Congressional Schedule

Senate

- Senate meets at 10am; resumes consideration of H.R. 6147, the vehicle for a “Minibus” appropriations bill that passed the House last week; Senate plans to replace the text of the House-passed bill with an amendment from Appropriations Chairman Richard Shelby containing the text of the Senate’s appropriation measures

House

- House meets at 10 am, first votes expected 2:15 pm-3:15 pm, last votes 5:30 pm-6:30 pm; lawmakers are up against several deadlines as they try to wrap up business before a planned August recess

Legislative Update

- Week in Review
  - House Dems launching Medicare for All Caucus. “House Democrats are launching an official Medicare for All Caucus in an effort to promote a single-payer health-care bill. The caucus, which will officially be announced Thursday, comes as an increasingly larger number of Democrats warm to the idea.”
  - GOP Chairman in talks with Trump officials on restarting key ObamaCare payments. “House Ways and Means Committee Chairman Kevin Brady (R-Texas) said Monday that he is in talks with the Trump administration about ways to restart key ObamaCare payments that the administration abruptly suspended this month. The administration’s surprise suspension of $10.4 billion in payments to insurers this month set off a round of warnings of rising premiums and condemnation from Democrats who said it was further GOP ‘sabotage’ of the health-care law.”
• **Week Ahead**
  
  o *Scalise reveals how Republicans plan to keep control of the House in November.*
    “Scalise said the GOP is working to revamp the health care system in the U.S., including working on a bill to get rid of the medical device tax, a 2.3% excise tax on the price of medical devices sold in the U.S. That tax, according to the Tax Foundation, is responsible for the loss of nearly 22,000 jobs from 2013 to 2015.”
  
  o *Senate panel to vote next week on banning ‘gag clauses’ in pharmacy contracts.*
    “The Senate health committee will vote next week on a bill that would ban ‘gag clauses’ that prohibit pharmacies from telling customers they can save money on a drug if they pay with cash instead of insurance. Such clauses are sometimes inserted into contracts pharmacies have with insurers or pharmacy benefit managers — the middlemen that manage pharmacy benefits for insurance companies and employers. The clauses prevent a pharmacist from telling a customer if, for example, their $20 co-pay is higher than the pharmacy’s cash price for a drug.”
  
  o *Senate set to confirm Wilkie for Veterans Affairs secretary.*
    “After months of tumult, Pentagon official Robert Wilkie is expected to become secretary of Veterans Affairs when the Senate votes Monday to confirm him, taking on the task of fulfilling President Donald Trump’s promises to fire bad VA employees and steer more patients to the private sector. Wilkie is Trump’s third pick for the job in 18 months. The long-time public official says he will ‘shake up complacency’ at VA, which has struggled with long waits in providing medical treatment to millions of veterans.”
    - Read more: [https://apnews.com/263e7e8d694d41d28a59e447bafde8eb/Senate-set-to-confirm-Wilkie-for-Veterans-Affairs-secretary](https://apnews.com/263e7e8d694d41d28a59e447bafde8eb/Senate-set-to-confirm-Wilkie-for-Veterans-Affairs-secretary)
  
  o *House panel to vote today on medical device tax repeal.*
    “A panel in the U.S. House of Representatives is slated to vote today on a measure that would do away altogether with the medical device tax. Although the 23% levy on prescribed medical devices was enacted as part of the Affordable Care Act in 2010, it didn’t go into effect until 2012 and was mothballed two years later; that moratorium, extended earlier this year, is slated to end in 2020.”
    - Read more: [https://www.massdevice.com/house-panel-to-vote-today-on-medical-device-tax-repeal/](https://www.massdevice.com/house-panel-to-vote-today-on-medical-device-tax-repeal/)

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**Regulatory and Administration Update**

• **CMS drops four quality incentive program measures in proposed rule.** “Four reporting measures in the ESRD Quality Incentive Program would be eliminated under a
proposed rule released by CMS on July 11. The four measures involve tracking health care personnel Influenza vaccinations, assessing pain levels in patients on dialysis, monitoring anemia and monitoring serum phosphorus levels. These would be eliminated based on CMS’s Meaningful Measures Initiative, which triggers an evaluation when ‘the cost associated with a measure outweighs the benefit of its continued use in the program,’ the agency said in a press release. ‘The proposals to remove these measures are consistent with CMS’ commitment to using a smaller set of more meaningful measures. CMS is focusing on measures that provide opportunities to reduce both paperwork and reporting burden on providers and patient-centered outcome measures, rather than process measures.’”

- **Trump’s migrant fiasco diverts millions from health programs.** “The health department has quietly dipped into tens of millions of dollars to pay for the consequences of President Donald Trump’s border policy, angering advocates who want the money spent on medical research, rural health programs and other priorities. The Department of Health and Human Services has burned through at least $40 million in the past two months for the care and reunification of migrant children separated from their families at the border — with housing costs recently estimated at about $1.5 million per day.”

- **Government shuts down website for doctors searching for treatment guidelines.** “After Monday, the website for the National Guideline Clearinghouse, which provides access to guidelines for practicing medicine, will no longer be available to its users -- mostly doctors -- due to a lack of funding, according to an announcement posted on the site in April. No stranger to financial uncertainty over its 20-year history, the clearinghouse is an initiative of the Agency for Healthcare Research and Quality of the US Department of Health and Human Services, which earmarked $1.2 million to fund the site in 2017. While some bemoan its demise, the website may soon be rescued, according to the agency, which noted in its announcement that it has received some interest from unnamed stakeholders wanting to carry on the work. However, it is not clear when or whether the national clearinghouse (or something resembling it) will go live again, the agency warned.”

- **Hospital group says it will refile suit over Trump cuts to drug programs.** “The American Hospital Association said it would refile a lawsuit against the Trump administration's cuts to a discount drug program after losing its appeal Tuesday. ‘We will continue our fight to reverse these unwarranted cuts and protect access for patients, and we expect to refile promptly in district court,’ the AHA said. Three judges from the U.S. Court of Appeals for the District of Columbia Circuit ruled Tuesday that AHA's suit against the Department of Health and Human Services (HHS) was premature.”

**FDA’s Gottlieb slams drug makers for stalling release of biosimilars.** “Food and Drug Administration Commissioner Scott Gottlieb on Wednesday accused drug makers who manufacture pricey biologic medicines of using ‘unacceptable’ anti-competitive tactics to keep competitors off the market, costing Americans billions. The tactics — some of which Gottlieb will refer to as a ‘toxin’ — have prevented other drug makers from launching biosimilar medicines, highly similar versions of the same drugs.”


**HHS opens door to possibility of importing some drugs to drive down prices.** “The Trump administration is opening up the door to importing prescription drugs — at least in a limited number of cases. The administration said Thursday that the Department of Health and Human Services will form a working group to look at the idea of importing drugs from other countries in cases in which there is a dramatic price increase for a drug produced by one manufacturer and not protected by patents or exclusivities. And although the announcement was cast as an early step, health secretary Alex Azar left little doubt the administration planned to eventually approve a significant policy change.”


**Proposed rule changes from CMS get mixed reviews.** “The proposed 2019 rule for the Medicare Quality Payment Program (QPP) was released July 12 by CMS, along with changes to the Physician Fee Schedule, and while doctors will find some beneficial changes, physician advocate groups say more needs to be done. CMS is proposing changes to eligibility requirements, coding, some documentation requirements and how certain categories are weighted, among others, with a goal of streamlining billing and expanding access to high-quality care.”


**FDA plans to ease OTC approvals for some prescriptions.** “U.S. regulators proposed new guidelines Tuesday to make it easier for some common medicines to be sold without a prescription — and more convenient for consumers to get them. The Food and Drug Administration is evaluating ways to make sure patients don't take an inappropriate over-the-counter drug, Commissioner Scott Gottlieb said in a statement. That could include adding information to the packaging label and offering online questionnaires to help people decide if a drug is right for them. Drugmakers would have to do studies showing those strategies allow consumers to safely pick a drug and use it without medical supervision.”

• **In a blow to PBM**s, **Trump administration mulling overhaul to drug rebate safe harbor protections.** “The Trump administration is considering a proposal to overhaul safe harbor protections for pharmaceutical company rebates, a plan that could lead to a significant shift in how drug prices are determined. The Office of Management and Budget is reviewing a proposed rule from the Department of Health and Human Services on the matter. Details of how exactly HHS wants to rethink safe harbors are scant, as the rule will not be released publicly until OMB signs off on it.”  

• **Obamacare fix said to be prepared after risk payments halted.** “The Trump administration is preparing a regulation that would allow the resumption of billions of dollars in payments to health insurers in Obamacare. The Office of Management and Budget was sent a rule on Wednesday from the Centers for Medicare and Medicaid Services tied to the risk-adjustment program, which transfers money to insurers who take on sicker customers. An administration official said the rule is an option being considered to resolve the legal dispute that has held up the payments.”  

• **4 Changes physician groups don't like in proposed MACRA, physician fee schedule rule.** “Doctors’ groups are still digesting the 1,473-page proposed federal rule updating the Medicare physician fee schedule and outlining changes for year three of the physician payment program implemented under MACRA. But in their preliminary review of the proposal released by the Centers for Medicare & Medicaid Services last Thursday, they’ve already found plenty to fault, including changes that would slow the move of physician practices to value-based payment and a failure to lower drug costs.”  

**Articles of Interest**

• **Study reveals long-term effectiveness of therapy for common cause of kidney failure.** “Among individuals with autosomal dominant polycystic kidney disease, those who were treated with tolvaptan for up to 11 years had a slower rate of kidney function decline compared with historical controls. Annualized kidney function decline rates of tolvaptan-treated patients did not change during follow-up.”  

• **Groups suggest 5 practices to avoid in pediatric nephrology.** “The American Academy of Pediatrics and the American Society of Pediatric Nephrology have released five pediatric nephrology practices that clinicians should strive to avoid, as part of the Choosing Wisely campaign. Among them: Well-child visits should not include routine urinalysis for asymptomatic patients. Work ups for hematuria or proteinuria shouldn't be initiated before repeating abnormal urine dipstick analysis (UA), given the high false-
positive test rate for UA. For patients with signs of clinical resolution of urinary tract infection following treatment, follow-up urine cultures aren't necessary. For asymptomatic patients, clinicians should repeat blood pressure measurements three times at one visit and at two more visits to document persistently elevated blood pressure. Before this, outpatient hypertension work up shouldn't be initiated. For children and adolescents with advanced chronic kidney disease or end-stage renal disease, central lines or peripherally inserted central lines shouldn't be placed without first consulting with pediatric nephrology.”

- **UCLA led the nation in organ transplants in 2017.** “Ronald Reagan UCLA Medical Center led the nation in the number of solid organ transplants performed in 2017, with 641 procedures that included kidney, pancreas, lung, liver, heart and intestine transplants, according to statistics from the Organ Procurement and Transplantation Network. UCLA recorded 363 kidney transplants in 2017, making it the year’s top kidney transplant center. Other medical centers with a high number of solid organ transplants in 2017 were UC San Francisco; Jackson Memorial Hospital in Miami, Barnes-Jewish Hospital in St. Louis, Missouri; and the University of Wisconsin’s University Hospital in Madison.”

- **Vanderbilt opens telemedicine clinic for kidney transplant screening.** “With the opening of a pre-transplant kidney evaluation clinic in Jackson, Tennessee, the Vanderbilt Transplant Center is joining a range of other clinical programs participating in telemedicine at Vanderbilt University Medical Center (VUMC). Intent on providing better access to patients seeking evaluations, the new clinic, a first for the Transplant Center to utilize telemedicine technology, will serve as a supplemental resource and offer appointments once a month.”

- **Restricting who gets an organ transplant.** “Almost 95,000 people in the United States are waiting for a life-saving kidney transplant. But thousands of other Americans aren’t on the list simply because they are not perceived as having enough support from family and friends, one of the national criteria for determining who gets an organ transplant of any kind. There is limited evidence suggesting that social support plays an important role in the success of organ transplants, said Keren Ladin, an assistant professor in the Department of Occupational Therapy, a fact that may have contributed to efforts by other countries, such as Canada and the European Union, to remove it as a criterion for organ transplantation.”

- **Iran pays kidney donors. Should the U.S. follow?** “In the U.S., Medicare spending on dialysis accounts for nearly 1 percent of the entire federal budget, and the cost is
growing. On the other hand, kidney transplants are actually less expensive and offer the possibility of getting back to work and off disability, but there are not enough for every patient in need. Economics correspondent Paul Solman looks at one idea for spurring donations.”

- Read more: https://www.pbs.org/newshour/show/iran-pays-kidney-donors-should-the-u-s-follow

- **How to better enable kidney exchanges to improve health and save money.** “Nearly 100,000 people with failing kidneys are on waiting lists for a kidney transplant in the United States, with an average wait of three to five years. Organs come from one of two sources — from living donors, typically a friend or family member willing to spare one of their own kidneys; or from a transplant donor who has died. Platforms for kidney exchanges such as the National Kidney Registry and the Alliance for Paired Donation provide a lifeline for people on the waiting list by expanding the pool of potential donors by matching potential recipients with living donors they’ve never met. But a new study shows that exchange platforms are not as effective as they could be.”
  - Read more: https://engineering.stanford.edu/magazine/article/how-better-enable-kidney-exchanges-improve-health-and-save-money

- **Potential DNA damage from CRISPR has been ‘seriously underestimated,’ study finds.** “From the earliest days of the CRISPR-Cas9 era, scientists have known that the first step in how it edits genomes — snipping DNA — creates an unholy mess: Cellular repairmen frantically try to fix the cuts by throwing random chunks of DNA into the breach and deleting other random bits. Research published on Monday suggests that’s only the tip of a Titanic-sized iceberg: CRISPR-Cas9 can cause significantly greater genetic havoc than experts thought, the study concludes, perhaps enough to threaten the health of patients who would one day receive CRISPR-based therapy.”
  - Read more: https://www.statnews.com/2018/07/16/crispr-potential-dna-damage-underestimated/?utm_campaign=rss

- **Investigation: Patients’ drug options under Medicaid heavily influenced by drugmakers.** “Medicaid, which uses state and federal tax dollars to pay for health care for 76 million poor or disabled Americans, tries to ensure that patients get drugs that work the best and yet are also affordable. States put those drugs on what they call ‘preferred drug lists.’ While Medicaid must pay for nearly all drugs by law, states can make it harder to get more expensive or less effective drugs by requiring doctors to fill out cumbersome administrative paperwork to prescribe those not on the preferred lists.”

- **Novartis pulls back on planned drug price increases.** “Novartis will not raise drug prices in the U.S. this year, the company’s CEO told Bloomberg on Wednesday. The announcement comes after Pfizer agreed to temporarily hold off on increasing the prices of some drugs after receiving criticism from President Trump. Trump has pressured drug companies to keep prices low, and met with Pfizer after it announced price increases for more than 100 drugs. After the meeting, Pfizer said it would hold off on
increasing prices until the administration releases its drug pricing plan or the end of the year, whichever comes first.”

- **New York City agrees to pay $20.8 million in nurses case: Justice Department.** “New York City has agreed to pay $20.8 million to settle federal discrimination charges brought by registered nurses and midwives who said their work was not recognized as ‘physically taxing,’ the Justice Department said on Wednesday. The settlement applies to 1,665 registered nurses and midwives hired from Sept. 15, 1965, to March 31, 2012. Once a court approves the settlement, the city would pay the registered nurses and midwives between $1,000 and $99,000 each, depending on years of service, the Justice Department said. The New York State Nurses Association union praised the settlement as a victory for all nurses, whose work is often physically demanding.”


- **These pills could be next U.S. drug epidemic, public health officials say.** “The growing use of anti-anxiety pills reminds some doctors of the early days of the opioid crisis. Considered relatively safe and non-addictive by the general public and many doctors, Xanax, Valium, Ativan and Klonopin have been prescribed to millions of Americans for decades to calm jittery nerves and promote a good night’s sleep. But the number of people taking the sedatives and the average length of time they’re taking them have shot up since the 1990s, when doctors also started liberally prescribing opioid painkillers. As a result, some state and federal officials are now warning that excessive prescribing of a class of drugs known as benzodiazepines or ‘benzos’ is putting more people at risk of dependence on the pills and is exacerbating the fatal overdose toll of painkillers and heroin. Some local governments are beginning to restrict benzo prescriptions.”


- **Study: Alcohol fuels drastic increase in liver disease.** “Deaths from liver disease, especially among young people, have increased dramatically since 1999, according to new research. A study published Wednesday in The BMJ examined deaths related to cirrhosis and liver cancer from 1999 to 2016. According to the study, from 2009 to 2016, ‘the period of worsening death rates,’ people aged 25 to 34 experienced the highest annual increase in cirrhosis-related deaths (10.5 percent), which was entirely fueled by alcohol-related liver disease. The researchers stated this finding is ‘reinforced by parallel changes in mortality due to alcohol use disorders and all alcohol-related liver disease.’”


- **Poll: Half of Americans find health care harder to afford this year.** “Nearly half of respondents in a new poll said they are now finding it more difficult to afford health care than they were a year ago, according to a poll released Thursday. The Navigator
poll found 49 percent of respondents said it’s more difficult to afford prescription drugs, insurance premiums and doctor visits compared to last year. Additionally, 78 percent of those surveyed said they believe the government should be doing more to make healthcare more affordable.”


- **Dialysis firms’ profits are obscene. What will happen if California tries to cap them?**
  “The worst maladies of the American healthcare system are related to corporate profits: The competition among insurance companies to avoid the sickest customers and extract the most money from the rest, and the rise of for-profit healthcare providers. In few fields do those factors come together as neatly as they do in the dialysis business. And a business it is — a terrifically profitable one. The two dominant for-profit dialysis firms, Denver-based DaVita and German-owned Fresenius, report pretax operating profits in the billions and margins of 18% to 19%. Proposition 8, an initiative appearing on California’s November ballot, would cap those profits at 15% over their direct spending on health services.”


- **Unpacking the bold – and the bluster – in Trump’s plan to bring down drug prices.**
  “When President Trump delivered his much-ballyhooed address on drug prices in May, even supporters conceded there were more question marks among his policy ideas than concrete proposals. But over the past week, the Trump administration has begun to put some periods at the ends of the sentences. Top health officials are exploring the idea of importing drugs from other countries, despite broad and long-standing opposition from drug makers. There’s a new pitch to lower the prices Medicare pays for new drugs, at least for the first few months they’re on the market. The Food and Drug Administration might soon allow some prescription drugs to be sold over the counter. The same agency also released a polished plan to speed biosimilar drugs to market and promote competition. And the administration got closer, too, to releasing a new plan to change the way pharmacy benefit managers get paid.”