

American Nephrology Nurses Association

Weekly Capitol Hill Update - Tuesday, April 19th, 2016

Congressional Schedule

House

- “Convened at 2 p.m. on Monday for consideration of eight measures under suspension of the rules, including a resolution (H.Con.Res. 119) that would authorize using Capitol Grounds for the Greater Washington Soap Box Derby. Votes were postponed until 6:30 p.m.” (CQ)
- **Week Ahead:** “On Tuesday, the House meets at 12 p.m. to consider seven bills under suspension of the rules, including a resolution (H.Res. 673) that would require the Internal Revenue Service to supply taxpayers with a free copy of rules for filing a tax return. On Wednesday and Thursday, the House is expected to take up a number of Internal Revenue Service (IRS) related measures, including a bill (H.R. 4890) that would bar the agency's employees from receiving bonuses until the Treasury secretary implements a customer service strategy.” (CQ)

Senate

- “On Monday, the Senate convened at 3 p.m. and at 5:30 p.m. was expected to adopt a substitute amendment that would reauthorize the Federal Aviation Administration (FAA), followed by a debate-limiting cloture vote on the underlying bill (H.R. 636). A cloture motion is also pending on the motion to proceed to the Senate Energy-Water spending bill (S. 2804), using a House-passed shell bill (HR 2028) in order to avoid certain procedural hurdles.” (CQ)

Legislative Updates

- **The Week Ahead.** The Senate Health, Education, Labor and Pensions (HELP) Committee continues to work on mental health reform and the Senate Innovation Package, the companion to the *House 21st Century Cures Act*. Senate Democrats continue to fight for mandatory funding for the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) as part of the Innovation legislation. HELP Chairman Alexander will likely follow suit of the House counterpart, which would provide \$8.8 billion over five years to NIH. Senate Democrats meanwhile have called for \$50 billion over ten years. The House Energy and Commerce Committee will mark-up twelve bills on the

opioids epidemic as a counterpart to the Senate-passed Comprehensive Addiction and Recovery Act (CARA).

- ***Reps. Marino, Welch, Blackburn and Chu Applaud Passage of Prescription Drug Enforcement Legislation.*** “Rep. Tom Marino (PA-10), Rep. Peter Welch (VT-AL), Rep. Marsha Blackburn (TN-07) and Rep. Judy Chu (CA-27) applauded the passage of the *Ensuring Patient Access and Effective Drug Enforcement Act of 2016* (S. 483/H.R. 471). This legislation is expected to be the first significant bill of the 114th Congress enacted to address prescription drug diversion. This bill, as amended by the Senate, passed the House by unanimous consent today and now awaits the president’s signature. It offers a critical and comprehensive approach to combat prescription drug abuse by increasing collaboration between the Drug Enforcement Agency (DEA), prescription drug distributors, and pharmacies. The bill received overwhelming bipartisan support and included strong protections for patients’ access to important medicines. It also directs intergovernmental agency collaboration between the Department of Health and Human Services (HHS), the Office of National Drug Control Policy (ONDCP), and the DEA to preserve patient accessibility and better implement drug abuse enforcement.”
 - To view the full press release, please see the following link:
<https://marino.house.gov/media-center/press-releases/rebs-marino-welch-blackburn-and-chu-applaud-passage-prescription-drug>
- ***GOP Group Promises ObamaCare Replacement Plan – Soon.*** “A group of senior House Republicans is promising to deliver proof that the party is making headway in its six-year struggle to replace ObamaCare. ‘Give us a little time, another month or so,’ House Energy and Commerce Committee Chairman Fred Upton (R-MI-6) told reporters this week. ‘I think we’ll be pretty close to a Republican alternative.’ Upton is one member of a four-person task force that is supposed to come up with a replacement plan for the healthcare law, at the behest of Speaker Paul Ryan (R-WI-1). For now, the group is still in ‘listening mode,’ Upton said. When asked who they are listening to, Upton said: ‘You name it – the world.’”
 - To read the full article, please see the following link:
<http://thehill.com/policy/healthcare/276547-gop-group-promises-obamacare-replacement-plan-soon>
- ***House Appropriators to Markup FDA Bill.*** Today, the full House Appropriations Committee will markup the FDA-Agricultural fiscal year (FY) 2017 appropriation bill, which passed out of committee last week. The \$21.3 billion bill includes \$2.7 billion in discretionary funding for FDA, which is \$33 million over the 2016 enacted level. The bill also provides \$10 million through FDA to combat Zika and Ebola outbreaks. The bill would also enact three sections of the *21st Century Cures Act* (H.R. 6) related to FDA.
- ***House Approves Bill to Speed Up Zika Drugs.*** “The House overwhelmingly approved a bill to offer incentives to companies seeking cures for the Zika virus amid Congress’s growing battle over funding for the epidemic. The bipartisan legislation would add the Zika virus to a list of diseases that qualifies for a “priority review” voucher from the Food and Drug Administration (FDA). It passed the Senate last month.”

- To read the full article, please see the following link:
<http://thehill.com/policy/healthcare/276045-house-approves-bill-to-speed-up-drugs-for-zika-virus>
- **60 Senators Ask CMS to Delay Hospital Compare Star Ratings.** Senators Rob Portman (R-Ohio) and Robert Casey (D-Penn.) wrote to CMS Acting Administrator Andy Slavitt on April 11th, asking the agency to delay the release of the ratings. The Senators write, “We are concerned that the Star Rating system may be misleading to consumers due to flaws in the measures that underpin the ratings. Many prominent hospitals that are in the top echelon of other quality rating reports, and handle the most complex procedures and patients, may receive 1 or 2 stars (out of a possible 5), indicating that they have the poorest quality in comparison to all other hospitals. As the Medicare Payment Advisory Commission (MedPAC) and other researchers have noted, these measures are not appropriately adjusted for socioeconomic status and patient complexity.”
 - Please see the following link for the full letter:
<https://www.aamc.org/download/458400/data/senatedearcolleagueletteronstaratings.pdf>

Regulatory Updates

- **CMS Releases Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Proposed Rule Issues for FY 2017.** Yesterday, “the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule to update fiscal year (FY) 2017 Medicare payment policies and rates under the Inpatient Prospective Payment System (IPPS) and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS). The proposed rule, which would apply to approximately 3,330 acute care hospitals and approximately 430 LTCHs, would affect discharges occurring on or after October 1, 2016. The IPPS pays hospitals for services provided to Medicare beneficiaries using a national base payment rate, adjusted for a number of factors that affect hospitals’ costs, including the patient’s condition and the cost of hospital labor in the hospital’s geographic area. The proposed rule proposes policies that continue a commitment to increasingly 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 give patients. The proposed rule includes policies that advance that vision and is one of several proposed rules that reflect a broader Administration-wide strategy to create a health care system that results in better care, smarter spending, and healthier people.”
 - To read the full fact sheet, please see the following link:
<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-18-2.html>
 - To review the rule, please see the following link:
<https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-09120.pdf>
- **Check Your 2015 Open Payments Data.** “The Centers for Medicare & Medicaid Services’ continues to publish data from applicable manufacturers and group purchasing

organizations (GPOs) about payments they make to physicians and teaching hospitals on its website, <https://openpaymentsdata.cms.gov/>. We're pleased that the public has searched Open Payments data more than 6.3 million times. Doctors, teaching hospitals and others receiving payments or other transfers of value that are sent to us from reporting entities, should take steps to ensure that this information about you, your related research, ownership, and other financial concerns are accurate. Doctors and teaching hospitals have the chance to review and dispute the information shared about them before we post the new and updated Open Payments data on June 30, 2016. The data we post on June 30th is now available for review through May 15, 2016. Since April 1, this is the only chance for these health care providers to dispute inaccurate or incomplete data before we post it. After that they only have until the end of the year that this financial data is published to review and dispute any payment records and how it was attributed from GPOs, drug and device manufacturers."

- Please see the following link for more information:
<https://blog.cms.gov/2016/04/14/check-your-2015-open-payments-data/>
- ***Today's Most Attractive National ACO Model Is Offered By... CMS.*** "A large national payer recently announced the opportunity for Accountable Care Organizations (ACOs) to share in 100 percent of the savings they create for the payer's largest book of business. Providers will have complete autonomy in how they manage the health of their population, and the payer will ensure the timely flow of datasets needed to support care improvement activities. The payer will pre-define the ACO's population and its spending benchmark, which will be adjusted for the risk of the ACO population. Consumers aligned to the ACO will be offered supplemental benefits and financial incentives to seek care from the ACO's network."
 - Please see the following link for the full article:
<http://healthaffairs.org/blog/2016/04/15/todays-most-attractive-national-aco-model-is-offered-bycms/>
- ***MedPAC Affirms 'First Step' Toward New Payment System.*** "The way home health agencies are reimbursed by Medicare could soon change, as members of the Medicare Payment Advisory Commission (MedPAC) voted to move ahead with an overhaul of the current payment system for post-acute care settings. The commission recommends to Congress how much providers should receive in Medicare payments every year, but the commission's April meeting affirmed its plan to create a single payment system across all post-acute care services. The aim of the new system is to reduce health care costs, improve care management and move away from the fee-for-service model in general."
 - For the full article, please see the following link:
<http://homehealthcarenews.com/2016/04/medpac-affirms-first-step-toward-new-payment-system/>
- ***Biosimilars Could Cost Patients More Than Reference Product.*** "Patients may pay more for biosimilar drugs than they would the original product, according to a report out today from Avalere Health, an independent consulting firm. Biosimilars, like generics, are expected to be less expensive than the primary innovator product. But higher out-of-pocket costs under Medicare Part D could discourage beneficiaries from using

biosimilars, the report says. Avalere suggests requiring manufacturer discounts to close the coverage gap for biosimilars and creating a biosimilar tier that would reduce beneficiary costs for biosimilars to the same level as the reference products as policy solutions. 'The unintended consequence of the *Affordable Care Act* (ACA) is that consumers have a financial disincentive to switch to a lower-cost biosimilar,' Caroline Pearson, senior vice president at Avalere, said in a statement. 'While the Medicare program will save money if beneficiaries take biosimilars, higher consumer out-of-pocket costs are a barrier to patient adoption.' The FDA has so far approved two biosimilar products for use." (Morning Consult)

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

http://go.avalere.com/acton/attachment/12909/f-02c0/1/-/-/-/-/20160412_Patient%20OOP%20for%20Biosimilars%20in%20Part%20D.pdf

- ***FDA Issues Three Draft Guidance Documents on Human Drug Compounding.*** "The FDA issued three draft guidance documents related to human drug compounding under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by Title I of the Drug Quality and Security Act (DQSA) in November 2013, that apply to both outsourcing facilities and compounders seeking to operate under section 503A. The draft guidance documents describe FDA's proposed policies concerning: the prescription requirement in section 503A of the FD&C Act, how the agency intends to apply the prescription requirement in section 503A to compounding in a hospital or health system pharmacy, and the definition of the term "facility" in section 503B of the FD&C Act. The draft guidance documents are:

- **Draft Guidance: Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act**

This draft guidance describes FDA's proposed policies concerning certain prescription requirements for compounding human drug products for identified individual patients under section 503A of the FD&C Act. It addresses compounding after the receipt of a prescription for an identified individual patient, compounding before the receipt of a prescription for an identified individual patient (anticipatory compounding), and compounding for office use (or "office stock").

- See the following link for the full draft guidance:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf>

- **Draft Guidance: Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act**

Pharmacies located within a hospital or standalone pharmacies that are part of a health system frequently provide compounded drug products for administration within the hospital or health system. Some of these compounders have registered with the FDA as outsourcing facilities under section 503B of the FD&C Act and others are state-licensed pharmacies subject to section 503A. This draft guidance describes how the FDA intends to apply section 503A of the FD&C Act to drugs compounded in state-licensed hospital or health system pharmacies for use within the hospital or health system.

- See the following link for the full draft guidance:
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496287.pdf>
- **Draft Guidance: Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act**
Section 503B defines an outsourcing facility, in part, as “a facility at one geographic location or address.” This guidance seeks to answer questions received from outsourcing facilities and other stakeholders about the meaning of the term “facility,” such as whether multiple suites used for compounding human drugs at a single street address constitute one or multiple facilities, or whether a single location where human drugs are compounded can be subdivided into separate operations compounding under different standards.”
 - See the following link for the full draft guidance:
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496288.pdf>
- Each draft guidance document is available for public comment for 90 days.”
- Please see the following link for more information:
<http://www.fda.gov/Drugs/DrugSafety/ucm493463.htm>

Articles of Interest

- ***Opioid Crisis: Scrap Pain as 5th Vital Sign?*** “Advocates are urging the Joint Commission and CMS to scrap policies that they say can lead to opioid overprescribing. In separate letters to both groups, signees asked the Joint Commission to re-examine its Pain Management Standards -- which once helped push the idea of pain as the ‘fifth vital sign’ -- and asked CMS to strike patient satisfaction questions about pain from its reimbursement procedures. The letters, sent by Physicians for Responsible Opioid Prescribing (PROP), had the support of senior health officials from Pennsylvania, Vermont, Alaska, and Rhode Island, as well as other physicians, medical organizations, and consumer groups.”
 - Please see the following link for the full article:
<http://www.medpagetoday.com/PublicHealthPolicy/PublicHealth/57336>
- ***Early Performance of Accountable Care Organizations in Medicare.*** “In the Medicare Shared Savings Program (MSSP) – the largest of the Medicare ACO programs – participating provider organizations share in savings with Medicare if they keep spending for an attributed population of fee-for-service beneficiaries sufficiently below a financial benchmark. Greater shared-savings bonuses are awarded to ACOs with higher performance on a set of quality measures. Unlike ACOs in the Medicare Pioneer program, very few ACOs in the MSSP face penalties for spending in excess of benchmarks because such downside risk is not currently required... The first full year of participation in the MSSP was associated with early savings among ACOs that entered the program in 2012 but not among those that entered in 2013. Savings in the 2012 cohort were on a par with savings estimated for Pioneer ACOs, suggesting that one-sided contracts without downside risk (shared savings only) also may elicit effective efforts to

reduce health care utilization. Owing to the one-sided nature of almost all MSSP contracts, however, the aggregate \$238 million spending reduction suggested by our estimates for the 2012 MSSP cohort did not result in net savings to Medicare, because Medicare paid \$244 million in bonuses without recouping losses from ACOs that had spending above benchmarks.”

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

<http://www.nejm.org/doi/full/10.1056/NEJMsa1600142#t=article>

Events

- The National Hospice and Palliative Care Organization will host its 31st Annual Management and Leadership Conference from April 21-23, 2016 at the Gaylord National Resort and Convention Center at the National Harbor, just outside of Washington, DC.
 - For more information, please see the following link:
<http://www.nhpco.org/mlc2016-0>

Hearings

- **Tuesday, April 19th, 2016**
The House Energy and Commerce Committee will hold a hearing titled, “Medicare Access and CHIP Reauthorization Act of 2015: Examining Physician Efforts to Prepare for Medicare Payment Reforms.”
 - For more information, please see the following link:
<https://energycommerce.house.gov/hearings-and-votes/hearings/medicare-access-and-chip-reauthorization-act-2015-examining-physician>