Congressional Schedule

House
- “Convenes at noon for consideration of four measures under suspension of the rules and to begin consideration of a major water projects bill (H.R. 5303).” (CQ)
- “Week Ahead: Later in the week, the chamber will take up bills on executive branch rules (H.R. 3438), Iran (H.R. 5461, H.R. 5931) and employee stockholder taxes (H.R. 5719), along with 14 more suspensions.” (CQ)

Senate
- “Convenes at 10 a.m. and, after leader remarks, will resume consideration of the expected legislative vehicle for a continuing resolution (H.R. 5325). The Senate will recess for weekly caucus lunches from 12:30 to 2:15 p.m. A cloture vote on a Republican-written substitute amendment is slated for 2:15 p.m., although it is not expected to get the 60 votes needed to move forward” (CQ)

Legislative Updates

- **Houses Passes Two Bipartisan Public Health Bills Considered Under Suspension**
  - H.R. 1877 - Mental Health First Aid Act of 2016, as amended (Sponsored by Rep. Lynn Jenkins (R-KS-2) / Energy and Commerce Committee)

- **Week Ahead: Spending Fight Shifts from Zika to Flint.** “There's a new public health crisis at the center of a government funding fight this week: Flint. Democrats in both chambers are threatening to reject the GOP's latest budget proposal because it ignores the city's lead contamination but provides relief for flood victims in Louisiana. Republican leaders will have five days to avert a shutdown when they return to Capitol Hill next week. The drama kicks off again Tuesday, when the Senate votes on a 160-page bill to fund the government through Dec. 9. Minority Leader Harry Reid (D-NV) has vowed to oppose that vote because it excludes Flint aid. The short-term government funding bill, which was formally unveiled Thursday, gives $500 million to help people in Louisiana whose homes were flooded in August storms. Democrats, led by Reid and
Appropriations Committee Ranking Member Barbara Mikulski (D-MD), have called the bill a nonstarter without new funding to help people in Flint, most of whom still can't drink water from their homes.”

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

- **Burgess, Kind Introduce Legislation to Protect Kidney Transplant Recipients.**
  “Congressmen Michael C. Burgess, M.D. (R-TX) and Ron Kind (D-WI) introduced the Immunosuppressive Drug Coverage for Kidney Transplant Patients Act. This legislation would allow individuals who are eligible for immunosuppressive drugs under Medicare Part B to continue to receive their vital treatment past the current 36 month cutoff. Without these drugs, transplant recipients are at risk to lose their transplanted kidneys – which too often occurs. “After the stress of undergoing an organ transplant and enduring the length of recovery, patients should not have to worry that a mandate from the federal government would prevent them from receiving treatment for as long as may be required,” said Burgess. “Patients should not have to sacrifice quality care due to the federal policy that denies coverage for anti-rejection drugs after 36 months. I am pleased to join Representative Kind in reintroducing this commonsense, bipartisan policy that will safeguard both patients and taxpayer dollars by preventing more costly alternatives such as organ rejection or return to dialysis.” “Our organ transplant patients and their families should not be concerned about an arbitrary federal policy denying them access to medications that help them keep their transplanted kidney,” said Kind. “The legislation Rep. Burgess and I have introduced will provide kidney transplant patients continued access to medication to ensure the success of their transplant, while keeping health care costs down by decreasing the need for further dialysis and the likelihood of a re-transplant.”

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

    “The National Kidney Foundation (NKF) would like to express its support for the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2016 recently introduced in the U.S. House of Representatives by Representative Michael C. Burgess, M.D. (R-TX) and Representative Ron Kind (D-WI). Extending Medicare coverage of immunosuppressive drugs for kidney transplant recipients is a critical step to ensuring a patient’s best chance of success post-transplant. Helping transplant recipients obtain the daily medications necessary to reduce the likelihood of organ rejection is not only what’s best for the patient long-term, it’s what best for Medicare long-term. Kidney transplantation significantly reduces Medicare expenditures compared to the costs associated with caring for a patient on dialysis.”

    - For NKF’s full statement, please see the following link:
• **Renal Physician Association (RPA) Letter in Support of Draft Immunosuppressive Drug Coverage Legislation.** “RPA appreciates your leadership efforts to enhance the care provided to the nation’s kidney disease population, and your perseverance specifically regarding immunosuppressive drug coverage for Medicare beneficiaries with kidney transplants. We believe that legislation in this area will be of tremendous benefit not only to Medicare beneficiaries with kidney transplants but also to the Medicare program at large by helping ensure the long-term viability of kidney transplants and reducing the necessity of costly dialysis treatments.”
  
  - For RPA’s full letter, please see the following link:

• **Kidney Care Community Celebrates Passage of the House of Representatives' ESRD Choice Act by Unanimous Vote.** “Kidney Care Partners – the nation's leading coalition of patient advocates, kidney disease professionals, dialysis care providers, and manufacturers – today applauded the U.S. House for passing legislation that would offer kidney disease patients enrolled in Medicare increased healthcare coverage options. The End-Stage Renal Disease (ESRD) Choice Act of 2016 (H.R. 5659), introduced by Representatives Jason Smith (R-MO), John Lewis (D-GA), Gus Bilirakis (R-FL), Kurt Schrader (D-OR), and Tom Marino (R-PA), would allow individuals who develop kidney failure – or end stage renal disease (ESRD) – the freedom to participate in Medicare Advantage (MA) plans just like all other Medicare beneficiaries. Currently, individuals who are diagnosed with ESRD are prohibited from enrolling in an MA plan and must stick with traditional Medicare, even if an MA plan would be better suited to the patient's needs. MA plans are especially beneficial to ESRD patients given that patients with kidney failure often suffer from multiple disease conditions, take multiple medicines, and benefit from more robust health care offerings, which are prevalent among MA plans. Since 2000, the Medicare Payment Advisory Commission (MedPAC) has recommended that Congress do away with this provision and extend the same level of Medicare choice to ESRD patients. KCP has supported this bill since its introduction in July and has previously championed similar legislation (H.R. 1130) spearheaded by Representatives Lewis and Marino, which would have eliminated the prohibitive policies that restrict MA plan access and discriminate against ESRD patients.”
  
  - For the full article, please see the following link:

• **Blue Cross of Nebraska Dropping out of ObamaCare market.** “Blue Cross Blue Shield of Nebraska announced Friday that is pulling out of the ObamaCare marketplace in the state, becoming the latest insurer to cite financial losses when reducing participation in the healthcare law. The move is especially significant given that it is a Blue Cross plan, which form the backbone of the ObamaCare marketplaces. In a few states, the Blue Cross plan will be the only one available on the marketplace next year. Nebraska, though, will still have two insurers, Aetna and Medica, on its marketplace next year. Like other insurers that have announced pullbacks, Blue Cross of Nebraska cited heavy financial losses. “Serious issues with the health care law have made the public
Marketplace unstable, which is driving increased costs and decreased competition and consumer choice,” Blue Cross of Nebraska said in a statement. “In fact, since we began selling our individual plans on the [Affordable Care Act's] public Marketplace, we have lost approximately $140 million,” the insurer continued. “We have a responsibility to all our members to remain stable and secure, and that responsibility will be at risk if we continue to sustain losses due to our participation in the ACA Marketplace.” The company will continue to offer some individual market plans outside of the health law’s marketplaces, but importantly, enrollees are not eligible for the law’s financial assistance on plans sold outside of the marketplace.

To read the full article, please see the following link:

Regulatory Updates

• **Upcoming Webinar: 2016 Dialysis Facility Compare – Understanding Measures, Star Ratings, and Quality Outcomes.** “The Centers for Medicare and Medicaid Services (CMS) has updated Dialysis Facility Compare and the methodologies used to calculate the Dialysis Facility Compare star ratings. During this webinar, CMS will focus on the recent changes to the Dialysis Facility Compare website based on public feedback and consumer testing. CMS will also discuss measure and specification changes, elaborate on the measure implementation process, and provide answers to clarifying questions.”
  o To register for the webinar, please see the following link:
    https://attendee.gotowebinar.com/register/8869939898976962564

• **Comment Request on In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (CAHPS).** “CMS is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public… Data collected in the national implementation of the In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey will be used to: (1) Provide a source of information from which selected measures can be publicly reported to beneficiaries as a decision aid for dialysis facility selection, (2) aid facilities with their internal quality improvement efforts and external benchmarking with other facilities, (3) provide CMS with information for monitoring and public reporting purposes, and (4) support the end-stage renal disease value-based purchasing program.”
  o For more information, please see the following link:

• **Federal Lawmakers Seek Pre-Claim Data Before Speaking Up.** “In light of the decision by CMS to delay the implementation of the Pre-Claim Review Demonstration in Florida, Texas, Massachusetts and Michigan, home health providers in Illinois say they are reeling as the program is still underway there. Agencies have spoken out about high denial rates on their claims submissions, inconsistency in the pre-claim process and significant administrative burdens in their attempts to comply with the regulations. The desperation has left many wondering how lawmakers are responding to the situation. Home health agencies recently voiced their complaints over a lack of action from
lawmakers representing Illinois in Washington, D.C.—especially in light of the fact that the two U.S. Senators from Florida, Ben Nelson (D) and Marco Rubio (R), sent a letter to CMS speaking out against pre-claim prior to the delay being granted. “Since the decision by CMS to delay it for all other states but Illinois, there has been some response [from lawmakers] this week, but nothing coordinated yet in Illinois,” Micah Roderick, director of public policy at the Illinois Homecare & Hospice Council (IHHC), told Home Health Care News. “We are hoping and waiting at this point.” The IHHC is working with other national industry groups, including the National Association for Home Care & Hospice (NAHC), to lobby for the pre-claim demonstration to be dismantled.”

To read the full article, please see the following link:

• **FDA Approves Humira Biosimilar - Amjevita OK'd for Same Indications as Adalimumab.** “A biosimilar version of the blockbuster rheumatology drug adalimumab (Humira) was approved Friday, the Food and Drug Administration (FDA) announced. The product, made by Amgen, will be sold as Amjevita and was approved for most of the same indications for adults as adalimumab. These include: Moderately to severely active rheumatoid arthritis; active psoriatic arthritis; active ankylosing spondylitis (an arthritis that affects the spine); moderately to severely active Crohn's disease; moderately to severely active ulcerative colitis; moderate to severe plaque psoriasis. It can also be used to treat moderately to severely active polyarticular juvenile idiopathic arthritis in children age 4 and older, the FDA said. The agency emphasized that the drug was not approved to be interchanged freely with adalimumab; to be designated as "interchangeable" would require that, in addition to meeting the agency's biosimilarity standard, the product would be "expected to produce the same clinical result as the reference product in any given patient," according to the FDA. It's the fourth biosimilar drug to win FDA approval. Others include copies of etanercept, filgrastim, and infliximab.”

For the full article, please see the following link:
http://www.medpagetoday.com/rheumatology/arthritis/60455?xid=nl_mpt_DHE_2016-09-26&eun=g1062526d0r&pos=6

• **CMS Increase in Mandated Nursing Facility CMPs.** “The Centers for Medicare & Medicaid Services (CMS) recently published a letter to State Survey Agency Directors describing revisions to Chapter 7 of the State Operations Manual (SOM) to reflect mandatory disciplinary requirements for skilled nursing facilities, nursing facilities and dually participating facilities. Effective September 1, 2016, CMS regional offices (ROs) are required to impose civil monetary penalties (CMPs) in the following circumstances:

- A finding of immediate jeopardy (J, K or L level deficiencies)
- A finding of deficiencies of substandard quality of care that are not immediate jeopardy
- A finding of a G level deficiency in Resident Behavior and Facility Practices, Quality of Life, or Quality of Care
- A finding of actual harm or above (G level deficiencies and above) on the current survey in addition to having findings of actual harm on the immediately preceding survey
A finding of an F level deficiency or higher at a facility classified as a Special Focus Facility
  • To read the full article, please see the following link:
    http://www.mondaq.com/article.asp?articleid=528564&email_access=on

**Medicare Advantage Premiums Remain Stable in 2017; Beneficiaries Have Saved over $23.5 Billion on Prescription Drugs.** “CMS announced that 2017 Medicare Advantage premiums will remain stable and more enrollees will have access to higher quality plans while, for the seventh straight year, enrollment is projected to increase to a new all-time high. In addition, CMS released today updated information that shows that millions of seniors and people with disabilities with Medicare continue to enjoy prescription drug discounts and affordable benefits as a result of the Affordable Care Act. Today’s announcement comes as CMS releases the premiums and costs for Medicare health and drug plans for the 2017 calendar year. CMS estimates that the average Medicare Advantage monthly premium will decrease by $1.19 (about 4 percent) in 2017, from $32.59 on average in 2016 to $31.40. This would be 13 percent lower than the average Medicare Advantage premium prior to passage of the Affordable Care Act. The majority of Medicare Advantage enrollees (67 percent) will experience no premium increase.”
  • To read the full press release, please see the following link:

**Resources, Regulations Holding Back Care Coordination.** “Care coordination is on the tips of tongues of care professionals these days, and home health agencies have a lot to gain within new payment models and care trends. From population health efforts to value-based purchasing, incentives pushing health care providers to collaborate across different settings is adding to the importance of home health and opening new channels for growth and revenue. Surprisingly, the majority of home health agencies have stated that care coordination is a top priority, but not too many are actually allocating resources to facilitate this goal, according to a recent survey on care coordination, conducted by Digital Collaboration Solutions (DCS), which surveyed health care professionals that included home health care providers. “It’s a universal understanding that improving the patient experience is the net focus of care coordination—did it work? Are you healthier? Did you have a better experience?” Tim Perkins, a partner at Digital Collaboration Solutions, which conducted the survey.”
  • For the full article, please see the following link:

**American Kidney Fund Urges CMS to Protect Low-Income Disabled ESRD Patients From Insurers' Discriminatory Efforts to Shift Them to Taxpayer-Funded Health Care.** “In its response to the Centers for Medicare & Medicaid Services' (CMS) August 18 Request for Information regarding "inappropriate steering of people eligible for Medicare and Medicaid into Marketplace plans," the American Kidney Fund (AKF)—the nation's leading nonprofit working on behalf of 31 million Americans with kidney disease—outlined its current and forthcoming safeguards to prevent steering by health
care providers and called on CMS to prevent insurer practices that inappropriately steer privately insured patients onto taxpayer-funded health care. At the same time, AKF voiced strong support for patient education to ensure that patients can make informed choices about the health plan that best meets their needs. The American Kidney Fund has been the safety net for U.S. dialysis patients since its founding in 1971, helping them access and pay for lifesaving dialysis and comprehensive health care. One of its programs—the Health Insurance Premium Program (HIPP), established under an Advisory Opinion from the U.S. Department of Health and Human Services in 1997—provides grants to pay health insurance premiums for low-income dialysis patients who could otherwise not afford their insurance. Noting that it fully supports CMS efforts to ensure that patients' coverage choices are in no way being manipulated, AKF's comment letter points out that insurers around the country have targeted patients with ESRD to steer them off the Marketplace plans under which they are insured. AKF's comments note that some insurers are sending letters to policyholders requiring them to sign declarations, under penalty of perjury, that they are not receiving charitable assistance to help them pay their premiums, and advising that the carrier cannot accept their payment if they have received such help.”

For the full article, please see the following link:

- **New Social Security Administration Fact Sheet on ESRD.** The SSA has added a new fact sheet about ESRD on its website. It provides guidance to individuals with ESRD about health insurance option.

**Articles of Interest**

- **Liberal Dialysis Use in the U.S. Elderly with Advanced CKD.** “Patients with very advanced chronic kidney disease (CKD) in the U.S. are much more likely to receive dialysis compared with those in other developed countries, researchers said. Moreover, this liberal use was especially marked in older patients with a high burden of comorbidity, according to the report appearing in the Clinical Journal of the American Society of Nephrology. The retrospective study found that 85.5% of the cohort of more than 28,000 patients in the Department of Veterans Affairs system with kidney failure had received or were slated to receive renal replacement therapy (RRT). This included more than 50% of patients 85 years of age or older, regardless of his or her burden of comorbidity. These data contrast with rates of RRT in Canada, New Zealand, and Australia, reported to be around 50% in patients with kidney failure, and just 5-7% among those 85 years of age and over, the investigators noted.”
  - For the full article, please see the following link:
    [http://www.medpagetoday.com/Nephrology/ESRD/60434?xid=nl_mpt_DHE_2016-09-24&eun=g939522d0r&pos=1](http://www.medpagetoday.com/Nephrology/ESRD/60434?xid=nl_mpt_DHE_2016-09-24&eun=g939522d0r&pos=1)

- **States Where Seniors Use Home Health the Most.** “Seniors in New England are using home health care services at a higher rate than seniors in other U.S. states, while seniors
in non-continental U.S. states are using home health at the lowest rates, according to data published last Thursday by the Centers for Disease Control and Prevention (CDC). The data was published as a supplement to the “Long-Term Care Providers and Services Users in the United States: Data From the National Study of Long-Term Care Providers, 2013–2014” report, which was released in February 2016. Massachusetts has the highest rate of seniors 65 years old and older utilizing home health care, with 133.85 out of 1,000 seniors whose episode of home health care ended anytime in 2013. Rhode Island posted the next highest home health care utilization rate, with 125.91 out of 1,000 seniors 65 and older receiving home health care services.”

For the full article, please see the following link:

**UPMC Launches Telemedicine Startup for Nursing Home Patients.** “Pittsburgh-based UPMC health system this week announced the launch of a telemedicine software company that will help patients reach doctors during off hours. The move is aimed at reducing avoidable hospital admissions among nursing home patients. The wholly owned UPMC subsidiary, Curavi Health, will provide nursing homes with telemedicine software and equipment so nurses and patients can consult University of Pittsburgh Physicians’ geriatricians on evenings and weekends, according to a UPMC statement released Thursday.”

For the full article, please see the following link:

**Medical Record Mix-Ups a Common Problem, Study Finds.** “A patient in cardiac arrest was mistakenly not resuscitated because clinicians confused him with a patient who had a do-not-resuscitate order on file. Another patient was given an okay to undergo surgery based on a different patient’s records and was found dead in his hospital room the next day. Such patient-identification mix-ups are common and can have deadly consequences, according to a report from the ECRI Institute, a nonprofit research group that studies patient safety. The report analyzed 7,613 cases of so-called wrong-patient errors at 181 health-care organizations from January 2013 to July 2015. The cases were submitted voluntarily, under a federal law that lets providers share safety data without fear of liability, and probably represent only a fraction of the mix-ups that occurred, ECRI officials said.”

To read the full article, please see the following link:

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**Hearings**

**Tuesday, September 27th**

- **House Energy and Commerce Health Subcommittee Hearing - Examining Expanded Access to Investigational Therapies**
  - Postponed
• House Energy and Commerce Oversight Subcommittee Hearing - *Bioresearch Labs and Inactivation of Dangerous Pathogens*
  o 2:00 pm @ 2322 Rayburn House Office Building

**Wednesday, September 28th**
• House Ways and Means Oversight Subcommittee - *Hearing on Health Care Fraud Investigations*
  o 10:00 a.m. @ 1100 Longworth House Office Building