

## American Nephrology Nurses Association

Weekly Capitol Hill Update - Tuesday, July 2, 2019

### Congressional Schedule

#### Senate

- Senate is out of session all week

#### House

- House is out of session all week

### Legislative Update

- **Week in Review**
  - *Senate HELP Committee passes Lower Health Care Costs Act:* “The Senate Committee on Health, Education, Labor and Pensions today voted 20-3 to pass the Lower Health Care Costs Act (S.1895) – bipartisan legislation focused on reducing health care costs. The bill would hold patients harmless from surprise medical bills, but use a benchmark rate to resolve payments between plans and out-of-network providers. During the mark up, Sens. Bill Cassidy, R-La., Lisa Murkowski, R-Alaska, Rand Paul, R-Ky., and Mitt Romney, R-Utah, expressed concerns about unintended consequences of using a benchmark rate. Sens. Cassidy and Murkowski specifically discussed how a benchmark rate could threaten access to care in rural areas.”
    - <https://www.aha.org/news/headline/2019-06-26-senate-help-committee-passes-lower-health-care-costs-act>
  - *Senate Finance leaders in talks on deal to limit drug price increases:* “The leaders of the Senate Finance Committee are in bipartisan talks on a potentially sweeping deal to limit drug price increases in Medicare, according to sources familiar with the negotiations. Sen. Ron Wyden (Ore.), the top Democrat on the panel, is pushing to make drug companies pay back rebates to Medicare’s prescription drug program, called Part D,

if their prices rise faster than inflation. Another measure would force drug companies to pay money back to Medicare if they launch a new drug with a high price.”

- <https://thehill.com/policy/healthcare/450341-senate-finance-leaders-in-talks-on-deal-to-limit-drug-price-increases>

### Regulatory and Administration Update

- ***FDA warns patients and health care providers about potential cybersecurity concerns with certain Medtronic insulin pumps:*** “The U.S. Food and Drug Administration is warning patients and health care providers that certain Medtronic MiniMed insulin pumps are being recalled due to potential cybersecurity risks and recommends that patients using these models switch their insulin pump to models that are better equipped to protect against these potential risks. To date, the FDA is not aware of any confirmed reports of patient harm related to these potential cybersecurity risks.
  - <https://www.fda.gov/news-events/press-announcements/fda-warns-patients-and-health-care-providers-about-potential-cybersecurity-concerns-certain>
- ***The Trump administration is quietly helping people get kidneys:*** “The Office of Information and Regulatory Affairs (OIRA), housed in the White House budget office, is often described as the most important federal agency you’ve never heard of. Its job is to evaluate, alter, delay, reject, and otherwise administer regulations making their way through the government. So you can imagine my joy upon discovering that not one but two rules that would increase the availability of kidneys and other organs for people who need transplants are on OIRA’s docket, set to be addressed in September. These obscure rules have the potential to save thousands of lives.”
  - <https://www.vox.com/future-perfect/2019/6/26/18744536/kidney-transplant-requirements-rules-trump-white-house>

### Articles of Interest

- ***Diabetes-coaching startup Livongo files to go public in a test for health tech:*** “Livongo, a startup that monitors and coaches patients with chronic diseases, on Friday filed papers to launch its initial public offering, in what is seen as a litmus test for health-tech companies seeking to translate early growth into value in the public markets. The offering is expected to be among the first for a new generation of slick and savvy venture-backed companies in the U.S. digital health sector, which hasn’t produced an IPO since 2016. (Another such company, medical records data startup Health Catalyst, filed to go public on Thursday.) Livongo’s offering had been anticipated for several months, as the company has

been expanding rapidly and running studies to try to show that its services can improve patients' outcomes and save their employers money."

- <https://www.statnews.com/2019/06/28/diabetes-coaching-startup-livongo-files-to-go-public-in-a-test-for-health-tech/>

- ***Insulin rationing higher among US diabetics than worldwide rate, survey finds:***

"In the latest indication of how some people are struggling to afford their medicines, a new survey finds that 18 percent of people who have diabetes around the world rationed their insulin at least once last year, but this occurred among nearly 26 percent of people with diabetes in the US. And although 70 percent reported having some coverage for their costs, two-thirds noted they have no financial support for the remaining out-of-pocket costs. In the US, 89 percent of people with diabetes had health care coverage, but 79 percent had no other form of assistance. Just 5.5 percent received government assistance, according to the survey by T1 International, a patient advocacy group that focuses on Type 1 diabetes."

- <https://www.bostonglobe.com/business/2019/06/21/insulin-rationing-higher-among-diabetics-than-worldwide-rate-survey-finds/s5mCCsNGwoWRE8pJenSZ2N/story.html>

- ***U.S. CPT® Code Granted for KidneyIntelX™:*** "NEW YORK, July 1, 2019 /PRNewswire/ -- Renalytix AI plc (RENX.L), a developer of artificial intelligence-enabled clinical diagnostics for kidney disease, announced today that the American Medical Association (AMA) has granted a CPT® Proprietary Laboratory Analyses (PLA) Code for its lead product, KidneyIntelX™. The new code, 0105U, has been approved and published by the AMA CPT Editorial Panel, and is scheduled to become effective on October 1, 2019. A payment rate for the new code will be established for Medicare patients through the 2019 Clinical Lab Fee Schedule (CLFS) Annual Public Meeting process. Renalytix AI will shortly provide comments and a recommendation on the appropriate basis for establishing a national Medicare price for this new CPT code expected to be effective January 1, 2020."

- <https://finance.yahoo.com/news/u-cpt-code-granted-kidneyintelx-123000641.html>

- ***Oregon passes landmark living donor protection act:*** "Oregon has made giant strides to protect living organ donors from discrimination, encouraging living donation and decreasing the wait time for transplant candidates with passage of Senate Bill 796. Nearly 114,000 people are waiting for a lifesaving organ transplant according to data from the United Network for Organ Sharing (UNOS). The benefits of receiving a transplant from living donors far outweigh those from deceased donors. In addition to decreasing the wait time, organs from living donors tend to survive longer in their new environment and recipients

experience fewer complications post-transplant. The average wait time for transplant candidates ranges between 3 to 5 years; 22 people die each day while waiting for a transplant. Currently, 851 Oregonians are waiting for a lifesaving organ donation.”

- <http://www.kidneyfund.org/news/news-releases/oregon-passes-living-donor-protection.html>

- ***The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program:*** “Medicare’s End-Stage Renal Disease Quality Incentive Program is a mandatory pay-for-performance program for US dialysis facilities, in which facilities are penalized up to 2 percent of their total Medicare payments based on their performance on quality metrics. While analyses of similar programs in other settings have shown performance to be related to social risk factors, it is unknown whether this program displays similar patterns. In this national study, facilities located in low-income ZIP codes and with high proportions of patients who were black or dually enrolled in Medicaid had lower performance scores and higher rates of penalization under the program. Independent (versus chain) status, large facility size, and urban location were also associated with penalties. Further study is needed to determine the degree to which these patterns reflect low-quality care delivery versus patient factors beyond providers’ control. In the meantime, the impact of these penalties on providers serving vulnerable populations should be tracked closely.”

- <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05406>

- ***Drug prices in 2019 are surging, with hikes at 5 times inflation:*** “Price hikes on prescription drugs are surging in 2019, despite vows from lawmakers and the Trump administration to rein in pharmaceutical costs. So far in 2019, more than 3,400 drugs have boosted their prices, a 17% increase compared with the roughly 2,900 drug price increases at the same time in 2018, according to a new analysis by Rx Savings Solutions, a consultant to health plans and employers. The average price hike for those 3,400 drugs stands at 10.5%, or about 5 times the rate of inflation, the study found. About 41 drugs have boosted their prices by more than 100%, including one version of the antidepressant fluoxetine -- also known as Prozac -- whose cost has surged 879%, Rx Savings Solutions said.”

- <https://www.cbsnews.com/news/drug-prices-in-2019-are-surging-with-hikes-at-5-times-inflation/>