already prevented one Zika-positive person from donating blood, the FDA confirmed for the first time Friday. Marks said that donor, whose blood tested positive before it could enter the national supply, was likely infected through travel. Earlier this month, a team of researchers that included members of the American Red Cross said they believed a person infected with the Zika virus had spread the mosquito-borne disease to two people who received blood transfusions. Blood banks in Florida and Puerto Rico will be required to "immediately" follow the new guidelines. Eleven other high-risk states, including Texas, New York and California, will have four weeks to comply. The rest of the country has 12 weeks."
  - For the full article, please see the following link: http://thehill.com/policy/healthcare/293440-fda-all-blood-donations-should-undergo-zika-testing

- ***As Zika Fear Spreads, FDA Gives Roche Test Emergency Authorization.*** "With concerns over a continued Zika outbreak growing, the Food and Drug Administration has given

Roche Holdings emergency approval to use one of its Zika blood testing kits. The approval, which lasts as long as the emergency is ongoing, will allow for testing of the virus through Roche's LightMix Zika rRT-PCR test, which has not been approved by the FDA yet. The test uses the company's LightCycler 480 Instrument II or cobas z 480 Analyzer to search for Zika. The systems, found in specialist laboratories, can help detect the virus which can be more easily be found in blood samples. The disease can also be found in urine. On its site Roche says the cobas z 480 can process 384 samples per day. The Roche emergency approval is the latest in the FDA's search to more quickly identify and contain the virus. The agency had previously approved nine other systems for detecting Zika since February under similar emergency use authorizations. It approved two systems that help detect the disease, one from InBios International and another from Luminex Corporation, earlier this month."

- For the full article, please see the following link: http://www.usatoday.com/story/money/2016/08/29/zika-fear-spreads-fda-gives-roche-emergency-authorization/89529704/