

## American Nephrology Nurses Association

Weekly Capitol Hill Update - Tuesday, August 2, 2016

### Congressional Schedule

#### House and Senate

- Not in session. Lawmakers will return after Labor Day.

### Legislative Updates

- ***House Dems Call for Stronger Nursing Home Standards.*** “Nearly three dozen House Democrats are urging the Centers for Medicare and Medicaid Services (CMS) to strengthen proposed regulations for nursing homes. Their urging comes as a final rule updating quality standards for nursing homes is expected to be released by CMS in September. The rule will update the standards for the first time in more than two decades. The letter, signed by 32 lawmakers, was sent last week. Led by Rep. Jan Schakowsky (D-IL), the lawmakers are calling on CMS to require nursing homes to have a registered nurse on staff 24-7, prohibit pre-dispute arbitration clauses when patients are admitted to the facilities, address the use of antipsychotics and other similar drugs and allow residents who have been denied readmission to a facility the right to appeal that decision. ‘These are a few of the critical issues that we believe must be resolved as CMS promulgates changes that will have a significant and lasting effect on the safety and well-being of millions of current and future nursing home residents, as well as the integrity of the publicly funded programs that pay for a majority of nursing home care,’ they write. ‘Given the acknowledged need to improve both resident care and program integrity, we call on CMS to take concrete steps to ensure that resident safety and resident rights are safeguarded throughout the transition period.’” (Morning Consult)
  - For the letter, please see the following link: <https://morningconsult.com/wp-content/uploads/2016/07/Final-Letter-to-CMS-on-LTC-Rule-July-2016.pdf>

### Regulatory Updates

- ***CMS Releases Final Fiscal Year 2017 Payment and Policy Changes for Skilled Nursing Facilities.*** “On July 29, 2016, the Centers for Medicare & Medicaid Services (CMS) issued a final rule outlining fiscal year (FY) 2017 Medicare payment policies and rates for the Skilled Nursing Facility Prospective Payment System (SNF PPS), the SNF Quality Reporting Program (SNF QRP), and the SNF Value-Based Purchasing (SNF VBP) Program. The policies in the final rule continue to shift Medicare payments from volume

to value. The Administration has set measurable goals and a timeline to move the Medicare program, and the health care system at large, toward paying providers based on the quality, rather than the quantity of care they provide to their patients. This final rule includes policies that advance that vision and support building a health care system that delivers better care, spends health care dollars more wisely, and results in healthier people.”

- To view the full fact sheet on the rule, please visit:  
<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-29.html>
- ***CMS Releases Final Fiscal Year 2017 Payment and Policy Changes for Inpatient Rehabilitation Facilities.*** “On July 29, 2016, the Centers for Medicare & Medicaid Services (CMS) issued a final rule outlining fiscal year (FY) 2017 Medicare payment policies and rates for the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS) and the IRF Quality Reporting Program (IRF QRP).”
  - To view the full fact sheet on the rule, please visit:  
<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-29-3.html>
- ***CMS Announces Next Phase in Largest-Ever Initiative to Improve Primary Care in America.*** “Today, the Centers for Medicare & Medicaid Services (CMS) opened the application period for practices to participate in the new nation-wide primary care model, Comprehensive Primary Care Plus (CPC+). CPC+ is a five-year primary care medical home model beginning January 2017 that will enable primary care practices to care for their patients the way they think will deliver the best outcomes and to pay them for achieving results and improving care. CPC+ is an opportunity for practices of diverse sizes, structures, and ownership who are interested in qualifying for the incentive payment for Advanced Alternative Payment Models through the proposed Quality Payment Program. CMS estimates that up to 5,000 primary care practices serving an estimated 3.5 million beneficiaries could participate in the model. CPC+ is a public-private partnership in 14 regions across the nation. CPC+ is a multi-payer model Medicare, state Medicaid agencies, and private insurance companies partner together to support primary care practices - so CMS selected the regions based on payer interest and coverage. By aligning Medicare, Medicaid, and private insurance, CPC+ moves the health care system away from one-size-fits-all, fee-for-service to a model that supports clinicians delivering the care that best meets the needs of their patients and improves health outcomes.”
  - To view the full press release, please visit:  
<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-01.html>
- ***CMS Releases Controversial Overall Star Ratings on Hospital Quality.*** “CMS on Wednesday released its star ratings for individual providers on its Hospital Compare website. Last week, CMS said 102 hospitals earned five stars in its update, while 934 scored four stars; 1,770 three stars; 723 two stars; and 133, one star. The analysis shows that all types of systems have both high performing and low performing hospitals, according to a blog released Wednesday by Kate Goodrich, M.D., director of Center for

Clinical Standards and Quality for CMS. Researchers found that hospitals with more stars on the Hospital Compare website tended to have lower death and readmission rates, she said. CMS had delayed the release of the star ratings due to concerns from providers over the methodology used and in particular, what providers said was CMS's failure to account for the sociodemographic characteristics of the patients they serve. In April, 60 U.S. Senators added their voices by sending a letter to Centers for Medicare and Medicaid Services Acting Administrator Andy Slavitt asking him to delay the release of the rankings until CMS could include factors for patients' income-level and other socioeconomic indicators."

- For the full article, please see the following link:

<http://www.healthcarefinancenews.com/news/cms-releases-controversial-overall-star-ratings-hospital-quality>

- ***CMS Extends, Expands Fraud-Fighting Enrollment Moratoria Efforts in Six States.*** On Friday, "CMS announced an extension and statewide expansion of fraud-fighting temporary provider enrollment moratoria efforts in six states, along with a new related demonstration project to allow for certain exceptions to the moratoria and heightened screening requirements for new providers. CMS also announced it is immediately lifting the current temporary moratoria on all Medicare Part B, Medicaid, and Children's Health Insurance Program (CHIP) emergency ground ambulance suppliers. 'CMS is continuing its efforts to tackle fraud, waste, abuse and protect benefits and services for those eligible for federal health care programs through expanding the existing temporary moratoria,' said Shantanu Agrawal, M.D., deputy administrator for program integrity, CMS. 'CMS is also increasing its oversight efforts through the use of heightened screening and investigative tools for new providers in the moratoria areas.' CMS announced it is extending for six months and expanding statewide the temporary provider enrollment moratoria on new Medicare Part B non-emergency ground ambulance suppliers in New Jersey, Pennsylvania, and Texas and home health agencies (HHAs) in Florida, Texas, Illinois, and Michigan. Additionally, the statewide expansion also applies to Medicaid and CHIP. CMS also announced the Provider Enrollment Moratoria Access Waiver Demonstration (PEWD), which gives CMS the ability to allow for provider and supplier enrollment exceptions in the moratoria areas if access to care issues are identified and for the development and improvement of methods of investigating and prosecuting fraud in Medicare, Medicaid, and CHIP."

- For the full press release, please see the following link:

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-07-29-2.html>

- ***Medicare Projects Relatively Stable Average Prescription Drug Premiums in 2017.*** Last week, "Medicare announced that the average basic premium for a Medicare Part D prescription drug plan in 2017 is projected to remain relatively stable at an estimated \$34 per month. This represents an increase of approximately \$1.50 over the actual average premium of \$32.56 in 2016. 'Stable Medicare prescription drug plan premiums help seniors and people with disabilities afford their prescription drugs,' said Andy Slavitt, Acting Administrator of CMS. 'However, I remain increasingly concerned about the rising cost of drugs, especially high-cost specialty drugs, and the impact of these costs on the Medicare program.' The stability in average basic Medicare Part D premiums for

enrollees comes despite the fact that Part D costs continue to increase faster than other parts of Medicare, largely driven by high-cost specialty drugs and their effect on spending in the catastrophic benefit phase. Although private prescription drug plans receive capitated payments for portions of the Part D benefit, Medicare is directly responsible for 80 percent of the cost of drugs purchased by beneficiaries while in the catastrophic benefit phase. As the recent 2016 Medicare Trustees report noted, growth in the costs of prescription drugs paid by Medicare continue to exceed growth in other Medicare costs and overall health expenditures. Medicare Part D expenditures per enrollee are estimated to increase by an average of 5.8 percent annually through 2025, higher than the combined per-enrollee growth rate for Medicare Parts A and B (4.0 percent). The report found that these costs are trending higher than previously predicted, particularly for specialty drugs. In addition, a March 2016 HHS report provided a detailed analysis of high-cost prescription drug spending trends.”

- For the full press release, please see the following link:  
<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-07-29.html>
- ***KCQA Measure Considered by National Quality Forum (NQF).*** On July 27, the Kidney Car Quality Alliance’s (KCQA) measure, NQF #2988: *Medication Reconciliation for Patients Receiving Care at Dialysis Facilities*, was reviewed for endorsement consideration by the NQF’s Patient Safety Standing Committee.
  - For more information, please see the following link:  
<http://www.qualityforum.org/ProjectMeasures.aspx?projectID=80757>
- ***The Future of Medical Device Manufacturing Is Here: FDA Issues Draft Guidance on Technical Considerations for 3D Printing.*** “A few years ago, a custom-fabricated bioresorbable tracheal splint saved the life of an infant suffering from a collapsed bronchus due to severe tracheobronchomalacia. The splint was implanted around the baby’s airway, expanding the bronchus and giving it a skeleton to assist with proper growth. Twenty-one days later, the baby was off ventilator support and breathing normally. The splint was the product of 3D printing (also known as additive manufacturing or AM). The U.S. Food and Drug Administration (FDA) and industry are currently grappling with how to address the unique issues related to 3D printing and its rapidly growing application in healthcare. While the implantable splint described above was for many people their first introduction to medical uses of 3D printing, other applications have included custom prosthetic limbs, hearing aids, drug formation, and human kidney tissue, and recent reports predict that the global 3D printing medical/healthcare market will exceed \$2.8 billion by 2022. In May 2016, FDA issued its much-anticipated draft guidance, ‘Technical Considerations for Additive Manufactured Devices,’ providing its ‘initial thinking’ on design, manufacturing, and device testing considerations related to AM devices.”
  - For the full article, please see the following link: <http://www.klgates.com/the-future-of-medical-device-manufacturing-is-here-fda-issues-draft-guidance-on-technical-considerations-for-3d-printing-07-29-2016/>

### Articles of Interest

- ***Potential Implications of Recent and Proposed Changes in the Regulatory Oversight of Solid Organ Transplantation in the United States.*** “Every 6 months, the Scientific Registry of Transplant Recipients (SRTR) publishes evaluations of every solid organ transplant program in the United States, including evaluations of 1-year patient and graft survival. CMS and the Organ Procurement and Transplantation Network (OPTN) Membership and Professional Standards Committee (MPSC) use SRTR's 1-year evaluations for regulatory review of transplant programs. Concern has been growing that the regulatory scrutiny of transplant programs with lower-than-expected outcomes is harmful, causing programs to undertake fewer high-risk transplants and leading to unnecessary organ discards. As a result, CMS raised its threshold for a “Condition-Level Deficiency” designation of observed relative to expected 1-year graft or patient survival from 1.50 to 1.85. Exceeding this threshold in the current SRTR outcomes report and in one of the four previous reports leads to scrutiny that may result in loss of Medicare funding. For its part, OPTN is reviewing a proposal from the MPSC to also change its performance criteria thresholds for program review, to review programs with ‘substantive clinical differences.’ We review the details and implications of these changes in transplant program oversight.”
  - For the full article, please see the following link: <http://onlinelibrary.wiley.com/doi/10.1111/ajt.13955/full>
- ***Long-Term Care Is An Immediate Problem – For The Government.*** “Experts estimate that about half of all people turning 65 today will need daily help as they age, either at home or in nursing homes. Such long-term care will cost an average of about \$91,000 for men and double that for women, because they live longer. In California and across the U.S., many residents can’t afford that, so they turn to Medicaid, the nation’s public health insurance program for low-income people. As a result, Medicaid has become the safety net for millions of people who find themselves unable to pay for nursing home beds or in-home caregivers. This includes middle-class Americans, who often must spend down or transfer their assets to qualify for Medicaid coverage. Medicaid, known as Medi-Cal in California, was never intended to cover long-term care for everyone. Now it pays for nearly 40 percent of the nation’s long-term care expenses, and the share is growing. As Baby Boomers age, federal Medicaid spending on long-term care is widely expected to rise significantly – by nearly 50 percent by 2026. The pressure will only intensify as people age, so both state and federal officials are scrambling to control spending.”
  - For the full article, please see the following link: <http://bit.ly/2aHnLKH>
- ***New Florida Zika Cases Prompt Miami Travel Warning.*** “Florida confirmed Monday 10 more homegrown cases of Zika in people infected by local mosquitoes, leading federal health officials to advise women who are pregnant or considering becoming pregnant to avoid the area just north of downtown Miami where Zika is spreading. That's the first time that the Centers for Disease Control and Prevention (CDC) has warned people to avoid an American neighborhood because of an outbreak for at least 25 years, said Tom Skinner, a CDC spokesman. The new Zika cases in Miami bring the number of Zika infections spread by local mosquitoes – as opposed to foreign travel – to 14. According

to the CDC, 1,658 people in the continental U.S. and Hawaii have been diagnosed with Zika. The local cases in Miami are a major development, because – with the exception of one Zika case related to a lab accident – all of the Zika infections in the U.S. until now have been diagnosed in people who traveled abroad or in people who had sex with a traveler. Although Zika is largely spread by mosquitoes, both men and women can transmit the virus sexually. The Florida Zika outbreak so far is limited to a 1-square-mile area just north of downtown Miami, Gov. Rick Scott said Monday. Six of the 10 people infected with Zika had no symptoms and were identified through door-to-door community outreach, according to Florida officials.”

- For the full article, please see the following link:

<http://www.usatoday.com/story/news/2016/08/01/florida-announces-10-more-homegrown-zika-cases/87910664/>

- *Zika is Spreading Exclusively in Puerto Rico, Report Says.* “The widespread Zika outbreak in Puerto Rico is exploding at an alarming rate, with the number of people infected jumping by nearly nine times between February and June, according to a report released Friday by the CDC. CDC officials said the rapid rise could lead to hundreds of infants being born with microcephaly or other severe birth defects in the coming year. Noting the ‘widespread and accelerating increase’ in cases, the report provides several indicators that show how quickly infections are spreading, especially among pregnant women, who face the greatest risk. As of July 7, Zika had been diagnosed in 5,582 people, including 672 pregnant women, the report said. Positive tests for people with suspected Zika virus infection have increased from 14 percent in February to 64 percent in June. Screening of the blood supply also turned up a 1.8 percent infection rate during the latest week of reporting, which started July 3. The numbers are likely to be underestimates because 4 out of 5 people infected with Zika don’t have symptoms and don’t seek medical care or are not reported to public health officials. People without symptoms can still pass the virus to mosquitoes that bite and infect other people, and asymptomatic people might unknowingly transmit the virus through sexual contact.”

- For the full article, please see the following link: <http://wapo.st/2aoVY3E>