American Nephrology Nurses Association

Weekly Capitol Hill Update – Monday, July 9, 2018

Congressional Schedule

Senate

- Senate returns from July 4 recess, meets at 3 pm

House

- House returns tomorrow. Rules Committee to meet at 5 pm on H.R. 50, related to regulatory process of unfunded mandates

Legislative Update

- Week in Review
  - Pair of Dem senators probe drug pricing ‘middlemen,’ distributors over high costs. “Democratic Sens. Elizabeth Warren (Mass.) and Tina Smith (Minn.) are probing nine drug distributors and pharmacy benefit managers (PBMs) over their role in high drug prices. Warren and Smith are asking the companies to respond to Secretary of Health and Human Services Alex Azar's comments that drug companies want to reduce prices but are being blocked by PBMs and drug distributors. PBMs manage drug benefits for insurers and employers, trying to get the best deal for both parties, but critics have argued that they drive up costs by negotiating secret deals and rebates with drug manufacturers.”

- Week Ahead
  - No summer vacation for 340B program stakeholders. “After an already active first half of 2018 for 340B Program developments, 340B Program stakeholders are not getting a summer respite. In just the past week, the US Government Accounting Office (GAO) released its much-anticipated report on 340B contract pharmacy arrangements, the Health Resources and Services Administration (HRSA) released two new policy updates, two new 340B-related bills have been introduced in the US House of Representatives, and the House Committee on Energy and Commerce Subcommittee on Health announced that it would be
holding a hearing on July 11 to discuss seven previously introduced House bills covering 340B issues and discussion drafts of an additional eight 340B bills.”

- Read more: https://www.natlawreview.com/article/no-summer-vacation-340b-program-stakeholders

  • Senate battle over court nominee threatens to stymie legislative progress. “The fight over the next Supreme Court nominee could claim several legislative victims in the Senate this year. Senators are griping that the looming nomination, with an announcement expected on Monday, will prevent them from being able to focus on legislation, as lawmakers dig in for a drawn-out rhetorical battle to confirm President Trump’s pick to succeed retiring Justice Anthony Kennedy. GOP Sen. Lisa Murkowski (Alaska), who’s expected to play a pivotal role in the confirmation process, noted that in addition to funding the government beyond Sept. 30, the Senate needs to pass a bill reauthorizing the Federal Aviation Administration (FAA). And she wants to pass an energy bill. Those three measures will require help from Democrats to get over the finish line.”

- Read more: http://thehill.com/homenews/senate/395474-senate-battle-over-court-nominee-threatens-to-stymie-legislative-progress

**Regulatory and Administration Update**

- Despite U.S. court’s ruling, Medicaid work requirements advance in other states. “The fallout from Friday’s federal court ruling that struck down the Medicaid work requirement in Kentucky was swift. The decision by Judge James Boasberg immediately blocked Kentucky from enacting the provision in Campbell County, which had been set to start Sunday and roll out statewide later this year. Meanwhile, Arkansas, New Hampshire and Indiana are moving ahead with the implementation of their versions of a Medicaid work requirement. It is not clear how or if Boasberg’s ruling invalidating the Trump administration’s approval of Kentucky’s plan affects these states.”


- Trump administration names new U.S. drug enforcement chief. “The Trump administration on Monday named a top White House lawyer as the new head of the U.S. Drug Enforcement Administration after the agency’s prior acting administrator announced his retirement last month. Uttam Dhillon, who most recently served as deputy White House counsel, was named as the DEA’s acting administrator at a time when the agency is devoting much of its attention to grappling with a national opioid epidemic. According to the Centers for Disease Control and Prevention, 42,000 people died from opioid overdoses in 2016. U.S. President Donald Trump declared the crisis a public health emergency in October.”

  - Read more: https://www.reuters.com/article/us-usa-justice-dea/trump-administration-names-new-u-s-drug-enforcement-chief-idUSKBN1JS2FN

- Pruitt is gone, but EPA’s risky strategy for health will remain. “Scott Pruitt, as of today, is gone at the EPA. But his replacement, Andrew Wheeler, is a longtime coal lobbyist expected to continue his predecessor’s deregulation agenda — with fewer travel
scandals, POLITICO's Eric Wolff reports. Those efforts included attempting to block a federal health study on a nationwide water-contamination crisis and other moves with health implications. POLITICO this morning is reporting on EPA's efforts to block warnings on a cancer-causing chemical, for instance.”

- [Read more](https://www.politico.com/newsletters/politico-pulse/2018/07/06/pruitt-is-gone-but-epa's-risky-strategy-for-health-will-remain-272347)

- **Trump narrows Supreme Court short list, top 3 contenders emerge.** “President Donald Trump has narrowed his list of contenders to replace retiring Supreme Court Justice Anthony Kennedy to three serious candidates, a source familiar with the selection process told NBC News on Thursday. Those candidates are appeals court judges Brett Kavanaugh, Raymond Kethledge and Amy Coney Barrett, the source, who was not authorized to speak publicly, said. Kavanaugh, 53, and Kethledge, 51, are both former law clerks to Kennedy, as was Neil Gorsuch, Trump's first Supreme Court nominee, who succeeded Antonin Scalia. Kavanaugh, also a veteran of George W. Bush’s White House, currently serves on the U.S. Court of Appeals for the District of Columbia.”

- [Read more](https://www.nbcnews.com/politics/politics-news/trump-narrows-supreme-court-short-list-top-3-contenders-emerge-n888981)

- **ESRD Claims error: Transitional drug adjustment add-on payment adjustment.** “End Stage Renal Disease (ESRD) claims are incorrectly reimbursed if they: Are eligible for Transitional Drug Adjustment Add-On Payment Adjustment and Contain non-covered charges. After we fix the system on January 1, 2019, your Medicare Administrative Contractor will mass adjust claims that were paid incorrectly. You do not need to take any action.”

- [Read more](https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Provider-Partnership-Email-Archive-Items/2018-07-05-eNews.html)

- **Comprehensive ESRD Care (CEC) Model Telehealth – Implementation.** “In order to emphasize high-value services and support the ability of ESCOs to manage the care of beneficiaries, CMS plans to design policies and use the authority under Section 1115A of the Social Security Act (Section 3021 of the Affordable Care Act) to conditionally waive certain Medicare payment requirements as part of the CEC Model. CMS will make available to qualified ESCOs a waiver of the originating site requirement for services provided via telehealth. This benefit enhancement will allow beneficiaries to receive qualified telehealth services in non-rural locations and locations that are not specified by statute, such as homes and dialysis facilities. The waiver will apply only to eligible aligned beneficiaries receiving services from ESCO providers.”

- [Read more](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10314.pdf)

- **Insurers warn of rising premiums after Trump axes Obamacare payments again.** “Health insurers warned that a move by the Trump administration on Saturday to temporarily suspend a program that was set to pay out $10.4 billion to insurers for covering high-risk individuals last year could drive up premium costs and create
marketplace uncertainty. The Affordable Care Act’s (ACA) ‘risk adjustment’ program is intended to incentivize health insurers to cover individuals with pre-existing and chronic conditions by collecting money from insurers with relatively healthy enrollees to offset the costs of other insurers with sicker ones.”


**Articles of Interest**

- **A dream starting to come true: wearable kidneys.** “Without a transplant, patients with kidney failure need dialysis to stay alive. Dialysis does a good job of cleaning the blood and removing extra fluid, but it takes a lot of time and can hurt a patient’s quality of life. Since the 1970s, doctors have been trying to make a dialysis machine that patients can wear. The hope has always been to free patients from a huge machine that keeps them tied down. But there were no parts small and light enough to make dialysis machines wearable -- until now. Groups in the United States and other countries are doing studies on different types of wearable kidneys. These include devices for hemodialysis, peritoneal dialysis, and one machine combines both hemodialysis and peritoneal dialysis. These machines have small parts that weigh less, long lasting batteries, and filters that can reuse dialysate without the need for a lot of purified water. These advances make it possible for people to wear a dialysis device that isn’t very heavy and can be worn under clothing.”
  - Read more: https://www.kidney.org/newsletter/dream-starting-to-come-true-wearable-kidneys

- **Union gives up on dialysis initiative.** “A California union has given up on its plan to ask Arizona voters to impose new service and cost restrictions on companies that perform dialysis. Sean Wherley, spokesman for Service Employees International Union, said on Monday his organizations has decided to focus its efforts elsewhere. Wherley said the SEIU already has filed petitions to get a similar measure on the ballot in California. And, he said paperwork is being turned in later this week in a bid to get Ohio voters to adopt a newly identical plan. But the union’s decision is still going to leave Arizonans with lots of issues to decide in November.”

- **Signatures submitted for initiative to improve dialysis care in Ohio.** “Advocates have submitted more than 475,000 signatures to election officials to put an issue on the Nov. 6 ballot that seeks to improve patient care at dialysis clinics. Supporters of the issue need 305,591 signatures from registered voters, according to a news release from the Service Employees International Union District 1199. The Kidney Dialysis Patient Protection Amendment would require annual health and safety inspections of dialysis clinics, limit how much clinics can charge for patient care, require annual reporting of patient care charges by dialysis clinics, and impose penalties on clinics for overcharging for patient care.”
• **More nurse practitioners are pursuing residency training to hone skills.** “Mitchell is part of a growing cadre of nurse practitioners — typically, registered nurses who have completed a master's degree in nursing — who tack on up to a year of clinical work and other types of training, often in primary care. Residencies may be at federally qualified health centers, Veterans Affairs medical centers or private practices and hospital systems. Patients run the gamut, but many are low-income and have complicated needs. Proponents say the programs help prepare new nurse practitioners to deal with the growing number of patients with complex health issues. But detractors say that a standard training program already provides adequate preparation to handle patients with serious health care needs. They say nurse practitioners who choose not to do a residency (the vast majority of the 23,000 who graduate each year do not) are already well qualified to provide good patient care.”
  
  o Read more: [https://www.npr.org/sections/health-shots/2018/07/03/624721718/more-nurse-practitioners-are-pursuing-residency-training-to-hone-skills](https://www.npr.org/sections/health-shots/2018/07/03/624721718/more-nurse-practitioners-are-pursuing-residency-training-to-hone-skills)

• **Having hypertension during pregnancy may affect cardiovascular health for life.** “Women with a history of preeclampsia or gestational hypertension in pregnancy developed chronic hypertension at a 2- to 3-fold higher rate and had 70 percent and 30 percent higher rates of type 2 diabetes and high cholesterol, respectively, than women who had normal blood pressure in pregnancy. These findings suggest that women with pregnancies complicated by high blood pressure may benefit from cardiovascular screening throughout their lives. The study is published in Annals of Internal Medicine.”
  

• **Sepsis is the third leading cause of death. Can a new blood test change that?** “Sepsis kills over 250,000 people a year in the United States — more than any cause other than cancer and heart disease. But still, many people have never heard of it. And hospitals often fail to notice the warning signs when a patient is spiraling downward. It’s a complex condition, and researchers are pursuing various avenues to reduce deaths. Last month, for instance, the Food and Drug Administration gave market clearance to a new test that will more rapidly identify the bug triggering a patient’s infection, potentially allowing doctors to give more targeted antibiotics. The detector, from T2 Biosystems, of Lexington, Mass., finds and identifies the extremely rare bacterial cells in blood samples, rather than having to culture bacteria in a lab dish, which can take days.”
  

• **Criminal prosecution for violating HIPAA: an emerging threat to health care professionals.** “The term ‘HIPAA violation’ can conjure up images of large-scale data breaches. But health care providers need to be aware that, in the midst of the federal
government’s increased focus on fraud in the health care sector, the privacy rule of the Health Insurance Portability and Accountability Act (HIPAA) is an emerging source of criminal liability. Prosecutions for HIPAA privacy violations are on the rise, possibly because they can be far easier for federal prosecutors to prove — and less conceptually complex for a jury to understand — than schemes involving kickbacks, misbranding, or false claims. The elements for demonstrating criminal liability under the privacy rule are straightforward, making violations easier for prosecutors to prove. Any provider who violates the privacy rule by knowingly using or obtaining individually identifiable health information or discloses it to someone else may be punished by a fine, prison time, or both.”

- Read more: https://www.statnews.com/2018/07/02/criminal-prosecution-violating-hipaa/

- **As drug resistance grows, combining antibiotics could turn up new treatments.**
  “Combining certain antibiotics could help them pack a one-two punch against harmful bacteria, according to a new study published Wednesday in Nature. Nassos Typas and his colleagues at the European Molecular Biology Laboratory in Germany tested 3,000 different combinations of antibiotics with each other or with drugs, food additives, and other compounds on three common types of bacteria that infect humans. They turned up hundreds of combinations that made antibiotic treatment more effective (along with many that didn’t). Pairs of drugs that targeted the same cellular processes were much more likely to be successful than combinations that worked in two different ways.”

- **Low quality healthcare is increasing the burden of illness and health costs globally.**
  “Poor quality health services are holding back progress on improving health in countries at all income levels, according to a new joint report by the OECD, World Health Organization (WHO) and the World Bank. Today, inaccurate diagnosis, medication errors, inappropriate or unnecessary treatment, inadequate or unsafe clinical facilities or practices, or providers who lack adequate training and expertise prevail in all countries. These are just some of the highlights from Delivering Quality Health Services – a Global Imperative for Universal Health Coverage. The report also highlights that sickness associated with poor quality health care imposes additional expenditure on families and health systems.”

- **Nurses take on expanded roles to provide access to health care in rural, underserved areas.** “To help address access to health care for rural and underserved areas, registered nurses can take on expanded roles in primary care delivery. ‘Nurses can practice to the full scope of the RN license and expand their scope of influence within the community-based primary care team,’ said South Dakota State University Associate Nursing Professor Heidi Mennenga. She pointed to care management, such as the hospital-to-home transition or management of chronic health conditions, and management of warfarin, a prescription medication designed to prevent blood clots, as examples.
However, many registered nurses have not been fulfilling these roles which are within the scope of their licensing simply because they have not historically done so.”

- Read more: [https://www.news-medical.net/news/20180704/Nurses-take-on-expanded-roles-to-provide-access-to-health-care-in-rural-underserved-areas.aspx](https://www.news-medical.net/news/20180704/Nurses-take-on-expanded-roles-to-provide-access-to-health-care-in-rural-underserved-areas.aspx)

- **Drugmakers defy Trump’s call to drop prices.** “President Donald Trump in May said that drugmakers would soon announce ‘massive’ price cuts, and his administration rolled out a plan to bring down the cost of medicines. But the companies don’t appear to have gotten that message. Bayer raised the price of two cancer drugs by hundreds of dollars in May and Novartis followed by boosting four pricey treatments in June. Pfizer, one of the largest U.S. pharmaceutical companies, announced increases on more than 41 products this week. They weren't alone.”