American Nephrology Nurses Association

Weekly Capitol Hill Update – Monday, August 13, 2018

Congressional Schedule

Senate

• Senate in recess; returns August 15

House

• House in recess until September 4

Legislative Update

• Week in Review
  o Top Republicans concerned over impact of potential Trump drug rule. “Two top Republicans are urging the White House to complete a thorough economic analysis before releasing a new policy that could completely upend the way prescription drugs are purchased. In a letter to Office of Management and Budget (OMB) Director Mick Mulvaney, House Energy and Commerce Committee Chairman Greg Walden (R-Ore.) and Senate Finance Committee Chairman Orrin Hatch (R-Utah) said they want a full analysis of a pending proposed rule regarding prescription drug rebates. The proposed rule is part of the administration’s efforts to bring down the costs of prescription drugs. The rule, which is currently under review by the OMB, could remove the legal protection of rebates paid by drug companies to insurers and pharmacy benefit managers.”

• Week Ahead
  o Senate returns to session on August 15; House is in recess until September 4

Regulatory and Administration Update

• ESRD Quality Incentive Program: CY 2019 ESRD PPS Proposed Rule Call. “During this call, learn about proposals for the End Stage Renal Disease Quality Incentive Program (ESRD QIP) in the CY 2019 ESRD Prospective Payment System (PPS) proposed rule.
Topics include: ESRD QIP legislative framework; Proposed updates to ESRD QIP measures, domain structure, and weights; Proposed modifications to data submission requirements and the National Healthcare Safety Network Validation Study; Methods for reviewing and commenting on the proposed rule. Please note: This call will not include a question and answer session. Target Audience: Dialysis clinics and organizations, nephrologists, hospitals with dialysis units, billers/coders, quality improvement experts, and other stakeholders.”

- **Medicare and Medicaid Programs: National Dialysis Accreditation Commission (NDAC) for approval of its End Stage Renal Disease (ESRD) Facility Accreditation Program.** “This proposed notice acknowledges the receipt of an application from the National Dialysis Accreditation Commission (NDAC) for recognition as a national accrediting organization (AO) for End Stage Renal Disease (ESRD) Facilities that wish to participate in the Medicare or Medicaid programs.”

- **National Institute of Diabetes and Digestive and Kidney Diseases Notice of Meetings.** “Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council. The meetings will be open to the public as indicated below, with attendance limited to space available. Date: September 7, 2018. Open: 8:30 a.m. to 12:00 p.m. Agenda: To present the Director’s Report and other scientific presentations. Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 10, 31 Center Drive, Bethesda, MD 20892. Closed: 1:00 p.m. to 4:30 p.m.”

- **FDA will broaden how it evaluates new addiction treatment drugs.** “The Food and Drug Administration on Monday announced a shift in the way it evaluates drugs to treat opioid addiction that the agency says will give it more flexibility to approve new treatments. Now, rather than merely examining whether a potential treatment reduces opioid use, the agency will consider factors like whether a drug could reduce overdose rates or the transmission of infectious diseases.”

- **Trump says will make announcement next week on reducing drug prices.** “U.S. President Donald Trump said on Tuesday that his administration would make an announcement next week on reducing drug prices, but he did not offer specifics. Trump has made lowering the cost of prescription drugs an issue for his administration.”
• **Trump administration gives insurers power to lower Medicare drug prices.** “Insurers participating in Medicare Advantage will be able to negotiate directly with drugmakers in an effort to lower the cost of prescription medications under a new policy announced by the Trump administration. The policy aims to allow Medicare Advantage plans access to the same tools as private insurers to try to lower the costs of treatments delivered in a physician's office or hospital under Medicare Part B.”

• **Trump admin urges states to cooperate on expansion of non-ObamaCare plans.** “Health and Human Services Secretary Alex Azar on Thursday urged states to cooperate with the Trump administration's expansion of "short-term" health plans outside of ObamaCare. Several state regulators have moved to restrict the sales of these plans in their states, arguing that, despite being less expensive than ObamaCare plans, they’re bad for consumers and aren’t an adequate substitute for comprehensive insurance. Unlike plans sold under ObamaCare, the administration's short-term health plans do not have to cover services like maternity care or prescription services, and they can deny coverage to people with pre-existing conditions.”

• **FDA approves first-ever RNAi-based therapy.** “The Food and Drug Administration on Friday approved a landmark rare disease treatment — the first to rely on a Nobel-prize-winning technique known as RNA interference, which silences disease-causing genes. The approval is a major accomplishment for Cambridge, Mass.-based Alnylam, which will be marketing the drug, patisiran, as Onpattro and which has been working to bring an RNAi-based therapy to market for more than a decade.”

• **Patient groups rattled by new Medicare power to negotiate lower drug prices.** “A new federal policy intended to drive down drug prices could have a negative effect on patients, particularly those with chronic conditions, according to health advocates. The policy announced Tuesday by the Department of Health and Human Services will give some private insurers the option to require patients try cheaper drugs before turning to more expensive ones, regardless of what their doctor prescribes.”

**Articles of Interest**

• **Medicaid eligibility expansions may address gaps in access to diabetes medications.** “Diabetes is a top contributor to the avoidable burden of disease. Costly diabetes
medications, including insulin and drugs from newer medication classes, can be inaccessible to people who lack insurance coverage. In 2014 and 2015 twenty-nine states and the District of Columbia expanded eligibility for Medicaid among low-income adults. To examine the impacts of Medicaid expansion on access to diabetes medications, we analyzed data on over ninety-six million prescription fills using Medicaid insurance in the period January 2008–December 2015. Medicaid eligibility expansions were associated with thirty additional Medicaid diabetes prescriptions filled per 1,000 population in 2014–15, relative to states that did not expand Medicaid eligibility. Age groups with higher prevalence of diabetes exhibited larger increases. The increase in prescription fills grew significantly over time. Overall, fills for insulin and for newer medications increased by 40 percent and 39 percent, respectively. Our findings suggest that Medicaid eligibility expansions may address gaps in access to diabetes medications, with increasing effects over time."

- **Twelve-month outcomes after transplant of Hepatitis C-infected kidneys into uninfected recipients: A single group trial.** "Background: Organs from hepatitis C virus (HCV)-infected deceased donors are often discarded. Preliminary data from 2 small trials, including THINKER-1 (Transplanting Hepatitis C kidneys Into Negative KidnEy Recipients), suggested that HCV-infected kidneys could be safely transplanted into HCV-negative patients. However, intermediate-term data on quality of life and renal function are needed to counsel patients about risk. Conclusion: Twenty HCV-negative recipients of HCV-infected kidneys experienced HCV cure, good quality of life, and excellent renal function. Kidneys from HCV-infected donors may be a valuable transplant resource."

- **2018’s Best & worst states for health care.** “According to the CDC, 88.1 percent of the population has a regular place to go for medical care. But the cost and service quality of that care can vary widely from state to state. The overall health of the population, more advanced medical equipment and a general lack of awareness regarding the best types of treatment, for instance, can all affect costs. Today, the average American spends more than $10,000 per year on personal health care, according to the most recent estimates from the Centers for Medicare & Medicaid Services. That’s about 17.9 percent of the U.S. GDP. Conditions aren’t uniform across the U.S., though. To determine where Americans receive the best and worst health care, WalletHub compared the 50 states and the District of Columbia across 40 measures of cost, accessibility and outcome. Read on for our findings, expert insight on the future of American health care and a full description of our methodology."

- **Can a phone app’s warning to avoid risky friends and places prevent opioid addiction relapses?** “You’re in recovery from opioid addiction, and your walk to work takes you down the same streets where you used to buy heroin. The drug’s calling to you, still. Just then, your phone buzzes, with a message that reads like a text from an old friend: ‘Hey, I know you’re near a risky area. You can do this.’ It’s from Hey,Charlie, an app —
conceived at a 2016 Massachusetts Institute of Technology health hackathon — that aims to help people avoid environmental triggers that might threaten their recovery from an opioid addiction. The app, now being piloted by several treatment centers in Boston and Framingham, Mass., monitors a user’s contacts and location, and sends pop-up notifications to caution them about risky acquaintances or neighborhoods.”

- **Responsive parenting intervention promotes healthy weight in young children.** “An intervention designed to promote healthy growth that taught first-time moms how to respond with age-appropriate responses to their babies’ needs resulted in children having lower body mass indexes (BMIs) when they were three years old. The intervention, which began shortly after the babies’ birth, taught moms various strategies for taking care of their babies when they were drowsy, sleeping, fussy, eating and playing. The researchers said having a healthy BMI early in life is an important factor in preventing obesity across their lifetime.”

- **Health care sharing ministries: what are the risks to consumers and insurance markets?** “Issue: Health care sharing ministries (HCSMs) are a form of health coverage in which members — who typically share a religious belief — make monthly payments to cover expenses of other members. HCSMs do not have to comply with the consumer protections of the Affordable Care Act and may provide value for some individuals, but pose risks for others. Although HCSMs are not insurance and do not guarantee payment of claims, their features closely mimic traditional insurance products, possibly confusing consumers. Because they are largely unregulated and provide limited benefits, HCSMs may be disproportionately attractive to healthy individuals, causing the broader insurance market to become smaller, sicker, and more expensive.”

- **Doctors nudged by overdose letter prescribe fewer opioids.** “In a novel experiment, doctors got a letter from the medical examiner’s office telling them of their patient’s fatal overdose. The response: They started prescribing fewer opioids. Other doctors, whose patients also overdosed, didn’t get letters. Their opioid prescribing didn’t change. More than 400 ‘Dear Doctor’ letters, sent last year in San Diego County, were part of a study that, researchers say, put a human face on the U.S. opioid crisis for many doctors.”

- **Surgery centers don’t have to report deaths in 17 states.** “A USA TODAY NETWORK and Kaiser Health News investigation found that surgery centers operate under such an uneven mix of rules across U.S. states that fatalities or serious injuries can result in no warning to government officials, much less to potential patients. The gaps in oversight enable centers hit with federal regulators’ toughest sanctions to keep operating, according to interviews, a review of hundreds of pages of court filings and government
records obtained under open records laws. No rule stops a doctor exiled by a hospital for misconduct from opening a surgery center down the street.”