Congressional Schedule

House

- “Convenes at noon and consider a bill (H.R. 5049) that would overhaul the management of National Science Foundation research facilities and a bill (H.R. 5053) that would prohibit the IRS from requiring tax-exempt 501(c) organizations to submit information regarding major contributions. The House also plans to begin general debate on its Defense spending bill (H.R. 5293), with amendments to come later. The House will hold a members-only briefing at 3 p.m. on the terrorist attack at a gay nightclub in Orlando, Fla., per Speaker Paul D. Ryan's request. FBI Director James Comey, Homeland Security Secretary Jeh Johnson, and National Counterterrorism Center Director Nicholas Rasmussen will conduct the briefing. The Senate will hold its members-only briefing on Wednesday.” (CQ)

- **Week Ahead**: “Later this week, the House will consider bills relating to Internal Revenue Service (IRS) data collection (H.R. 5053) and fiscal 2017 Defense spending (H.R. 5293).” (CQ)

Senate

- “Convenes at 10 a.m. to vote on remaining amendments to the fiscal 2017 defense authorization bill (S. 2943), followed by a vote on passage of the bill itself. The Senate is expected to vote on limiting debate on the motion to proceed to the Commerce-Justice-Science appropriations bill (H.R. 2578).” (CQ)

Legislative Updates

- **Week Ahead: Lawmakers Heading to Zika Talks.** “Pressure is building in the coming week for action on Zika funding, now that both chambers have voted to set up a conference committee to bridge the divide between House and Senate. Sen. John Cornyn (R-TX), the Senate's No. 2 Republican, said that after the conference committee is set up, he thinks the process will move ‘pretty quickly.’
  - “Zika isn't the only big item on the agenda. On Wednesday, there will be a major step forward for mental health reform, as the House Energy and Commerce Committee marks up a long-delayed mental health bill from Rep. Tim Murphy (R-PA). Democrats on the committee have long opposed the bill, but are now
more favorable to the legislation after lawmakers made significant changes to address their concerns. Democrats are still pushing for additional changes aimed at increasing funding and access to mental health services, ahead of the Wednesday markup.”

- “The Senate has also still not voted to go to conference committee on opioid legislation. Taking action on the drug abuse crisis is a priority for lawmakers, especially those facing tough reelection races.”
  - For the full article, please see the following link: http://thehill.com/policy/healthcare/283045-week-ahead-lawmakers-heading-to-zika-talks

**Upton Casts Doubt on Adding Mental Health to Opioid Conference.** “Energy and Commerce Committee Chairman Fred Upton (R-MI) is expressing skepticism about the idea of attaching a mental health bill to the conference committee working on opioid legislation. The idea of adding in mental health, particularly a bill from Sens. Bill Cassidy (R-LA) and Chris Murphy (D-CT), has been floated on the Senate side as a way to push the mental health issue forward, given that the opioid legislation is likely to move. But the House is working on its own mental health bill. ‘I think that’ll be hard,’ Upton said of adding mental health to the opioid conference. ‘I mean we all want that [opioid] bill to move for sure, we all want mental health, there's enough time, there is enough time to get this done.’”
  - For the full article, please see the following link: http://thehill.com/policy/healthcare/282845-upton-casts-doubt-on-adding-mental-health-to-opioid-conference

**McConnell Steers Republicans Away From Obamacare Fights.** “For the first time in seven years, the Senate Appropriations Committee last week passed a bipartisan bill funding the departments of Labor and Health and Human Services (LHHS). It’s the largest spending bill after the one for the Defense Department and a perennial source of partisan strife. The bill is not likely to go anywhere because the House has slim chance of passing a Labor-HHS spending bill, but the drama-free passage was an important victory for Sen. Mitch McConnell (R-KY), who has staked the Senate Republican majority on the argument that Republicans know how to govern... The full Senate is now poised to act on the LHHS bill, which hasn’t passed the chamber as a stand-alone measure since 2007.”
  - For the full article, please see the following link: http://thehill.com/homenews/senate/283116-mcconnell-steers-republicans-away-from-obamacare-fights

**Regulatory Updates**

**GAO Recommends HHS Take Steps to Reduce Medicare Appeals.** “The Department of Health and Human Services (HHS) should take certain steps to reduce the number of Medicare appeals and strengthen oversight of the Medicare fee-for-service appeals process, the Government Accountability Office (GAO) said in a report issued today. ‘Without more reliable and consistent information, HHS will continue to lack the ability to identify issues and policies contributing to the appeals backlog, as well as measure
the funds tied up in the appeals process,’ the report concludes. ‘Finally, the manner in
which appeals of certain repetitive claims are adjudicated is inefficient, which leads to
more appeals in the system than necessary.’ Requested by leaders of the Senate Finance
Committee, the report examines trends in appeals for fiscal years 2010 through 2014;
data HHS uses to monitor the appeals process; and HHS efforts to reduce the number of
appeals filed and backlogged. The third appeal level, in which Administrative Law
Judges hear the appeal, experienced a 936% increase in filed appeals over the period,
largely driven by appeals of hospital and other inpatient stays, GAO found. Appeal
decisions exceeding statutory time frames at the first four levels of appeal generally
increased over the period, with most frequent delays occurring at the third and fourth
levels. In the report, HHS said it agreed with most of the recommendations.”

For more information, please see the following link:
http://news.aha.org/article/160609-gao-recommends-hhs-take-steps-to-reduce-
medicare-appeals

**CMS Moves from National to Regional ACO Benchmarking.** “A final rule issued this
week will allow accountable care organizations (ACOs) to benchmark their results to
regional Medicare spending, rather than nationally, but only after their first three-year
contract. The final rule created a phased approach to incorporating regional fee-for-

service (FFS) spending into calculations for resetting, adjusting, and updating a
Medicare Shared Savings Program (MSSP) ACO’s rebased historical benchmark in its
second or subsequent agreement period, beginning in 2017. Changes from the proposed
rule included revising the benchmarking methodology for national FFS calculations to
use “assignable” Medicare FFS beneficiaries instead of all FFS beneficiaries. The Centers
for Medicare & Medicaid Services (CMS) planned to also apply the use of assignable
beneficiaries to ACOs that started as early as 2014. National benchmarks will continue to
be used in an ACO’s first three-year term. Benchmark changes to the second or
subsequent agreement period will include phasing in the transition to a higher weight in
calculating the regional adjustment.”

For the full article, please see the following link:
http://www.hfma.org/Content.aspx?id=48478

**University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) Seeks Input.**
“UM-KECC is preparing a report for CMS that investigates avenues for acquiring the
evidence, data, and infrastructure necessary to implement ESRD patient-driven
measures, such as patient-reported outcomes (PROs) quality of life; patient centered
outcomes (PCOs) and experience of care; and other measures that are patient driven. To
complete this report UM-KECC are seeking feedback from the kidney community on the
following:

1. What ESRD patient reported outcomes/patient centered outcome measures are
   meaningful to patients and health care providers?
2. What data may be available to support future development and testing of these
   measures?”

Please send your feedback to dialysisdata@umich.edu by June 30, 2016 to
ensure consideration for the report.
• **AHRQ’s Safety Program for Nursing Homes: On-Time Pressure Ulcer Healing.** “AHRQ created “On-Time Pressure Ulcer Healing” to help nursing homes with electronic medical records address pressure ulcers that are slow to heal. Pressure ulcers remain a serious problem in nursing homes despite regulatory and market approaches to encourage prevention and treatment. Pressure ulcers cause pain, disfigurement, and increased infection risk and are associated with longer hospital stays and increased morbidity and mortality. Median annual nursing home pressure ulcer prevalence was 7.5 percent in 2009, with associated costs of $3.3 billion annually.”
  o For more information on the program, please see the following link:

• **FDA Drug Guidance May Threaten Compliance for Literally Every Long-Term Care (LTC) Facility.** “New repackaging guidelines from FDA could place ‘...literally every LTC facility and associated pharmacy in America,’ at risk of failing to meet Medicare and Medicaid regulatory requirements, a senior care executive said last week. During a June 6 FDA listening session, Senior Care Pharmacy Coalition President and CEO Alan Rosenbloom said the added regulations under the Drug Quality and Security Act could place the health and safety of LTC patients at risk. Under the new policy, repacking drug products would become subject to a variety of different regulations, including repackaging timeframes and where the packaging can take place. In a previous letter sent to the FDA by Rosenbloom in December 2015, he said the Drug Quality Security Act (DQSA) provisions would force pharmacies and regulatory reviewers to severely alter their policies, placing an increased financial burden on the repacking process. He expressed these same concerns in the recent session, saying the provisions would ‘...materially alter long-standing LTC pharmacy practices and procedures.’ He also said other organizations in the industry share his opinion.”
  o For the full article, please see the following link:

• **Home Health Prior Authorization Demonstration.** “CMS is implementing a new pre-claim review demonstration in five states -- Illinois, Florida, Texas, Michigan, and Massachusetts -- CMS will help make sure that home health services are medically necessary without delaying or disrupting patient care or access. The pre-claim review demonstration will begin in Illinois no earlier than August 1, 2016, and the remaining states will phase in during 2016 and 2017.”
  o For the full press release, please see the following link:

• **White House Announces New Pentagon Effort to Improve Organ Transplants.** “The White House announced an effort Monday to improve organ transplants in the United States, including a $160 million investment spearheaded by the Defense Department that
could lead to an innovative new way to replace organs. The Pentagon, in partnership with the private sector, will create a new institute that will research and develop next-generation technology that can be used to repair and replace human cells and tissues. The technology to be developed through the new Advanced Tissue Biofabrication Manufacturing Innovation Institute could eventually lead to full-fledged organ replacements, the administration said. The institute will help coordinate industry, academia, and nonprofit groups in pursuit of that goal.”

- For the full article, please see the following link: https://www.statnews.com/2016/06/13/white-house-organ-summit/
- For the White House’s press release, please see the following link: https://www.whitehouse.gov/the-press-office/2016/06/13/fact-sheet-obama-administration-announces-key-actions-reduce-organ

- **OIG Released its 2016 Mid-Year Work Plan.** The report notes that the End-Stage Renal Disease Facility – Payment System for Renal Dialysis Services and Drugs has been removed from the Work Plan. There are no new items directly related to dialysis or ESRD.
  - For the full report, please see the following link: http://oig.hhs.gov/reports-and-publications/archives/workplan/2016/WorkPlan_April%202016_Final.pdf

- **CMS Reduces Risk in Comprehensive ESRD Care Model to Entice Smaller Dialysis Providers.** “The Centers for Medicare & Medicaid Services had limited success in keeping small dialysis providers and payers at the table in two previous demonstration projects looking at alternative payment models. But with the new Comprehensive ESRD Care demonstration, it’s not throwing in the towel again. The agency has re-opened the application process for the five-year project, hoping to add more small dialysis providers to the 13 already-approved sites that began working with the model last October. CMS reviewed details of the request for proposal (RFP) during a webinar on May 31. The deadline for submission is July 15. In the care model, dialysis clinics, nephrologists and other providers join together to create an End-Stage Renal Disease Seamless Care Organization (ESCO) to coordinate care for matched beneficiaries. ESCOs are accountable for clinical quality outcomes and financial outcomes measured by Medicare Part A and B spending, including all spending on dialysis services for their patients.”
  - For the full article, please see the following link: http://www.nephrologynews.com/cms-reduces-risk-comprehensive-esrd-care-model-entice-dialysis-smaller-providers/

**Articles of Interest**

- **Travel Costs for Kidney Donors to be Reimbursed by Insurer.** “Travel costs that could dissuade potential kidney donors from volunteering for life-saving transplants will be reimbursed by the nation’s biggest insurer starting next year in a move designed to encourage more donations. UnitedHealth Group says that it will pay back up to $5,000, not counting lost wages from missed work, becoming the latest insurer to reimburse people who donate for an organ transplant. Insurers cover the medical expenses for
someone who donates an organ, but many plans do not pay the cost of getting to the surgery site, staying near it while recovering and making medical appointments tied to the donation. Some states offer tax breaks for these costs.”

- For the full article, please see the following link:
  https://www.washingtonpost.com/business/travel-costs-for-kidney-donors-to-be-reimbursed-by-insurer/2016/06/12/64db9f0c-30a6-11e6-ab9d-1da2b0f24f93_story.html?_hsenc=p2ANqtz- _VPCM7EqILkb7USyHdAGkT3GPY0Knl32s5LVzANTVzue27h19e7rOjzT5hEgco ld2jycYH1tFO9Es6hK_zAqvYYw5ljA&_hmsi=30516140&utm_campaign=KHN% 3A

- **Study: Repealing ObamaCare Would Increase Uninsured by 24M.** “If ObamaCare were repealed, 24 million fewer people would have health insurance in 2021, according to a new study. The study from the Urban Institute finds that 14.5 million fewer people would have coverage through Medicaid or the Children’s Health Insurance Program and 8.8 million fewer people would have individual private coverage like that offered on the health law’s marketplaces. Another 700,000 fewer people would have health insurance through their jobs. At the same time, repeal would reduce federal government spending on healthcare by $927 billion over 10 years, the study finds. However, the Congressional Budget Office has found that despite the lower spending, the deficit would increase because ObamaCare’s tax increases and Medicare cuts would also be repealed. State health spending would also increase without the Affordable Care Act (ACA), by $68.5 billion, as states would have to pick up more of the cost of care for people who lacked insurance.”
  - For the full article, please see the following link:
    http://thehill.com/policy/healthcare/283272-study-repealing-obamacare-
    would-increase-uninsured-by-24m

- **With Tens of Millions on Hand, Drug Makers Fight State Efforts To Force Down Prices.** “Drug makers are sick and tired of coming under attack for high prices. And they’re spending tens of millions to try to make it stop. ‘We’re under unprecedented pressure because there really is profound misunderstanding out there,’ Acorda Therapeutics CEO Ron Cohen, who chairs the industry trade group Biotechnology Innovation Organization, told a crowd at BIO’s conference here this week. ‘Together we’re going to fight back, and we’re going to win,’ Jim Greenwood, the CEO of BIO, said in his keynote address. Bills that would have required drug companies to justify, explain, or even cap their prices have faltered in about a dozen states in recent months. Last week, however, brought two blows to the industry: Vermont Governor Peter Shumlin signed into law a transparency act that requires drug makers to justify price hikes. Similar legislation passed in the California state Senate.”
  - For the full article, please see the following link:
    https://www.statnews.com/2016/06/09/drug-companies-fight-back/

- **Why Do Health Costs Keep Rising? These People Know.** “The Geisinger Health Plan, run by one of the nation’s top-rated health care organizations, foresees medical costs increasing next year by 7.5 percent for people buying insurance under the Affordable Care Act. So when Geisinger requested a rate increase of 40 percent for 2017, consumer
advocates were amazed. And Kurt J. Wrobel, Geisinger’s chief actuary, found himself, along with other members of his profession, in the middle of the health care wars still raging in this political year. Actuaries normally toil far from the limelight, anonymous technicians stereotyped as dull and boring. But as they crunch the numbers for their Affordable Care Act business, their calculations are feeding a roaring national debate over insurance premiums, widely used to gauge the success of President Obama’s health care law. Health plans around the country have just filed proposed rates for 2017. State insurance commissioners are still reviewing them. But questions about the proposed increases are reverberating through the health care system and into the political campaign.”
  o For the full article, please see the following link:

• **White House Rolls Out Zika Crisis Plan.** “The White House is amplifying its efforts to contain the chaos from a nearly inevitable outbreak of Zika virus in the U.S. in upcoming weeks. Senior health officials outlined the national Zika response plan for the first time Thursday during a video briefing with officials from nine states deemed most vulnerable to an outbreak. CDC is arming the states with a step-by-step emergency plan to respond to the first locally transmitted cases of Zika. The virus, which is spread by mosquitoes, is expected to begin hitting Southern U.S. states later this month. The document, which the CDC says is still a draft, includes ‘detailed guidance’ about the protocol for federal and state officials when Zika spreads to the U.S. for the first time. The document has not yet been made public, according to a CDC spokeswoman, though some details were included in a release from the Obama administration late Thursday.”
  o For the full article, please see the following link:

**Hearings**

**Tuesday, June 14th**

• **House Energy and Commerce Full Committee** – *Markup and Vote on H.R. 2646*
  o 5:00 pm @ 2123 Rayburn House Office Building
  o Continues June 15th - 10:00 a.m. @ 2123 Rayburn House Office Building

• **House Energy and Commerce Oversight and Investigations Subcommittee Hearing** - *Combatting Superbugs: U.S. Public Health Responses to Antibiotic Resistance*
  o 10:00 am @ 2322 Rayburn House Office Building