

American Nephrology Nurses Association

Weekly Capitol Hill Update - Monday, July 11th, 2016

Congressional Schedule

House

- “Convenes at 2 p.m. for consideration of 23 bills under suspension of the rules, including a measure (H.R. 636) that would reauthorize the Federal Aviation Administration (FAA) for 14 months. Also on tap is a bill on judicial deference in rule-making (H.R. 4768).” (CQ)
- **Week Ahead:** “On Tuesday the House will take up Interior-Environment appropriations measure (H.R. 5538). Later in the week the chamber will consider several measures related to Iran (H.R. 5631, H.R. 5119, and H.R. 4992).” (CQ)

Senate

- “Convenes at 4 p.m. and will resume consideration of the motion to proceed to the fiscal 2017 Defense spending bill (H.R. 5293). The next roll call votes are expected Tuesday.” (CQ)
- **Week Ahead:** “The Defense spending bill is up, but the chamber could also pivot to take action on the FAA bill or the final version of a bill (S. 524) to fight opioid addiction. The House OK'd the latter back on Friday.” (CQ)

Legislative Updates

- **House Stand-Alone MA Expansion Bill Introduced.** Representatives Jason Smith (R-MO), John Lewis (D-GA), Gus Bilirakis (R-FL), Kurt Schrader (D-OR), and Tom Marino (R-PA) introduced legislation (H.R. 5659) that would expand Medicare Advantage to cover individuals with end-stage renal disease (ESRD). The bill was referred to the House Ways and Means Committee and the House Energy and Commerce Committee.
- **Senators Urge CMS to Keep Six Protected Classes in Drug Benefit.** “Medicare should continue its policy of requiring prescription drug plans to include substantially all covered drugs in six categories, two members of the Senate Finance Committee told the CMS in a letter released July 5. Sens. Charles Grassley (R-IA) and Sherrod Brown (D-OH) said they objected to recommendations by a congressional advisory panel that

would permit removal of two classes from the six that are protected. The policy is intended to protect vulnerable beneficiaries, they said. 'Despite Part D's success and the effectiveness of the six protected classes policy, the Medicare Payment Advisory Commission (MedPAC) report released earlier this month included a recommendation to make changes to this popular policy,' Grassley and Brown wrote to acting CMS Administrator Andy Slavitt in a June 30 letter."

- To see the full article, please see the following link:
<http://www.bna.com/senators-urge-cms-n57982076684/>
- ***Week Ahead: Scramble on Zika; Opioid bill Poised for Passage.*** "The fate of Congress's opioids bill became a lot clearer Friday after House Democrats backed down in their fierce fight for more funding. The Senate is now all but certain to meet its self-imposed deadline to send the bill to President Obama's desk by next week, before lawmakers leave town for a seven-week recess."
 - ***Zika Update.*** "There's still a big question mark on the other health-related bill that Congress had pledged to pass before the summer break - the Zika funding bill. The White House and Capitol Hill Democrats are aggressively ramping up pressure on the GOP to advance a bipartisan Zika bill, rather than the one that Obama has threatened to veto. Obama this week has personally lobbied Senate Majority Leader Mitch McConnell (R-KY). But McConnell is still planning to vote on the same sharply House partisan bill that was already blocked by Democrats in the upper chamber. Democrats have insisted the Senate GOP should instead take up the \$1.1 billion emergency funding bill they ready approved - rather than the one that pays for new Zika funding out of ObamaCare funds and targets Planned Parenthood. McConnell's office argues they cannot make changes to the House-passed bill without starting from scratch because it's part of a conference report."
 - For the full article, please see the following link:
<http://thehill.com/policy/healthcare/287015-week-ahead-scramble-on-zika-opioid-bill-poised-for-passage>
- ***Congress Set to Pass Bill to Combat Opioid Abuse.*** "Congress this week is expected to send President Obama legislation to combat heroin and painkiller abuse, despite lingering disputes over whether there is enough funding to support new treatment and prevention programs. Senate Democrats have pushed for additional funding arguing that without it the bill will not be able to deliver on its promise to help thwart the opioid epidemic. But they do not plan to block the agreement that House and Senate negotiators finalized last week, according to a spokesman for Minority Leader Harry Reid (D-NV). It's unclear how many Democrats will support the bill, but it is expected to easily be approved just in time for the height of the election season. The House passed the legislation Friday on a 407 to 5 vote. All House Democrats voted for the bill despite decrying its lack of funding. The bill would create or modify existing education, prevention and treatment programs and put more life-saving anti-overdose drugs in the hands of first responders. Republicans and Democrats will continue wrangling over whether there should be additional funding later this year when final spending bills are debated. 'We can't do it on the cheap,' Reid said last week. 'And that's what they're trying to do.' Democrats are also expected to make what they see as a lack of funding for

the opioid crisis as well as the Zika virus and the water emergency in Flint, Mich., an issue on the campaign trail when lawmakers depart Washington at the end of the week for a seven week break.”

- For the full article, please see the following link: <http://wapo.st/29DiiDS>
- ***GOP Backs New Fund for Public Health.*** “With Congress remains deadlocked over funding to fight the Zika virus, senior GOP leaders are working to head off yet another big public health funding fight. House Majority Leader Kevin McCarthy (R-CA), Appropriations Chairman Hal Rogers (R-KY) and others for weeks behind the scenes have been working on legislation to create an emergency fund for public health crises. They call it “FEMA for public health,” a reference to the Federal Emergency Management Agency that helps communities hurt by disasters. The creation of the reserve fund was unveiled this week in a GOP health spending bill. It would contain \$300 million to tackle crises like Zika and Ebola, and would give the administration's top disease control official ‘immediate access’ to the money. Rogers said he’s talked at length over the idea with Tom Frieden, the head of the Centers for Disease Control and Prevention.”
 - For the full article, please see the following link:
<http://thehill.com/policy/healthcare/287047-gop-backs-new-fund-for-public-health>
- ***Aging Committee Holds Hearing on Person-Centered Care.*** “The Senate Special Committee on Aging held a hearing last week focusing on how to best promote person-centered care for those living with serious illnesses. The committee focused on how providers can make patients the most comfortable while still providing high quality care. Testifying at the hearing was Dr. Atul Gawande, best-selling author, executive director of the Ariadne Labs, and a professor at both Harvard School of Public Health and Harvard Medical School; Dr. Kate Lally, Chief of Palliative Care at Care New England Health System; and Amy Berman, Senior Program Officer at the John A. Hartford Foundation. Dr. Gawande emphasized the necessity of closing the gaps of coordination between care providers, especially for those with serious illness or receiving end-of-life care. He said that having more in depth conversations about these services and creating a system that allows for better coordination of services is critical for patients to receive the highest quality of care. Committee Chairwoman Susan Collins (R-ME) recalled a story of a close friend who received end-of-life care at a home-like setting and expressed concern that such opportunities are not available to most Americans due to lapses in the way Medicare incentives care. Committee member Senator Sheldon Whitehouse (D-RI) also brought up concerns with the way payment systems are created, noting that current structures do not do enough to promote quality care over volume. Sen. Whitehouse introduced a bill during the hearing to alleviate some of the problems he identified within the current Medicare payment system. The bill, titled: “Person- Centered Care Act,” aims to streamline regulations and allow providers to better coordinate care and find the right setting for patients with serious illness. The bill also seeks to alleviate the “three-day stay” rule, which requires patients to have spent three days in a hospital to qualify for Medicare coverage of skilled nursing care.”

- For the full article, please see the following link:
<http://www.longtermcareleader.com/2016/07/aging-committee-holds-hearing-on-person.html>

Regulatory Updates

- ***ESRD Measures Manual.*** “The Centers for Medicare and Medicaid Services (CMS) has released the first version of the ESRD Measures Manual. It will be updated periodically and comments can be provided via JIRA, a software program used by the Office of the National Coordination and that KCP has supported using in the past.
 - For more information, please see the following link:
https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/CMS-ESRD-Measures-Manual-Final-v1_0.pdf
- ***Proposed Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year (CY) 2017.*** “On July 7, 2016, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that updates payment policies, payment rates, and quality provisions for services furnished under the Medicare Physician Fee Schedule (PFS) on or after January 1, 2017. This year, CMS is proposing a number of new physician fee schedule policies that will improve Medicare payment for those services provided by primary care physicians for patients with multiple chronic conditions, mental and behavioral health issues, and cognitive impairment or mobility-related disabilities. CMS is proposing to expand the Diabetes Prevention Program model starting January 1, 2018. This is the second CMS Innovation Center – and first preventive services – model that has been certified for expansion. Expansion of this model will enhance access to these important services for Medicare beneficiaries who are at risk for developing diabetes.
 - Additionally, CMS is:
 - Proposing modifications to the Medicare Shared Savings Program to update the quality measures set and align with the proposals for the Quality Payment Program, changes to take beneficiary preferences for ACO assignment into consideration, and changes that would improve beneficiary protections when ACOs are approved to use the skilled nursing facility (SNF) 3-day waiver rule;
 - Requiring health care providers and suppliers to be screened and enrolled in Medicare in order to contract with Medicare Advantage health plans to provide Medicare-covered items and services to beneficiaries enrolled in Medicare Advantage;
 - Increasing transparency of Medicare Advantage pricing data and medical loss ratio (MLR) data from Medicare health and drug plans, and;
 - Continuing to implement Appropriate Use Criteria for advanced diagnostic imaging services, including proposals for priority clinical areas and clinical decision support mechanism (CDSM) requirements, among other proposals as detailed in this fact sheet.

- The CY 2017 PFS proposed rule is one of several proposed rules that reflect a broader Administration-wide strategy to create a health care system that results in better care, smarter spending, and healthier people.”
- For the article, please see the following link:
<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-07-2.html>
- **Renal Project 2015-2017.** “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. Measures of interest to the National Quality Forum (NQF) in this topic area include outcome measures; measures applicable to more than one setting; measures for adults and children; measures that capture broad populations; measures of chronic care management and care coordination, and eMeasures. Four (4) NQF-endorsed measures that are due for maintenance will be re-evaluated against the most recent NQF measure evaluation criteria. A multi-stakeholder Standing Committee will evaluate measures and make recommendations for endorsement. Members of this Standing Committee possess relevant knowledge and/or proficiency in process and outcome quality measurement and/or clinical expertise associated with renal conditions (e.g., CKD, ESRD, etc.) across various care settings for children and adults.”
 - For more information, please see the following link:
<http://www.qualityforum.org/ProjectDescription.aspx?projectID=80747>
- **Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements.** “On March 30, 2016, the U.S. Department of Health and Human Services (HHS) published a Notice of Proposed Rulemaking (NPRM) to increase the highest patient limit for qualified physicians to treat opioid use disorder under section 303(g)(2) of the Controlled Substances Act (CSA). On July 6, 2016, HHS published a final rule based on the NPRM but delayed finalizing the reporting requirements outlined in the NPRM. In this Supplemental Notice of Proposed Rulemaking (SNPRM), HHS seeks further comment on the same reporting requirements outlined in the NPRM. These reporting requirements would require annual reporting by practitioners who are approved to treat up to 275 patients under subpart F to help HHS ensure compliance with the requirements of the “Medication Assisted Treatment for Opioid Use Disorders” final rule published elsewhere in this issue of the Federal Register. HHS will consider the public comments on this SNPRM as well as any comments already received on the March 30, 2016 NPRM before issuing a final rule pertaining to the reporting requirements.”
 - **HHS Eases Buprenorphine Prescribing.** “The Obama administration announced a new rule that could lower the death toll from opioid overdoses, but the changes will be mostly meaningless without additional funding, officials said. HHS officially raised the limit on the number of individuals for whom prescribers can order medication assisted treatment (MAT), specifically buprenorphine, from 100 to 275. ‘In the absence of congressional action, we’re taking every step forward that we can,’ said HHS Secretary Sylvia Burwell, referring to the stalemate in Congress over appropriating adequate funding for opioids. Burwell announced

the final rule alongside other key leaders in the administration during a press call Tuesday afternoon. She also announced a Request for Information soliciting public comments about current HHS prescriber education and training programs and seeking new proposals; and spoke of plans to launch a dozen studies aimed at understanding opioid abuse and pain management. Burwell will be speaking with governors about the epidemic late next week, she said. More than 28,000 Americans died from opioid overdoses in 2014. The White House announced plans in February to spend \$1.1 billion to alleviate the opioid crisis, but Congress has yet to make the needed appropriations.”

- For the full article, please see the following link:
<http://www.medpagetoday.com/Psychiatry/Addictions/58923>
- For the proposed rule, please see the following link:
https://www.regulations.gov/document?D=HHS_FRDOC_0001-0635
- ***Drug Shortages. GAO Report: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge.*** “Drug shortages are a serious public health concern. The Government Accountability Office (GAO) previously found that many shortages were of sterile injectable drugs and could generally be traced to supply disruptions caused by manufacturers slowing or halting production to address quality issues... GAO found that, as part of the Food and Drug Administration’s (FDA) oversight of drug safety and quality, it generally issued an increasing number of warning letters to sterile injectable drug establishments during the time period GAO reviewed for noncompliance with manufacturing standards outlined in federal regulations. However, the percentage of inspections resulting in warning letters remained relatively small as the number of inspections also increased. Moreover, seven establishments that were linked to widespread shortages and received warning letters all had previous indications of difficulty complying with manufacturing standards.”
 - For the GAO fact sheet, please see the following link:
http://www.gao.gov/assets/680/678282.pdf?utm_medium=email&utm_source=govdelivery
- ***CMS is Proposing Medicare Help Pay for Hep B Screenings.*** “CMS is proposing covering hepatitis B virus screening for Medicare beneficiaries following a recommendation from the U.S. Preventive Services Task Force. A screening test would be covered for asymptomatic beneficiaries who are deemed at high risk for a hepatitis B infection. The agency defines this population as those born in countries and regions with a high prevalence of infection of the virus.”
 - For more information, please see the following link:
<https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=283>
- ***CMS Releases Proposed Payment Changes for Physician Fee Schedule (PFS).*** “On July 7, CMS released its annual proposed changes to the PFS. The proposal updates payment policies, payment rates and quality provisions for services provided in CY 2017. CMS indicates that physician payment rates will decrease less than 1 percent next year. The proposed rule contains several proposals intended to improve how Medicare pays for

services provided by primary care physicians and other practitioners for patients with multiple chronic conditions and mental and behavioral health issues, as well as cognitive impairment or mobility-related impairments. The proposed rule would also pay for new telehealth services, such as critical care consultations, ESRD-related services for dialysis and advanced care planning services. Starting in 2018, providers will be able to bill Medicare for diabetes prevention services. It also requires that providers who contract with Medicare Advantage be screened and enrolled in Medicare. CMS will accept comments on the proposed rule until September 6, 2016.”

- For the full article, please see the following link:
<http://www.lexology.com/library/detail.aspx?g=78e0dd6a-4601-41fc-89c8-10cfa51e5b97>

- ***CMS Proposes Hospital Outpatient Prospective Payment Changes for 2017.***

- **“Organ Transplant Enforcement**
 - The Medicare Conditions of Participation for Organ Transplant programs at 42 CFR sections 482.80 and 482.82 contain an outcome requirements standard for one-year patient and graft survival. A transplant program is out of compliance with this standard if all of the thresholds in the standard are crossed. One of the thresholds, the number of observed events divided by the number of expected events, is based on the program’s outcomes in relation to the risk-adjusted national average. Currently, that threshold, which was adopted in 2007, is 1.5. However, as national outcomes for organ transplants have improved over time, the margin for compliance and noncompliance has narrowed. So, we are proposing to restore the CMS tolerance limit for patient and graft survival closer to the level allowed under the original 2007 rule by changing this threshold to 1.85. If the threshold is changed, this would mean that transplant programs would not be out of compliance unless the number of observed events (one-year patient deaths or graft failures) divided by the number of expected events exceeds 1.85.
- **Changes to the Conditions for Coverage for Organ Procurement Organizations (OPOs)**
 - The Organ Procurement and Transplantation Network (OPTN) establishes the types and frequencies of the data to be submitted by the Organ Procurement Organizations (OPOs) to the Scientific Registry of Transplant Recipients (SRTR) through its policies. The OPTN/SRTR collect and analyze the data pursuant to the Health Resources Service Administration (HRSA) mission to increase organ donation and transplantation. Periodically, the OPTN revises its OPO data reporting policies based on methodologies and clinical practice improvements that enable them to draw more accurate conclusions about donor and organ suitability for transplantation. We are proposing to change the definition of “eligible death” and the aggregate donor yield metric in the OPO Conditions for Coverage (CfCs) to align the definitions, criteria and

outcome measures with those requirements set forth by the OPTN and SRTR. CMS does not want OPOs to have to submit two sets of numbers, some to the SRTR and some to CMS. We are also proposing to revise the OPO CfC that requires certain documentation to be transported to the transplant center together with an organ. Blood type and infectious disease information, which are two of the most important pieces of information, will continue to be required in written format and sent along with the organ. Other donor information is now available to the transplant center electronically. This reduction in the amount of hard copy documentation that must be sent with the organ would allow OPOs better use of their time during the donation process.

- Transplant Technical Correction and Other Proposed Revisions
 - We are also proposing several revisions to the special procedures for approval and re-approval of organ transplant centers. We are proposing to extend the time for organ transplant programs to notify CMS of their intent to request mitigating factors approval from 10 days to 14 calendar days; to clarify that the time period for submission of the mitigating factors information is calculated in calendar days; and to clarify CMS discretion regarding organ transplant Systems Improvement Agreements (SIAs).
- For the full article, please see the following link:
<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-06.html>
- ***Hospitals Incensed Over CMS Plans for Site Neutral Rates.*** “CMS released its proposed rule for the 2017 Hospital Outpatient Prospective Payment System, sending hospitals into a tizzy. The proposed rule endorses site-neutral payments for certain services, meaning off-campus facilities would be reimbursed the same amount as hospital-based outpatient departments. ‘The American Hospital Association quickly issued a harshly worded statement criticizing the CMS for declining to include support for hospital outpatient departments’ Modern Healthcare reported. The proposed rule would also delink scores on pain management questions from a widely used patient survey from the Hospital Value Based Purchasing program. ‘Although CMS is not aware of any scientific studies that support an association between scores on the pain management dimension questions and opioid prescribing practice,’ said a CMS press release, it proposed the change out of “an abundance of caution.””
- For the full article, please see the following link:
http://www.medpagetoday.com/Washington-Watch/Washington-Watch/58977?xid=nl_mpt_DHE_2016-07-11&eun=g939522d0r

Articles of Interest

- ***Former Lobbyist Launches Kidney Cancer Relief Effort.*** “Dena Battle, the onetime House staffer turned tax lobbyist, is taking on an entirely new role as co-founder and president of the fundraising-centric Kidney Cancer Research Alliance, or KCCure. The dramatic career change – Battle quit Capitol Counsel in order to focus on the fledgling nonprofit – is the latest step in the life-changing journey she set upon in 2009 when her husband, GOP communications aide Chris Battle, was diagnosed with metastatic kidney cancer. ‘We met on Capitol Hill,’ Battle said of the romance that blossomed while she was serving as legislative director for retired lawmaker and lymphoma survivor Dave Camp of Michigan and Chris was assisting former Rep. Asa Hutchinson of Arkansas with messaging. As they wrestled with Chris’ illness, a 4½-year ordeal the duo chronicled on a deeply personal blog, Dena said she became very involved in ‘navigating the patient community.’ After Chris’ passing in 2013, she turned her attention to advocacy, lending her voice to the advisory board for the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, and the Patient and Family Advisory Council, as well as staying in touch with Chris’ oncologist, Dr. Hans Hammers. Earlier this year, she and Hammers got to talking about the dearth of financial resources for cancer researchers. She said they both bemoaned the lack of a ‘competitive grant process,’ and subsequently resolved to remedy the puzzling situation.”
 - For the full article, please see the following link:
http://www.rollcall.com/news/former-lobbyist-launches-kidney-cancer-relief-effort?utm_name=newsletters&utm_source=rollcallnewsalerts&utm_medium=email#sthash.AVToHML1.dpuf

- ***Apple Pushes Organ Donor Registration for US iPhone Users.*** “Apple will give US users the ability to sign up as organ donors on their iPhones as part of its upcoming iOS 10 update. The chief executive, Tim Cook, says he hopes the easy sign-up button in the Health app will help ease a longstanding donor shortage in the US. He said that the problem hit home when Apple co-founder Steve Jobs endured an ‘excruciating’ wait for a liver transplant in 2009. Jobs died of pancreatic cancer in October 2011, aged 56. Apple is adding the option to enroll in the US national donor registry by tapping a button within the iPhone’s Health app, which can be used to manage a variety of health and fitness data. The software will come to all US-based iPhones when the company updates its mobile operating system this autumn. The move follows action by the US government to attempt to reduce long waiting lists for organ transplants, in which someone is added to the list every 10 minutes and 22 people die while waiting for life-saving transplants every day. One initiative will see greater automation in the donor and matching service, and increased connectivity with transplant centers, which it is hoped will speed up the matching process to get donor organs to more patients in less time. Almost \$200m has also been allocated for research into next-generation manufacturing techniques for tissue creation and repair, which could result in organ replacement.”
 - For the full article, please see the following link:
<https://www.theguardian.com/technology/2016/jul/05/apple-organ-donor-registration-us-iphone-users-tim-cook-steve-jobs-health-app>

- New Kidneys 40 Years Apart Show Transplant Progress, Hurdles.*** “Brenda Hudson recalls weeks spent in a glass-enclosed isolation room after her first kidney transplant, her family allowed to visit only when suited up against germs. That transplant lasted a remarkable four decades – and now Hudson's recovery from a second one, this time faster and surrounded by germ-y visitors, showcases how far organ transplants have come and the hurdles that still await. ‘I'm ready to be well again,’ Hudson exclaimed before being wheeled into an operating room at MedStar Georgetown University Hospital last month, far more confident than back at age 17 when she was that hospital's first recipient of a living-donor kidney. Transplants still require courage, but medical advances haven't just helped patients. Hudson's initial donor, her older sister, has a scar stretching from belly to side where doctors cut into her rib cage. This time Hudson's husband donated, and went home two days after surgeons squeezed his kidney through a roughly 3-inch incision. Hudson's own lupus-damaged kidneys were removed about a month before her first transplant. That's hardly ever done anymore – nonworking kidneys shrink to make room. Back then, finding a donor was pretty miraculous. It still is. And with more than 120,000 people on the national waiting list for a kidney or other donated organ – but only about 30,000 transplants performed each year – new moves are getting underway to try to ease the critical shortage. Efforts range from smartphone apps letting would-be donors register with a few clicks, to helping transplant centers use some organs that today would be discarded for fear they're not good enough.”

 - For the full article, please see the following link: <http://nyti.ms/29IblSp>
- Cancer Moonshot: How to Get There Faster.*** “The professional health community is on a mission to cure cancer. Too many people are dying when we have in our collective grasp all the pieces to slow -- and even reverse -- this onerous trend. Spurred by Vice President Biden’s Cancer Moonshot, for the next five years, there will be renewed urgency to develop new cancer treatments and therapies. To advance this research more quickly, the Cancer Moonshot initiative should be tightly aligned with President Obama’s Precision Medicine Initiative (PMI). Precision medicine is revolutionizing cancer treatment by decoding patient DNA, finding nuanced differences at the molecular level in patients’ conditions, and translating those molecular differences into to personalized care for individual patients. For instance, with precision medicine treatments, survival rates for colorectal cancer patients have increased by 15 percent. We made it to the moon with a singular belief that the mission was important and an understanding that all necessary resources would be made available to realize that mission. We can – and must – do the same for the Cancer Moonshot. The government is ideally positioned to bring together all the health, technology, and regulatory forces necessary to make this happen, and we need to capitalize on this.”

 - For the full article, please see the following link: <http://thehill.com/blogs/pundits-blog/healthcare/287173-cancer-moonshot-how-to-get-there-faster>
- Advocates Hope Shaming Drugmakers Discourages Price Spikes.*** “Frustrated by the rising cost of prescription drugs, California health advocates hope sunlight and a dose of shame will discourage drugmakers from raising their prices too quickly or introducing new medications at prices that break the bank. They're promoting legislation that would require drugmakers to provide advance notice before making big price increases.

Pharmaceutical companies have come out in force against the measure, warning it would lead to dangerous drug shortages. Attention to prescription drug pricing has mounted since Turing Pharmaceuticals bought an old drug commonly used with HIV patients and raised the price from \$13.50 per pill to \$750. The company's combative chief executive, Martin Shkreli, was widely castigated for the price hike. 'Yes, they should make a profit, but not so much they gouge the public at the expense of the consumer and the taxpayer,' State Sen. Ed Hernandez, a Democrat from Azusa who wrote the legislation, said of drug companies. 'There needs to be a balance.' Vermont passed the nation's first drug price transparency legislation earlier this year, and similar measures were introduced in at least five other states, including California. California voters also will decide in November on a ballot measure that would prohibit the state – which covers millions of poor people, inmates and government retirees – from paying more than the U.S. Veterans Administration (VA) for drugs. The VA's massive negotiating power allows it to secure some of the lowest rates for drugs."

- For the full article, please see the following link: <http://nyti.ms/29yUalk>
- ***1st Death Related to Zika Virus Seen in Continental US.*** "A person infected with Zika has died in Utah, and while the exact cause is unclear, authorities said Friday it marks the first death related to the virus in the continental U.S. The unidentified Salt Lake County resident contracted the virus while traveling abroad to an area with a Zika outbreak, health officials said. The patient who died in late June was elderly and also suffered from another health condition, according to the Salt Lake County Health Department. The person had Zika symptoms – including rash, fever and conjunctivitis – but it's unclear if or how the virus contributed to the death, said Centers for Disease Control and Prevention spokesman Benjamin Haynes. Officials discovered the case while reviewing death certificates, and lab tests confirmed their suspicions, said Gary Edwards, executive director of the Salt Lake County Health Department. Utah authorities refused to release additional information about the patient or where he or she traveled, citing health privacy laws. The virus causes only a mild illness in most people. But during recent outbreaks in Latin America, scientists discovered that infection during pregnancy has led to severe brain-related birth defects."
 - For the full article, please see the following link: <http://nyti.ms/29y31Xe>
- ***Aetna Meets With Justice Department Over Merger With Humana.*** "Aetna Inc executives met with top Justice Department antitrust officials on Friday to convince the government that asset sales it proposed would address potential competitive problems that could threaten its deal to buy rival Humana Inc., according to a source familiar with the matter. Aetna's plan to buy Humana would combine two of the largest providers of Medicare Advantage plans for elderly people, and investors are concerned that antitrust regulators could oppose the deal. The Justice Department's Antitrust Division is assessing both Aetna's \$34 billion merger as well as Anthem's \$44 billion deal to buy rival Cigna. The two mergers, if they close, would reduce the number of big, national health insurance companies from five to three. In the meeting on Friday, Aetna argued that asset sales it was proposing would fix any potential competition problems that the deal creates, the source said, adding that major players were interested in acquiring them. The source did not specify which assets were on the chopping block. Reuters reported last week that Aetna had begun the process of auctioning off about \$1 billion of

Medicare Advantage assets to address antitrust concerns. Before the meeting, the Justice Department had significant concerns about the deal, Reuters reported on Thursday. It was not known if antitrust enforcers planned to file a complaint to stop the deal or would accept the divestiture package and allow the deal to go forward. In the review, antitrust regulators are focused on whether the deal would limit consumer choices for Medicare Advantage health plans for the elderly, a separate source familiar with the matter said. Aetna has argued that Medicare Advantage competes not just with other Medicare Advantage plans but with traditional Medicare, which is managed by the government with data showing consumers switch between them. The Justice Department has previously disagreed with that approach, according to antitrust experts. Consumers Union, Consumer Federation of America, Consumer Action, Families USA, U.S. PIRG, and Consumer Watchdog issued a white paper on Thursday which argued that divestitures could not counter the harm done by the two massive mergers, at least partially because it would be contracts rather than solid assets that are divested.”

- For the full article, please see the following link: <http://nyti.ms/29yV0OS>
- ***RPA Response to KECC Request for Information on ESRD Patient Reported Outcomes and Patient Centric Measures.*** On June 30th, the Renal Physicians Association (RPA) wrote to Dr. Joseph Messina, Director of the University of Michigan Kidney Epidemiology and Cost Center, to respond to questions on the Information Request on End-Stage Renal Disease (ESRD) Patient Reported Outcomes and Patient Centric Measures posed by KECC. The letter addressed ESRD patient reported outcomes and patient centered outcome measures, and data that might be available to support future development and testing of these measures.
 - To see the letter, please see the following link: <http://www.renalmd.org/legis.aspx?id=5733>
- ***Kidney Care Partners Encouraged by House and Senate Interest in Care Coordination for Patients with Kidney Failure.*** “As Congress continues to work with the kidney community to refine coordinated care models for patients with kidney failure – or end-stage renal disease (ESRD) – Kidney Care Partners (KCP) underscored its belief that improved care coordination will lead to improved patient outcomes. ‘We believe it is important for policymakers to examine novel models of care coordination for kidney patients because a majority of patients are living with multiple chronic conditions and medical challenges.’ said Dr. Franklin Maddux, KCP chair. ‘We also believe that dialysis facilities, nephrologists, and other providers can and should partner to coordinate Medicare benefits for ESRD patients with the goal of truly quarterbacking patient care. Data indicates that for patients diagnosed with kidney failure integrated care has resulted in fewer hospital days and disease-related complications, which therefore reduces costs,’ said Dr. Maddux. To that end, KCP expressed appreciation to lead sponsors and staff for their willingness to engage with the kidney care community as they drafted the legislation, specifically, Sens. Bill Nelson and Dean Heller and Reps. Todd Young and Earl Blumenauer, the lead sponsors of the Patient Access To Integrated-Care, Empowerment, Nephrologists and Treatment Demonstration Act of 2016, H.R. 5506 and S. 3090 respectively.”

- For the full press release, please see the following link:
<http://kidneycarepartners.com/press/kidney-care-partners-encouraged-by-house-and-senate-interest-in-care-coordination-for-patients-with-kidney-failure/>
- **KCP Applauds Legislation to Expand Medicare Coverage Options for Dialysis Patients.**
 “KCP, the nation’s leading coalition of patient advocates, dialysis professionals, care providers and manufacturers working together to improve quality of care for individuals with kidney disease, today applauded the introduction of legislation that would expand Medicare coverage options for dialysis patients. Under the ESRD Choice Act of 2016 (H.R. 5659), introduced by Representatives Jason Smith (R-MO), John Lewis (D-GA), Gus Bilirakis (R-FL) and Kurt Schrader (D-OR), individuals who develop kidney failure would be given the same freedom of choice offered to other Medicare beneficiaries by allowing end-stage renal disease (ESRD) patients access to Medicare Advantage (MA) plans. ‘We commend Congressmen Lewis, Smith, Bilirakis, and Schrader for introducing this pro-patient legislation to ensure kidney failure patients have equal access options to coordinated care services that support quality outcomes, improved efficiencies and a positive patient experience. We look forward to working with these lawmakers to build support for this legislation,’ said Dr. Franklin Maddux, KCP Chair. Current law prohibits individuals who develop ESRD from enrolling in MA. This is true despite recommendations from the Medicare Payment Advisory Commission (MedPAC) since 2000, which has urged Congress to eliminate this prohibition.”
 - To see the full press release, please see the following link:
<http://kidneycarepartners.com/press/kcp-applauds-legislation-to-expand-medicare-coverage-options-for-dialysis-patients/>

Hearings

Tuesday, July 12th

- House Energy and Commerce Subcommittee on Health. *Strengthening our National Trauma System*
 - Time: 10:00 am
 - 2322 Rayburn
- House Ways and Means Committee. *Hearing on Rising Health Insurance Premiums Under the Affordable Care Act*
 - Time: 10:00 am
 - 1100 Longworth

Wednesday, July 13th

- House Appropriations Committee. *FY 2017 Labor, Health and Human Services, and Education Bill*
 - Time: 10:00 am EST
 - Location: 2359 Rayburn
- House Energy and Commerce Subcommittee on Commerce, Manufacture, and Trade. *Disrupter Series: Health Care Apps*
 - Time: 10:15 am

- Location: 2322 Rayburn
- Senate Finance Committee. *Medicare Access and CHIP Reauthorization Act of 2015: Ensuring Successful Implementation of Physician Payment Reforms*
 - Time: 10:00 am
 - Location: 215 Dirksen
- Senate Homeland Security & Governmental Affairs Subcommittee on Investigations. *Combatting the Opioid Epidemic: A Review of Anti-Abuse Efforts by Federal Authorities and Private Insurers*
 - Time: 20:00 pm
 - Location: 342 Dirksen
- House Oversight and Government Reform Subcommittee on Health Care, Benefits, and Administrative Rules. *From Premium Increases to Failing Co-ops: An Obamacare Checkup*
 - Time: 1:00 pm
 - Location: 2154 Rayburn

Thursday, July 14th

- Senate Health, Education, Labor & Pensions Committee. *ESSA Implementation: Perspectives from Stakeholders on Proposed Regulations*
 - Time: 10:00 am
 - Location: 430 Dirksen

Events

Monday, July 11th – Tuesday, July 12th

- The National Academies of Sciences, Engineering, and Medicine will host a workshop on the Institute of Medicine Report, “Strategies to Improve Cardiac Arrest Survival: A Time to Act.”
 - For more information, please see the following link:
<http://www.nationalacademies.org/hmd/~media/Files/Activity%20Files/PublicHealth/TreatmentofCardiacArrest/JULY%202016%20Workshop/agenda.pdf>

Wednesday, July 13th

- “FDA’s Arthritis Advisory Committee will discuss biologics license application 761042, for GP2015, a proposed biosimilar to Amgen Inc.’s ENBREL (etanercept) submitted by Sandoz, Inc. The proposed indications (uses) for this product are: (1) Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (in combination with methotrexate (MTX) or used alone); (2) reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older; (3) reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (in combination with MTX in patients who do not respond adequately to MTX alone); (4) reducing signs and symptoms in patients with active ankylosing spondylitis; and (5) treatment of adult

patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.”

- 7:30 am - 5:00 pm
- FDA White Oak Campus
10903 New Hampshire Avenue
Building 31 Conference Center
The Great Room (Rm. 1503)
Silver Spring, Maryland 20993
- For more information, please see the following link:
<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm506330.htm>