GOVERNMENT AFFAIRS WEEKLY

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IN THIS REPORT…

NEXT WEEK IN WASHINGTON…

* The House is in recess until November 16.
* On Tuesday, November 17, the Energy and Commerce Health Subcommittee will hold a hearing to examine the regulation of diagnostic tests and laboratory operations.

1. AAFP LEADERS MEET WITH LEGISLATORS, OFFICIALS IN WASHINGTON

AAFP President Wanda Filer, MD; President-elect John Meigs, MD; Board Chair Bob Wergin, MD and CEO Doug Henley, MD came to Washington, DC on November 3 and 4 to participate in an array of advocacy activities. They met with key legislators, staff and administration officials to communicate AAFP recommendations on a variety of issues including the new Congressional Primary Care Caucus; funding for primary care research and training; Teaching Health Centers GME; Veterans Administration GME; Direct Primary Care; Meaningful Use and Mental Health and Opioid Abuse.

2. MENTAL HEALTH REFORM DEBATE ADVANCES

On November 5, the House Energy and Commerce's Health Subcommittee approved the *Helping Families in Mental Health Crisis Act* (HR 2646) by a vote of 18-12. The legislation, sponsored by Reps. Tim Murphy (R-PA) and Eddie Bernice Johnson (D-TX), would reform the Substance Abuse and Mental Health Services Administration and increase mental health access within Medicare and Medicaid. It would allow for same day billing for physical and mental health services in community health settings and federally qualified health centers. The legislation seeks to prohibit insurance companies from discriminating against prescription drug coverage for anti-psychotics and antidepressants. The bill supports state primary care and behavioral health integration grants. HR 2646 also includes a controversial policy to amend *Health Insurance Portability and Accountability Act* and allow physicians to share more patient information with caregivers.

3. HOUSE SUBCOMMITTEE BILL AIMED AT CONTROLING SYNTHETIC DRUGS

On November 4, the House Energy and Commerce's Health Subcommittee approved the *Synthetic Drug Control Act* (HR 3537). Rep. Charlie Dent (R-PA) introduced this legislation, which would add over 200 synthetic drugs to Schedule I controlled substances. HR 3537 also would cover the manufacture, importation, sale, and distribution of these controlled substances.

4. MENU LABELING BILL APPROVED BY HOUSE SUBCOMMITTEE

On November 5, the Health Subcommittee also approved the *Common Sense Nutrition Disclosure Act* (HR 2017). The legislation would exempt certain retail establishments from providing calorie content as required by the Food and Drug Administration's (FDA) menu labeling standards. Currently, businesses that provide food items such as chain pizza stores and movie theaters are working to delay or weaken the policy, which is scheduled to go into effect next month. In 2010, the AAFP supported the FDA's proposed menu labeling rule and commented on the importance improving our patients' knowledge of nutritional choices.

5. AAFP SUPPORTS BILL TO ALLOW EXEMPTIONS TO MEANINGFUL USE STAGE 2

The AAFP informed Rep. Tom Price (R-GA) of its support for the *Meaningful Use Hardship Relief Act* (HR 3940), which would give the Centers for Medicare and Medicaid Services (CMS) authority to issue blanket exemptions to practices that cannot attest that they have met the Stage 2 requirements for Meaningful Use (MU) in 2015. CMS did not issue modified regulations concerning MU2 until mid-October, which made compliance in 2015 nearly impossible for many practices. While CMS has authority to provide hardship exemptions for those practices, it can do so only on a case-by-case basis – a time-consuming and inefficient process. This legislation would allow CMS to define exemptions broadly.

6. LETTERS SENT ON CONCERNS WITH THE STAGE 3 REQUIREMENTS

In letters sent November 2 to leadership in the House and Senate, the AAFP and other medical specialty organizations expressed strong concerns with the decision by CMS to move ahead with implementation of Stage 3 of the Meaningful Use program despite the many problems with Stage 2. While the goal is to promote widespread adoption of electronic health records, the letter argues that Meaningful Use Stage 3 requirements are inconsistent with promoting better coordinated and higher quality patient care. The letter calls on Congress to refocus this program before physicians abandon the program completely.

7. CMS RELEASES 2016 FINAL MEDICARE PHYSICIAN FEE SCHEDULE

On October 30, the Centers for Medicare & Medicaid Services (CMS) released the 2016 final Medicare Physician Fee Schedule (link expires 11/16). The regulation reflects the end to the often threatened double-digit cut in Medicare physician payments that resulted from the now repealed Sustainable Growth Rate (SGR) and also points to the importance of moving health care delivery away from fee-for-service and toward value-based payment. Of note to family physicians, the 2016 final rule:

- Sets the 2016 conversion factor, which stipulates Medicare physician payments, to $35.827. This reflects a required budget neutrality adjustment, the positive 0.5 percent update adjustment specified under the MACRA, and a negative 0.77 percent "Target Recapture Amount" since CMS was able to identify only 0.23 percent in reductions in Relative Value Units (RVU). The required "Target Recapture Amount" stems from federal laws to address overvalued codes. The combined estimated impact of the 2016 final Medicare physician fee schedule on total allowed charges for family physicians is 0 percent.
- Begins Medicare payment for Advance Care Planning services for Medicare beneficiaries who choose to pursue it. In 2016 CMS will reimburse CPT codes 99497 and 99498 based on RUC-recommended values. Payment for the codes are approximately $86 for 99497 (initial 30-minutes) and $75 (subsequent 30-minutes) for 99498.

The fee schedule includes several changes to the Physician Quality Reporting System (PQRS):

- Requires the reporting of nine measures covering three National Quality Strategy domains. If a physician or group practice does not satisfactorily report or participate in PQRS for 2016, a 2-percent negative payment adjustment will apply to covered professional services furnished during 2018.
- Finalizes 281 measures in the PQRS measure set, 18 measures in the Group Practice Reporting Option (GPRO) Web Interface for 2016, and adds a reporting option that will allow group practices to report quality measure data using a Qualified Clinical Data Registry (QCDR).
- Makes all 2016 physician and group practice PQRS measures publicly available online.

Regarding the Physician Value-Based Payment Modifier, the rule includes these specifications:

- Establishes policies to transition from the Value Modifier to the Merit-Based Incentive Payment System (MIPS) including applying the Value Modifier to non-physicians (PAs, NPs, CNSs, CRNAs) in the 2018 payment adjustment period.
- Applies quality-tiering methodology to all groups and solo practitioners that meet the criteria to avoid the downward adjustment under the PQRS.
- Sets the maximum upward adjustment under the quality-tiering methodology for the 2018 Value Modifier at:
    - +4.0 times an adjustment factor (to be determined after the conclusion of the performance period), for groups of physicians with ten or more eligible professionals;
    - +2.0 times an adjustment factor, for groups of physicians with between two to nine EPs and physician solo practitioners; and
    - +2.0 times an adjustment factor for groups that consist of nonphysician EPs and solo practitioners who are PAs, NPs, CNSs, and CRNAs; and
- Sets the amount of payment at risk under the 2018 Value Modifier to:
    - -4.0 percent for groups of physicians with ten or more EPs,
    - -2.0 percent for groups of physicians with between two to nine EPs and physician solo practitioners, and
    - -2.0 percent for groups that consist of nonphysician EPs and solo practitioners who are PAs, NPs, CNSs, and CRNAs.
- Waives the application of the Value Modifier for groups and solo practitioners, as identified by their Taxpayer Identification Number (TIN), if at least one eligible professional bills for Medicare physician fee schedule services under the TIN during the applicable performance period for the Value Modifier participated in the Pioneer ACO Model, Comprehensive Primary Care (CPC) initiative, or other similar Innovation Center model.
- Uses 2016 as the performance period for the 2018 Value Modifier and continues to apply the 2018 Value Modifier based on participation in the PQRS by groups and solo practitioners;
- Increases the minimum episode size for the Medicare Spending per Beneficiary measure to be included in the Value Modifier to 125 episodes for all groups and solo practitioners. For solo practitioners and groups with two to nine eligible professionals and to only use measures that are reliable, CMS finalizes that the All-Cause Hospital Readmissions measure will not be used in the quality composite calculation for the Value Modifier.

Federal law requires that beginning in 2017 physicians and providers who order advanced diagnostic imaging services must consult with Appropriate Use Criteria (AUC) via a clinical decision support mechanism. However, for CMS to implement this requirement, the agency must specify AUC from among those developed or endorsed by national medical professional specialty societies and other provider-led entities. CMS also must approve clinical decision

support mechanisms, collect additional information on the Medicare claim form, and develop a prior authorization program based upon the claims information. Citing the limitations of AUC, clinical decision support mechanisms, and EHRs, CMS delays enforcement of this program and will further develop these policies during 2017 and 2018 rulemaking cycles. Thus CMS does not intend to require that ordering professionals meet this requirement by January 1, 2017.

CMS also includes provisions to implement MACRA changes to the Medicare Physician and Practitioner Opt-Out process. Prior to MACRA, physicians and practitioners that wished to renew their opt-out were required to file new valid affidavits every 2 years. Valid opt-out affidavits filed on or after June 16, 2015 are not required to file renewal affidavits.

The AAFP had commented on the proposed version of this regulation in an August 26, 2015 regulatory comment letter. As part of the final rule, CMS issued a press release, a fact sheet, and a fact sheet specific to the PQRS. The AAFP recently posted an article on the Getting Paid blog. The AAFP is examining portions of the final rule open for further comment and will respond to CMS before December 29, 2015.

8. AAFP COMMENTS ON NONDISCRIMINATION PROPOSED RULE

In a letter sent to HHS on November 6, the AAFP commented on the proposed rule titled, "Nondiscrimination in Health Programs and Activities," published by the Office of Civil Rights. Though the AAFP supported the policies that prohibit discrimination, the letter also discussed AAFP policy to make funding available for culturally sensitive interpretive services for those who have limited English proficiency, or who are deaf and mute, or who are otherwise language-impaired. The AAFP policy states that health-plan and governmental funding should be made available directly to the interpreters for culturally sensitive interpretive services. The AAFP called on HHS to fund the estimated $1,135 otherwise borne by physician practices. The AAFP outlined significant concerns that primary care practices are already taking a financial loss for treating patients that require interpretive services because of the historical undervaluation of primary cares services in the resource-based relative value scale system. If HHS is unable to procure funding, the AAFP calls on HHS to eliminate this requirement from this proposed rule.

9. MONTANA MEDICAID WAIVER APPROVED

On November 2, the Centers for Medicare and Medicaid (CMS) submitted a letter approving Montana's application for a five-year Medicaid demonstration project entitled "Montana Health Economic Livelihood Partnership (HELP) Demonstration." This demonstration waiver will expand coverage access to adults aged 19-64 in Montana who have incomes up to 133 percent of the federal poverty line. The demonstration is approved through December 31, 2020.

Cost sharing for all individuals under the demonstration will be consistent with Medicaid regulations and cost sharing and premiums will be subject to an aggregate cap of 5 percent of household income. To encourage beneficiaries to seek medical care that promotes health and well-being, certain services will be exempt from cost sharing, such as medically necessary health screenings and preventive health care services, including primary, secondary, and tertiary preventive care and medication and services to help beneficiaries manage chronic conditions. It also authorizes demonstration provisions specific to individuals in the new adult group with incomes between 50 and 133 percent of the federal poverty line who are not medically frail or exempt under federal or state law.

10. ELECTION DAY RESULTS IN THE STATES

Three states went to the polls to elect a Governor on Tuesday, November 3. Mississippi re-elected Republican Governor Phil Bryan by a vote of 67 percent to 32 percent. Kentucky elected Republican Matt Bevin, becoming only the second Republican governor in four decades in the state. Louisiana will go back to the polls on November 21 for a runoff election. Democrat and

state legislative leader John Bel Edwards will face Republican Senator David Vitter. Edwards grabbed 40 percent of the vote on Tuesday.

In addition to gubernatorial elections, New Jersey and Virginia held elections for various legislative seats. The New Jersey General Assembly remains controlled by the Democrats. In Virginia, Republicans retain majorities in the House of Delegates and the Senate. There were also several ballot initiatives this election cycle.

11. REGULATORY BRIEFS

- On October 30, CMS released the 2016 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System final rule. CMS updated OPPS rates based on the projected hospital market basket increase of 2.4 percent minus both a 0.5percentage point adjustment for multi-factor productivity (MFP) and a 0.2 percentage point adjustment required by law. There is an additional finalized 2.0 percentage point adjustment to the payment update to redress inflation in the OPPS payment rates resulting from excess packaged payment for laboratory tests that continue to be paid separately outside of the OPPS. The final rate update will be -0.3 percent. For ASCs, the CPI-U update is 0.8 percent for CY 2016. The MFP adjustment is 0.5 percent, resulting in an MFP-adjusted CPI-U update factor of 0.3 percent.
- On November 3, CMS announced an interactive online mapping tool that allows the public to search Medicare Part D opioid prescription claims data at the state, county, and ZIP code levels. The data used in this mapping tool is from 2013 Medicare Part D prescription drug claims prescribed by health care providers and does not contain beneficiary information.
- On November 3, HHS announced that HealthCare.gov is piloting a new feature that allows consumers to search plans by their preferred provider or health facility. Some consumers will be part of a pilot that allows them to use the beta Doctor Lookup feature as they compare their coverage options in window shopping or when selecting a plan.
- On November 5 CMS posted a blog entitled, “Prescription Drugs: Advancing Ideas to Improve Access, Affordability, and Innovation.” The post discusses the importance of finding ways to improve affordability and access for patients, supporting and increasing innovation in the industry, and making people healthier. CMS also issued a notice to all 50 state Medicaid directors and sent letters to the CEOs of several drug manufacturers about providing access to therapy for Hepatitis C patients.
- On November 5, CMS announced the agency is partnering with the New York State Department of Health (NYSDOH) and the Office for People with Developmental Disabilities (OPWDD) to test a new model for providing Medicare-Medicaid enrollees with a more coordinated, person-centered care experience. This partnership will create a program demonstration known as Fully Integrated Duals Advantage for Individuals with Intellectual and Developmental Disabilities (FIDA-IDD) to better serve individuals with intellectual and developmental disabilities who are eligible for both Medicare and Medicaid and will focus on these individuals’ long-term care needs. The FIDA-IDD Demonstration will offer more opportunities for individuals to direct their own services, be involved in care planning, and live as independently in the community as possible.
- CMS will host the following free educational calls, registration is required:
    - Clinical Diagnostic Laboratory Test Payment System Proposed Rule, November 10, 2:00pm
    - National Partnership to Improve Dementia Care and QAPI, December 1, 1:30pm
    - Medicare Quality Reporting Programs: 2016 Physician Fee Schedule, December 8, 1:30pm
    - ESRD QIP: Access PY 2016 Performance Score Report and Certificates, December 9, 2:30pm