GOVERNMENT AFFAIRS WEEKLY

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IN THIS REPORT…

NEXT WEEK IN WASHINGTON…

* Congress has adjourned for the year. The House of Representatives will reconvene on January 5, and the Senate will return on January 11, 2016.

1. CONGRESS COMPLETES ACTION ON FY 2016 HHS SPENDING

On Friday, December 18, by a bipartisan vote of 316 to 113, the House passed the *Consolidated Appropriations Act* (HR 2029) to provide discretionary funding for the federal government through September 30, 2016. The measure then passed the Senate, 65 to 33, and the President signed it hours later. Within the Department of Health and Human Services' section of the spending bill, Congress increased by $2 billion to $32 billion funding for the National Institutes of Health (NIH). The legislation provided $7.2 billion for the Centers for Disease Control and Prevention (CDC), which is $308 million more than in 2015. The fiscal year 2016 omnibus spending law provides funding for these family medicine priorities:

Agency for Healthcare Research and Quality (AHRQ)

Congress appropriated $334 million for AHRQ. This represents a cut of approximately 8.2 percent from last year's $364 million. However, AHRQ will receive nearly $95 million in funding from the Patient-Centered Outcomes Research (PCOR) Transfer. This transfer raises the funding for AHRQ to $428.4 million, a $14.5 million cut in program level funding – or a 3.4 percent reduction.

Centers for Medicare and Medicaid Services (CMS)

The measure includes $3.6 billion for CMS management and operations, the same level as FY 2015, which is $575 million below the President's budget request. Congress noted "concerns" about the proposal to eliminate the Critical Access Hospital (CAH) status from facilities located

less than 10 miles from another hospital and reducing the reimbursement rate from 101 to 100 percent. The agreement directs the CMS to engage with CAH facilities to assess the impact of the proposed reimbursement reduction and provide a report within 6 months to the appropriate congressional committees on the impact of the proposed rate reduction from the perspective of the CAHs' ability to operate fully.

Health Resources and Services Administration (HRSA)
The bill provides HRSA with $6.14 billion, which is a $34.8 million increase over FY 2015. The Primary Care Training and Enhancement Grants (Title VII, Section 747) administered by HRSA were level-funded at $ 38.9 million. Additional programs in Title VII health workforce programs funded by this measure include:

- Centers of Excellence, which were level-funded at $21.7 million
- Health Careers Opportunity Program, which received level funding of $14.2 million
- Faculty Loan Repayment, which was level-funded at $1.2 million
- Scholarships for Disadvantaged Students, which were level-funded at $46 million
- Area Health Education Centers, which were level-funded at $30.3 million.
- the consolidated Title VII and Title VIII Comprehensive Geriatric Education programs, which were increased by $4.5 million to $38.7 million

Other HRSA programs include:

- Community Health Centers received a level appropriation of $1.5 billion in FY 2016 to supplement the CHC trust fund.
- Children's Hospitals Graduate Medical Education was increased by $30 million to $295 million which is $195 million above the President's FY 2016 request.
- Title X Family Planning was level-funded at $286 million.
- Maternal and Child Health (MCH) Block Grant program was funded at $845 million, $211 million above the 2015 level.
- Ryan White HIV/AIDS Programs were largely level-funded for a total of $2.3 billion, but the early intervention program received $4 million more than in FY 2015.

Substance Abuse and Mental Health Services Administration (SAMHSA)
The bill increases the appropriation for SAMHSA by $160 million to $3.8 billion, and includes $12 million for discretionary grants to states to help them equip and train first responders with the use of devices that rapidly reverse the effects of opioids. In addition, the agreement provides $10 million for the Strategic Prevention Framework Rx program to increase awareness of opioid abuse and misuse in communities. SAMHSA will collaborate with CDC to implement the most effective outreach strategy and to reduce duplication of activities. Congress urged SAMHSA to use Substance Abuse and Prevention Block Grant funds to incorporate robust evidence-based opioid safety education and training for licensed healthcare professionals, including paramedics, to emergency devices used to rapidly reverse the effects of opioid overdoses.

Prescription Drug Monitoring
The portion of the omnibus which funds the Justice Department includes $13 million for state grants to prescription drug monitoring programs which is a $2 million increase over the funding included in PL 113-235 for FY 2015.

Public Health Priorities
Overall, the omnibus appropriations bill supported several of the administration's public health priorities, such as the president's early childhood education initiative, *Food Safety Modernization Act* implementation, and antibiotic resistance. The AAFP supports many of these same policies, in particular, the programs aimed at preventing chronic health conditions. The following is a summary of key public health funding levels.

Chronic Disease Prevention. The omnibus bill provides $210 million for CDC Tobacco Prevention, which is $6.5 million less than the 2015 enacted level and $105 million more than the House bill. The AAFP has consistently supported tobacco prevention, pushed back against efforts to weaken federal product regulations and supported policies to reduce second-hand smoke exposure.

The measure does not include a House provision allowing thousands of unregulated tobacco products to escape full FDA review. The House provision would have exempted e-cigarettes, little cigars, cigarillos, hookah, cigars and other products from the Tobacco Control Act's pre-market review requirement, allowing products to escape regulations and requirements. The AAFP opposed this weakening of the FDA's authority over tobacco and nicotine products. The bill does allocate $1 million for FDA's Center for Tobacco Products and the National Academy of Medicine to conduct a thorough study of the health effects of e-cigarettes to help direct future e-cigarette research.

CDC's budget includes a $10 million obesity prevention program targeted in counties with the most need.

The funding bill also specifies a one-year delay of the FDA's menu labeling requirement, a policy AAFP supports.

Environmental Health. The omnibus includes $104.5 million for the FDA's food safety program. It more than doubles the 2015 funding amount, which will help support the agency's Food Safety Modernization Act implementation activities, which the AAFP supported.

Infectious Disease. While the funding bill provides $1.1 billion for the CDC's National Center for the Prevention of HIV, Viral Hepatitis, and STD Prevention, the figure is $6 million lower than the 2015 level. The appropriations bill also specifies $775 million on antibiotic resistance across several different agencies. The AAFP supports this policy and will continue to engage the administration in the upcoming year.

Injury Prevention. The omnibus funding bill provides $236 million for CDC's National Center on Injury Prevention and Control, a $42 million increase above the 2015 level. Within those funds, $70 million is set aside for evidence-based opioid prevention activities. The bill also increases funding for SAMHSA's Medication-Assisted Treatment Access Program from $13 million to $25 million. Increasing access to MAT is consistent with the AAFP's opioid abuse priorities.

The legislation also maintains the annual gun policies, including the Dickey-Wicker gun research language, which restricts CDC from performing any research "to advocate or promote gun control." The AAFP opposed the research ban.

Reproductive Health. The omnibus bill provides $286 million for Title X Family Planning, which is the same as the 2015 enacted level and excludes language restricting Planned Parenthood's participation. The AAFP highlighted Title X as a funding priority within its September letter to Congressional leaders. The Teen Pregnancy Prevention program provides evidence-based health education and is funded at $108 million, which is the same as the 2015 enacted level.

2. AAFP PRESIDENT MEETS WITH SENATE, ADMINISTRATION OFFICIALS

AAFP President Wanda Filer, MD came to Washington on December 16 to participate in meetings with the U.S. Surgeon General Vivek Murthy, MD, MBA, key Senate staff, and administration officials on a number of AAFP priority initiatives to address opioid abuse.

3. SENATE STUDIES OPTIONS TO IMPROVE CARE OF CHRONIC DISEASE

On December 18, Senate Finance Committee Chairman Senator Orrin Hatch (R-UT), senior Democratic member, Sen. Ron Wyden (D-OR)., along with Sens. Johnny Isakson (R-GA), and Mark Warner (D-VA)., co-chairs of the Finance Committee Chronic Care Working Group, released an options paper outlining policies being considered as a part of the committee's effort to improve how Medicare treats beneficiaries with multiple, complex chronic illnesses. Policies in the options paper include:

- allowing Medicare Advantage (MA) plans to tailor benefits specifically for chronically ill enrollees,
- adding additional tools for Accountable Care Organizations (ACO),
- making permanent the Independence at Home (IAH) demonstration program that helps primary care providers give high-quality care in the home, and
- giving greater flexibility to MA and ACOs to deliver non-health services that are pivotal for beneficiaries with multiple, complex chronic illnesses.

The paper comes as a part of a 7-month long process to explore and develop legislation to address the challenges facing beneficiaries with chronic conditions enrolled in Medicare. The committee launched the Chronic Care Working Group in May 2015 following the committee's second hearing on chronic care, and proceeded to solicit comments on potential policy changes. The working group received comments from some 530 groups and individuals, including the AAFP, and conducted 80 stakeholder meetings, including one with the AAFP, to discuss ideas that improve the delivery of care to Medicare beneficiaries with chronic diseases.

4. CONGRESS EXPANDS CMS's POWER TO GRANT WAIVERS FROM MEANINGFUL USE

On December 18, the House and Senate passed bipartisan Medicare reforms in the *Patient Access and Medicare Protection Act* (S. 2425). The President is expected to sign the bill. The measure includes the following provisions affecting family medicine:

- CMS's authority to grant eligible professionals hardship waivers from Meaningful Use compliance is expanded. Under existing law, CMS must process applications for hardship waivers on a case-by-case basis. S. 2425 grants the Medicare agency authority to process "categories" of eligible professionals, in anticipation of a large spike in applications for the 2015 program year. For a hardship application to be processed, family physicians must file on or before March 15, 2016. Receiving a hardship waiver for 2015 will avoid a reduction of 3 percent in Medicare payments in 2017.
- The bill also will shield the service codes for radiation treatment delivery and related imaging services, from mandatory statutory reductions that CMS must make to the Medicare Physician Fee Schedule during 2017 and 2018. This provision makes it marginally more likely that CMS will make corresponding reductions in the 2017 and 2018 conversion factors, which could partially offset the expected 0.5 percent positive updates.

5. PRIMARY CARE PHYSICIAN REENTRY ACT IS INTRODUCED

On December 10, Rep. John P. Sarbanes (D-MD) introduced the *Primary Care Physician Reentry Act (*HR 4234) which the AAFP supports. The bill would authorize a demonstration program to help physicians reenter clinical practice. Participating primary care physicians would be retrained and credentialed to practice at VA medical centers, community health centers, and school-based health centers in exchange for the program's support.

6. IDAHO GOVERNOR PROPOSES A PARTIAL ALTERNATIVE TO MEDICAID EXPANSION

Idaho Governor Butch Otter (R) is proposing a state-funded partial alternative to Medicaid expansion. The proposal would deliver basic primary care for 78,000 individuals who have little or no access to health care coverage. The proposal calls for state payments to primary care providers to cover basic preventive health care for Idahoans in the coverage gap. The preliminary plan does not cover emergency room visits, acute care, hospitalization or prescription drugs. Idaho is researching funding options, potentially a higher tobacco tax, to pay for the $30 million proposal. Supporters say that the proposal is not a replacement for Medicaid expansion, only a practical first step towards helping the uninsured.

7. CMS APPROVES THE HEALTHY MICHIGAN PLAN

The Centers for Medicare and Medicaid Services have approved Michigan's waiver amendment entitled the Healthy Michigan plan. The Healthy Michigan plan launched April 1, 2014, and now serves nearly 600,000 individuals. Under Healthy Michigan, individuals and family with an income of about 133 percent of the federal poverty level are eligible. In 2013, Michigan decided to expand the Medicaid program. However, for years, its program was limited to children, parents of young children, and elderly and disabled people. The waiver expands to single adults who can now receive preventative services. The federal waiver was required because nearly every participant has certain co-pays and there are incentives in the program for healthy behaviors.

8. OKLAHOMA PROVIDERS COULD SEE A 3-PERCENT CUT IN MEDICAID RATES

The Oklahoma Health Care Authority approved a measure that will cut provider reimbursement rates for Medicaid by 3 percent. The rate cut excludes services financed through money to other state agencies; services provided under a waiver; and services where a "reduction could severely limit access or not cover costs." This is in response to a projected budget shortfall between $600 million and $1 billion. The authority anticipates that the state will save $20 million. If approved by the Senate, the new rates would go into effect January 1.

9. AAFP DISCUSSES GAO REPORT ON THE RUC WITH CMS

In a December 16 letter to the Centers for Medicare & Medicaid Services, the AAFP wrote in regard to a U.S. Government Accountability Office (GAO) report titled, “Medicare Physician Payment Rates: Better Data and Greater Transparency Could Improve Accuracy.” The report, mandated by the Protecting Access to Medicare Act, demonstrates Congressional intent to improve the Relative Value Scale Update Committee (RUC) process that contributes to the establishment of relative value units (RVUs) that, in turn, help determine Medicare physician payments. The AAFP asked what steps CMS has taken so far and what actions the agency is planning to take to implement the recommendations in this report. The AAFP letter expressed agreement with GAO recommendations, that CMS should better document its process for establishing relative values, develop a process to inform the public of potentially misvalued services identified by the RUC, and develop a plan for using funds appropriated for the collection and use of information on physicians’ services in the determination of relative value units. The letter also expressed concern that weaknesses in the RUC’s relative value recommendation process persist and that its survey data continues to present significant barriers for achieving accurate Medicare payment rates for physician services. The AAFP called on CMS to do more to improve the accuracy of Medicare physician payments, especially before CMS builds the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APM) programs.

10. AAFP COMMENTS ON 2017 MARKETPLACE PROPOSED RULE

In a comment letter sent December 16, the AAFP responded to the proposed rule to set payment policies for the federally facilitated Marketplaces operating in 2017. The AAFP first offered support for standardizing plans offered in the Marketplaces as a means to reduce consumers’ confusion.

The letter applauded CMS for including primary care visits, generic drugs, and other services as a covered benefit before the deductible is applied in standardized plans. Regarding how cost sharing in standardized plans would work, the AAFP urged CMS to take into account quality, outcomes and patient satisfaction and to utilize the principles of value-based insurance design.

The letter supported the Navigator program to help consumers understand the differences in cost and coverage between a visit to the emergency department and a visit to a primary care provider. The letter encouraged CMS and health plans to take further steps and provide consumers with information regarding the cost and coverage differences between primary care providers and sub-specialty providers and between office-based settings and facility-based settings.

Regarding network adequacy, the AAFP response agreed that protecting consumer access to health care providers is important since accurate and current provider directories are essential for accessibility. The AAFP supported a proposal to require Marketplaces to notify enrollees within 30 days about a discontinuation in network coverage of a contracted provider. The letter urged CMS and private payers to make public the performance measures used in determining which providers are included in which network. The AAFP called for an appeals process and conclude the letter discussing how primary care is the most cost-effective access point for care and that reducing access to primary care is shortsighted.

11. AAFP NOMINATES TWO PHYSICIANS TO CHILDHOOD VACCINE COMMISSION

In a letter sent on December 16, the AAFP nominated Jennifer Lynn Hamilton, MD, PhD, FAAFP and Jamie Loehr, MD, FAAFP to serve on the Advisory Commission on Childhood Vaccines Commission. The AAFP letter expressed the belief that their expertise and clinical experience would assist the commission advise the Secretary of Health and Human Services on the implementation of the Vaccine Injury Compensation Program.

12. AAFP COMMENTS ON GARDISAL VACCINE INFORMATION

In a letter sent December 16 to the CDC, the AAFP wrote in response to the comment period regarding vaccine information materials for Human Papillomavirus Gardasil®-9 Vaccine. This pertains to the vaccine information material that all health care providers are required to give to patients or parents prior to administration of the human papillomavirus Gardasil®-9 vaccine. The AAFP reviewed the vaccine information material and generally supported it as written since we find it more streamlined than the current vaccine information statement for (quadravalent) Gardasil. However, we urged the CDC to:

- Make the benefits of vaccination even clearer.
- Reference breastfeeding in a separate bullet rather than within the pregnancy section.
- Further highlight fainting and lightheadedness possibilities since it is the most common side effect encountered at the time of this vaccine's administration.

13. FamMedPAC ON PACE FOR RECORD CYCLE

Thanks to strong support from our members in 2015, FamMedPAC is on pace to reach its election-cycle goal of raising $1 million by the end of next year. The PAC received just over $480,000 in donations from 2,400 AAFP members so far this year. Those donations allowed the PAC to contribute $484,700 to 116 candidates and committees in 2015. Democratic candidates received 52 percent of the PAC's donations, with Republicans receiving 48 percent. The PAC supported the following legislators last week:

- **Rep. Mike Simpson (R-ID)**, a dentist and member of the Health Subcommittee of the House Appropriations Committee.

14. REGULATORY BRIEFS

- On December 11, CMS announced new HealthCare.gov consumer decision support features such as a new Out of Pocket Cost calculator, Doctor and Facility Lookup, and Prescription Drug Lookup features that will help consumers to more easily search for the plan that best meets their budget and health needs.
- On December 11, the Department of Health and Human Services and the Department of the Treasury posted guidance for states interested in seeking a State Innovation Waiver under section 1332 of the Affordable Care Act. The guidance provides states with flexibility to pursue innovative waiver proposals while preserving the important protections of the Affordable Care Act, consistent with the statutory language. The guidance explains how the Secretaries will evaluate waiver applications, so that states have the information they need as they consider a waiver application.
- On December 16 the Government Accountability Office named seven new members to the Medicaid and CHIP Payment and Access Commission. The commission was created by the Children's Health Insurance Program Reauthorization Act of 2009 to review Medicaid and CHIP access and payment policies and advise Congress on issues affecting Medicaid and CHIP.
- On December 18, CMS posted the draft Quality Measure Development Plan which is a strategic framework for the development of clinician quality measures for application under the provisions of the Merit-based Incentive Payment System and certain Medicare alternative payment models. CMS is seeking input and comments on the draft plan from clinicians, payers, patients, caregivers, and other stakeholders. Comments should be submitted by March 1, 2016, which will be considered in developing the final Measure Development Plan, which will be posted by May 1, 2016.
- On December 18, CMS released a new dataset, the Home Health Agency Utilization and Payment Public Use File (Home Health Agency PUF). This data set, which is part of CMS's Medicare Provider Utilization and Payment Data set, details information on services provided to Medicare beneficiaries by home health agencies. These new data include information on 11,062 home health agencies, over 6 million claims, and over $18 billion in Medicare payments for 2013.
- CMS will host the following free educational calls, registration is required:
    - ESRD QIP: Payment Year 2019 Final Rule Call, January 19, 2:00pm
    - Collecting Data on Global Surgery as Required by MACRA Listening Session, January 20, 2:30pm
    - IMPACT Act: Connecting Post-Acute Care across the Care Continuum Call, February 4, 1:30pm