American Nephrology Nurses Association

Weekly Capitol Hill Update – Tuesday, February 2nd, 2016

Congressional Schedule

House:

- "The House convened yesterday at 2 p.m., after cancelling last week's session due to the blizzard. The House will consider eight bills under suspension of the rules, including concurrence in Senate amendments to a bill (H.R. 515) that would require the U.S. to tell other countries when convicted sex offenders are traveling there and a number of financial services measures." (CQ)

- **Week Ahead: "**On Tuesday, the House met at noon for consideration of an Iran sanctions measure (H.R. 3662), a Republican override of the president's veto message on a bill (H.R. 3762) to repeal provisions of the health care law (P.L. 111-148, P.L. 111-152), and a housing measure (H.R. 3700). Wednesday, the House will consider a bill (H.R. 1675) requiring the Securities and Exchange Commission to revise rules. The House on Thursday takes up a bill (H.R. 766) that would limit how bank regulators participate in a controversial Justice Department program, known as Operation Choke Point, aimed at financial firms providing questionable services to industries." (CQ)

Senate:

- "The Senate (convened) at 3 p.m. on Monday and will resume work on the wide-ranging energy policy bill (S. 2012)." (CQ)

Legislative Updates

- **The Food and Drug Administration (FDA) Working Through Generic Backlog, Official Tells Panel: "**Increasing competition in the pharmaceutical industry through generic drugs could help curb rising drug costs, senators suggested Thursday at a Health, Education, Labor and Pensions Committee hearing. A FDA official said the agency has made significant progress in working through a backlog of generic drug applications… But some senators, including Chairman Lamar Alexander (R-Tenn.), said the FDA's approvals of generic drugs are still too slow, despite Congress's $1 billion investment to speed up the efforts. 'I understand that the FDA has met most of the goals laid out in the agreement for industry user fees for regulatory actions, hiring staff, and increasing inspections,' Alexander said in his opening remarks at the hearing. 'But I look forward to hearing whether these metrics are the most appropriate, given I continue to

hear that generic drug approval is too slow from manufacturers and patients.' For generic drug applications that are submitted after September of this year, there will be a 10-month review clock, Janet Woodcock, director of the Center for Drug Evaluation and Research at the FDA, told the committee. 'If we're successful, they will get an approval at the end, not a lot of questions about their application,' she said. 'So that's pretty successful as it is.'" To read more please see the following link: http://bit.ly/1PJUOwJ

Regulatory Updates

- **Request for Advisory Committee on Organ Transplantation Nominees**: "The Health Resources and Services Administration (HRSA) is requesting nominations to fill vacancies on the Advisory Committee on Organ Transplantation (ACOT). The Agency receives nominations on a continuous basis."
    - For details on submitting nominations, please see the following link: https://www.federalregister.gov/articles/2016/01/21/2016-01126/advisory-committee-on-organ-transplantation-request-for-nominations-for-voting-members

- **Request for Medicare Payment Advisory Commission Nominations:** The Medicare Payment Advisory Commission (MedPAC) is accepting nominations for new members through March 9.
    - Please see the following link for details on how to submit nominations: http://1.usa.gov/20bkaJ2

- **Proposed Rule - Medicare Program: Expanding Uses of Medicare Data by Qualified Entities**: The Centers for Medicare & Medicaid Services (CMS) has proposed rules that will "expand access to analyses and data that will help providers, employers, and others make more informed decisions about care delivery. The new rules, as required by the Medicare Access and CHIP Reauthorization Act (MACRA), will allow organizations approved as qualified entities to confidentially share or sell analyses of Medicare and private sector claims data to providers, employers, and other groups who can use the data to support improved care. In addition, qualified entities will be allowed to provide or sell claims data to providers. The rule also includes strict privacy and security requirements for all entities receiving Medicare analyses or data, as well as new annual reporting requirements. This initiative is part of a broader effort by the Obama Administration to create a health care system that delivers better care, spends dollars more wisely, and results in healthier people. "Increasing access to analyses and data that include Medicare data will make it easier for stakeholders throughout the healthcare system to make smarter and more informed healthcare decisions," said CMS Acting Administrator Andy Slavitt. The rules seek to enhance the current qualified entity program to allow innovative use of Medicare data for non-public uses while ensuring the privacy and security of beneficiary information."
    - Comments are accepted through **March 29, 2016**.
      The proposed rule is available online at: http://federalregister.gov/a/2016-01790

- **CMS Announces Proposed Improvements to Medicare Shared Savings Program (MSSP):** CMS "has released a proposed rule to update the methodology used to measure the performance of Accountable Care Organizations (ACOs) in the MSSP. The proposal builds on the momentum of growth in the Shared Savings Program and charts a path for long-term sustainability by improving the long-term incentives for ACOs as they continue to provide efficient, high quality health care to Medicare beneficiaries."
    - Comments are accepted through **March 28th**.
    - For the full press release, please see the following link: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-01-28-2.html.
    - The proposed rule is available here: https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-01748.pdf.

- **CMS Releases Guide to Preventing Readmissions among Racially and Ethnically Diverse Medicare Beneficiaries:** The CMS Office of Minority Health (CMS OMH) "has released a new Guide to Preventing Readmissions among Racially and Ethnically Diverse Medicare Beneficiaries. The Guide was developed in collaboration with the Disparities Solutions Center at Massachusetts General Hospital and the National Opinion Research Center (NORC) at the University of Chicago as part of the CMS Equity Plan for Improving Quality in Medicare, and is designed to assist hospital leaders and stakeholders focused on quality, safety, and care redesign in identifying root causes and solutions for preventing avoidable readmissions among racially and ethnically diverse Medicare beneficiaries."
    - To see the full press release, please see the following link: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-01-26.html

- **CMS Issues Report on Overall Hospital Star Ratings Methodology, Summary Results:** CMS has "posted a report describing the final methodology for its overall hospital star ratings, and summary results for the first overall star ratings to be added to the Hospital Compare website in April. Hospitals participating in the inpatient and outpatient quality reporting programs can preview their overall hospital quality star rating through Feb. 14 at the QualityNet Secure Portal."
    - Please see the following article's link to view the results: http://www.beckershospitalreview.com/quality/cms-issues-final-report-on-its-overall-hospital-star-ratings-methodology.html

- **CMS, in conjunction with the Office of the National Coordinator (ONC), published the *Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures under CMS Programs* on December 31, 2015**. A comment period extension notice has been posted in the Federal Register. "Now, the RFI has a 45-day comment period. Comments are due February 16, 2016. As outlined in the RFI, CMS and ONC seek public comment on several items related to the certification of health information technology (IT), including Electronic health record (EHR) products used for reporting to the: EHR Incentive Programs; and Certain CMS quality reporting programs such as, but not limited to, the Hospital Inpatient Quality Reporting (IQR) Program and the Physician Quality Reporting System (PQRS). CMS and ONC request

feedback on how often to require recertification, the number of CQMs a certified Health IT Module should be required to certify to and ways to improve testing of certified Health IT Module(s). The feedback will inform CMS and ONC of elements that may need to be considered for future rules relating to the reporting of quality measures under CMS programs. This request for information is part of the effort of CMS to streamline/reduce Eligible Professional (EP), eligible hospital, critical access hospital (CAH), and health IT developer burden around government requirements.
    - The notice can be found here: https://www.federalregister.gov/articles/2015/12/31/2015-32931/request-for-information-certification-frequency-and-requirements-for-the-reporting-of-quality.
    - To see the official notice, please see the following link: https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-01937.pdf.

- **HHS: Generic drugs not 'important part' of drug cost problem: "**Despite recent price spikes of some generics, the copycat drugs are not an "important part" of the country's drug cost problem, a new HHS report concludes. The generic drug market continues to provide downward pressure on drug prices, according to the Assistant Secretary for Planning and Evaluation. Overall, the report finds the generic drug market is quite competitive, with two-thirds of generic drugs experiencing price declines in 2014. The investigation finds that some segments of the generic drug market experienced large price increases, but said these products didn't affect overall spending. "These spikes are on one hand troubling in that they disadvantage particular patient groups but also sufficiently limited so they exert no sizable influence on overall drug spending," the report said. HHS says reasons for the high generic drug prices includes drug shortages, mergers and acquisitions that led to fewer companies making a generic drug, complicated distribution systems, and cases in which a small market exists for a generic product. These factors will be the subject of future study and should be addressed to make the generic market more competitive, HHS concludes."
    - See the following link for the issue brief: https://aspe.hhs.gov/sites/default/files/pdf/175071/GenericsDrugpaperr.pdf

Articles of Interest

- **Altarum: Prices Grew Slowly In 2015: "**The Altarum Institute released a "Health Sector Trend Report, which is full of interesting nuggets, including a detail on remarkably slow price growth. "Health care prices grew by 1.1 percent in 2015, the slowest annual rate ever in our historical series going back to 1990," Altarum concludes. One major driver of that trend: Physician prices actually fell last year."
    - Please see the following link for the full report: http://altarum.org/sites/default/files/uploaded-publication-files/Altarum%20RWJF%20Trend%20Report%20January%202016.pdf

Hearings

Thursday, February 4, 2016

- The Energy and Commerce Subcommittee on Health will hold a hearing entitled, "Examining Implementation of the Biologics Price Competition and Innovation." Please see the following press release for more details: http://energycommerce.house.gov/press-release/hearing-subhealth-examine-biosimilars-implementation-issues#sthash.3OK7CR8m.dpuf.

- The Full House Oversight and Government Reform Committee will hold a hearing on "Developments in the Prescription Drug Market: Oversight." Please see the following link for more details: https://oversight.house.gov/hearing/developments-in-the-prescription-drug-market-oversight/.