Congressional Schedule

Senate

- Senate meets at 2pm; begins consideration of set of bills, H.R. 6, that would modify Medicare and Medicaid rules to combat opioid epidemic

House

- House on recess until September 25

Legislative Update

- Week in Review
  - **Lawmakers reach deal to avoid government shutdown.** “House and Senate negotiators reached a deal to avoid a government shutdown Thursday that would spare them a nasty fight before November's midterm elections. The deal includes both a long-term funding package for the departments of Defense, and Labor, Health and Human Services and Education for fiscal 2019 along with a short-term measure that would keep remaining agencies funded through Dec. 7 while negotiations continue.”
  
- **House bill to delay or repeal parts of Obamacare would cost nearly $52B: CBO.** “A House bill to delay or repeal certain parts of Obamacare would cost the federal government $51.6 billion over a decade, according to a new government analysis released Tuesday. The latest report, from the nonpartisan Congressional Budget Office, comes ahead of a meeting House lawmakers have scheduled for Wednesday to discuss the bill, known as the Save American Workers Act.”
• **House approves four Medicare-related bills.** “The House of Representatives yesterday approved legislation (H.R. 6690) that would establish a three-year pilot program to test using smart card technology to combat Medicare fraud and protect beneficiary identity. Also approved were bills that would codify the process by which Medicare administrative contractors make local coverage determinations for their regions (H.R. 3635); codify a regulation allowing non-deemed Medicare Cost Plan enrollees to take advantage of the special enrollment period offered to deemed enrollees (H.R. 6662); and direct the Department of Health and Human Services to finalize regulations this year for the Program of All-Inclusive Care for the Elderly (H.R. 6561). The bills cleared the Ways and Means Committee last week.”

• **House GOP blocks Trump-supported drug pricing provision from spending bill.** “House Republicans on Thursday blocked a drug pricing amendment supported by President Trump from inclusion in a health-care spending bill. The provision, which passed the Senate on a bipartisan basis last month, would require drug prices to be disclosed in television advertisements for drugs in an effort to increase transparency and bring down prices. Lawmakers and aides said that House Republicans objected to including the provision in the final version of the funding bill, which was finished by House and Senate negotiators on Thursday.”

• **Week Ahead**
  - **Republicans lack votes – and appetite – to end ‘Obamacare’.** “After years of trying to demolish former President Barack Obama’s prized law, GOP leaders still lack the votes to succeed. Along with the law’s growing popularity and easing premium increases, that’s left top Republicans showing no appetite to quickly refight the repeal battle. Any serious push to annul the statute would almost certainly hinge on Republicans retaining House control and adding Senate seats in November’s elections, neither of which is assured. If either goal eludes them on Election Day, President Donald Trump’s ability to deliver on one of his top campaign promises would have to wait for a second term, if he gets one.”

  - **What’s in, what’s out, and what’s still on the table as the Senate is poised to vote on an opioids package.** “The Senate will vote this week on a bill to prevent illicit fentanyl trafficking, account for drug diversion in opioid manufacturing quotas, and improve access to addiction treatments via telemedicine. Many senators, soon to campaign for re-election in states hard-hit by the epidemic, say the bill is enough. Many advocates for better addiction treatment beg to differ. And, perhaps as importantly, many key policy differences remain between
Senate and House versions of legislation to address the epidemic, leaving Congress plenty of work to do before the bill reaches President Trump’s desk. That effort is expected to begin in earnest after Election Day.”


- Flake opposes quick vote on Kavanaugh, putting confirmation in doubt. “Brett Kavanaugh’s nomination to the Supreme Court hit a serious roadblock Sunday night, as GOP Senate Judiciary Committee member Jeff Flake said he is uncomfortable voting to advance Kavanaugh’s nomination later this week after the nominee’s sexual assault accuser went public. Sen. Bob Corker (R-Tenn.), who is not a member of the committee but whose vote is critical to Kavanaugh’s confirmation, similarly said late Sunday that the committee should pause. Flake (R-Ariz.) said he needs to hear more about the allegations raised publicly by Christine Blasey Ford on Sunday in a Washington Post article, and said other Republicans share his view. Flake is one of 11 Republicans on the narrowly divided panel and without his support, the committee cannot advance his nomination. However, GOP leaders could try to bring Kavanaugh’s nomination directly to the Senate floor.”


Regulatory and Administration Update

- **FDA unveils plan to combat antibiotic resistance.** “On Friday, Sept. 14, 2018, at 10 a.m. EDT, join The Pew Charitable Trusts as it hosts Dr. Scott Gottlieb, commissioner of the U.S. Food and Drug Administration, as he announces the agency’s plans to combat antibiotic resistance. Following Gottlieb’s remarks, a panel of FDA senior officials will further explore the agency’s new and ongoing activities to support antibiotic innovation and ensure that antimicrobial drugs are used according to good stewardship practices in human medicine and animal agriculture.”


- Statement from FDA Commissioner Scott Gottlieb, M.D., on new warning letters FDA is issuing to companies marketing kratom with unproven medical claims; and the agency’s ongoing concerns about kratom. “Science and evidence matter in demonstrating medical benefit, especially when a product is being marketed to treat serious diseases like opioid use disorder (OUD). However, to date, there have been no adequate and well-controlled scientific studies involving the use of kratom as a treatment for opioid use withdrawal or other diseases in humans. Nor have there been studies on how kratom, when combined with other substances, may impact the body, its dangers, potential side effects, or interactions with other drugs. Today’s action is based on these concerns. The FDA issued warning letters to two more unscrupulous vendors, Chillin Mix Kratom and Mitra Distributing, for marketing kratom products with scientifically unsubstantiated claims including to ‘relieve opium withdrawals’ and to ‘treat a myriad of ailments including but not limited to: diarrhea, depression, diabetes,
obesity, high blood pressure, stomach parasites, diverticulitis, anxiety, alcoholism, and opiate withdrawal.’ Simply, selling these unapproved kratom products with claims that they can treat opioid withdrawal and addiction and other serious medical conditions is a violation of federal law.”

- **Health groups sue to block Trump expansion of non-ObamaCare plans.** “Seven health-care groups on Friday sued to block the Trump administration’s expansion of non-ObamaCare health insurance plans. The groups argued the move harms people with pre-existing conditions. The lawsuit in federal district court in Washington seeks to stop the Trump administration’s rules issued last month expanding short-term health insurance plans, so that they can last up to one year instead of just three months. The Trump administration argues these plans provide a cheaper alternative to costly ObamaCare plans, but opponents call them ‘junk’ plans because they are not required to cover people with pre-existing conditions and can exclude coverage of certain health services.”

- **Medicaid rolls set to be slashed under Trump-approved work rules.** “The thousands of people who lost Medicaid coverage this month in Arkansas for not following newly implemented work requirements may be a sign of what’s to come in other GOP-led states. Indiana and New Hampshire are slated to implement their Medicaid work requirements next year, and a slew of other states are awaiting approval from the Trump administration to do so. Arkansas has served as a test case of sorts since it was the first state to implement work requirements, and this month it became the first state to kick off beneficiaries for not following them. The state removed more than 4,000 people from the Medicaid rolls, with some estimates saying that number could climb to 50,000 when the requirements are fully implemented in 2019.”

- **New Medicare Advantage tool to lower drug prices puts crimp in patients’ choices.** “Starting next year, Medicare Advantage plans will be able to add restrictions on expensive, injectable drugs administered by doctors to treat cancer, rheumatoid arthritis, macular degeneration and other serious diseases. Under the new rules, these private Medicare insurance plans could require patients to try cheaper drugs first. If those are not effective, then the patients could receive the more expensive medication prescribed by their doctors.”

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**Articles of Interest**

- [Read more](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620106.htm)
- [Read more](http://thehill.com/policy/healthcare/406674-health-groups-sue-to-block-trump-expansion-of-non-obamacare-plans)
- [Read more](http://thehill.com/policy/healthcare/406624-medicaid-rolls-set-to-be-slashed-under-trump-approved-work-rules)
• **Fresenius Medical Care North America celebrates Nephrology Nurses Week with $100,000 contribution to ANNA.** “Fresenius Medical Care North America (FMCNA), the nation’s leading renal care company, is making a $100,000 contribution to the American Nephrology Nurses Association (ANNA), a professional nursing organization with more than 8,500 members. In recognition of the organization’s 50th anniversary year and Nephrology Nurses Week, the donation will fund an ongoing scholarship program, help increase awareness of the profession, and strengthen engagement with nurses dedicated to caring for patients with chronic kidney disease.”

• **Seven U.S. states now have adult obesity rates of 35 percent or higher.** “Seven U.S. states now have adult obesity rates of 35 percent or higher, up from zero states just five years ago, according to federal data released Wednesday. The 2017 data, from the Centers for Disease Control and Prevention, highlight continuing discrepancies in adult obesity rates across geographic areas, race, and education levels. The seven states with obesity rates of at least 35 percent in 2017 were Alabama, Arkansas, Iowa, Louisiana, Mississippi, Oklahoma, and West Virginia, which itself had the highest rate in the country at 38.1 percent. Colorado had the lowest obesity rate, at 22.6 percent.”
  - Read more: [https://www.statnews.com/2018/09/12/seven-u-s-states-now-have-adult-obesity-rates-of-35-percent-or-higher/](https://www.statnews.com/2018/09/12/seven-u-s-states-now-have-adult-obesity-rates-of-35-percent-or-higher/)

• **Patient-reported experiences of dialysis care with-in a national pay-for-performance system.** “Are patient, dialysis facility, and geographic characteristics associated with dialysis facility performance on patient experience surveys? In a cross-sectional analysis of 2939 US dialysis facilities, mean In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems scores varied geographically and were lower in facilities owned by large chains as well as in for-profit and free-standing facilities. These scores were higher in facilities with more nurses per patient, and black and Native American populations reported less favorable experiences. The perceived quality of dialysis care delivered in certain settings appears to be of concern, and opportunities appear to exist for improved implementation of patient experience surveys in dialysis pay-for-performance programs.”
  - Read more: [https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2701630](https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2701630)

• **Caffeine consumption and mortality in chronic kidney disease: a nationally representative study.** “An inverse relationship between coffee consumption and mortality has been reported in the general population. However, the association between caffeine consumption and mortality in patients with chronic kidney disease (CKD) remains uncertain. Conclusions: We detected an inverse association between caffeine consumption and all-cause mortality among participants with CKD.”

• **High blood sugar during pregnancy ups risk of mother’s type 2 diabetes, child’s obesity.** “Mothers with elevated blood glucose during pregnancy – even if not high enough to
meet the traditional definition of gestational diabetes – were significantly more likely to have developed type 2 diabetes a decade after pregnancy than their counterparts without high blood glucose. For children born to mothers with elevated or normal glucose, researchers found no statistically significant difference between the two groups of children in terms of their combined overweight and obesity, the study’s primary outcome. However, when obesity was measured alone, children of mothers with elevated blood glucose were significantly more likely to be obese.”

- **Nearly 30% of all opioid prescriptions lack medical explanation.** “How large a role do doctors play in the opioid crisis? Nearly 30% of all opioids prescribed in US clinics or doctors’ offices lack a documented reason -- such as severe back pain -- to justify a script for these addictive drugs, new research finds. In total, opioids were prescribed in almost 809 million outpatient visits over a 10-year period, with 66.4% of these prescriptions intended to treat non-cancer pain and 5.1% for cancer-related pain, according to a study published Monday in the journal Annals of Internal Medicine. However, for the remaining 28.5% of prescriptions -- about three out of every 10 patients -- there was no record of either pain symptoms or a pain-related condition, the Harvard Medical School and RAND Corp. researchers say.”


- **Insurer to Perdue Pharma: We won’t pay for OxyContin anymore.** “The largest insurer in Tennessee has announced it will no longer cover prescriptions for what was once a blockbuster pain reliever. It's the latest insurance company to turn against OxyContin, whose maker, Purdue Pharma, faces dozens of lawsuits related to its high-pressure sales tactics around the country and contribution to the opioid crisis. Last fall, Cigna and Blue Cross Blue Shield of Florida both dropped coverage of the drug. Top officials at Blue Cross Blue Shield of Tennessee say newer abuse-deterrent opioids work better, and starting in January, the insurer covering 3.4 million Tennesseans will pay for those opioids made by other pharmaceutical companies instead.


- **Fast-acting flu drug shows strong potential, but clinical trial results also raise concerns.** “A new, fast-acting flu drug showed strong potential but also some surprising and even concerning results in two newly published clinical trials. The drug, baloxavir marboxil, cut the time people were sick with flu symptoms by a little over a day. And it dramatically reduced the amount of viruses that people with infections had in their upper respiratory tracts, suggesting they might be less likely to infect others through coughs and sneezes. Still, the single-dose drug didn’t make people feel better faster than oseltamivir, sold as Tamiflu. And the studies, published last week in the New England Journal of Medicine, showed viral resistance could develop rapidly to the drug — a finding flagged as concerning in an editorial the journal published with the studies.”

The new Apple Watch, with FDA’s blessing, comes with an EKG app. “After years of coming close, Apple has officially broken into the medical device space. The company announced Wednesday that it received Food and Drug Administration clearance to market its latest Apple Watch, which is capable of conducting an electrocardiogram to measure heart rhythm. The company also received clearance to alert people who may be at risk for atrial fibrillation, an irregular heartbeat that can lead to more serious health concerns, based on measurements the watch takes. Theirs is the first electrocardiogram ever to be available over the counter, Apple’s COO Jeff Williams said. The Apple Watch Series 4 will cost at least $399.”