GOVERNMENT AFFAIRS WEEKLY

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IN THIS REPORT…

NEXT WEEK IN WASHINGTON…

* On Monday, July 16, the House Energy and Commerce Committee will begin consideration of several public health related bills.
* On Tuesday, July 17, the Senate Finance Committee will conduct a hearing on Chronic Illness: Addressing Patients' Unmet Needs

1. CMS RELEASES DRAFT MEDICARE PAYMENT RULE

Last week, on July 3, the Centers for Medicare and Medicaid Services (CMS) released the details of the proposed Medicare payment for 2015. The AAFP recently prepared a summary of this 2015 proposed Medicare Physician Fee Schedule (MPFS). This regulation would update payment policies and rates for services furnished under the Medicare physician fee schedule beginning January 1, 2015. In an AAFP media statement released after the proposed rule became available, the AAFP expressed disappointed that current law requires CMS to slash Medicare physician payments by 20.9 percent unless Congress intervenes before March 31, 2015. The AAFP continues to call on Congress to repeal the flawed sustainable growth rate (SGR) formula and pass payment reform legislation that builds on the value of the services provided rather than the volume of those services.

As part of this regulation's release, CMS issued three fact sheets discussing overall payment policy proposals, outlining changes to the quality reporting programs, and summarizing proposals on the Value Modifier. Among the topics the AAFP summary describes are:

- changes to Medicare physician payments
- the development and payment rate for the new Chronic Care Management (CCM) code
- additional services added to the Medicare Telehealth Services list
- the manner in which CMS is addressing misvalued codes and adjusting relative value units (RVUs)
- variations in the 2015 Physician Quality Reporting System

- additional information to be included on the Physician Compare website
- CMS's expanded use of the Physician Value-based Payment Modifier.

Notable for family physicians, Medicare predominately pays for care management services as part of face-to-face visits. However, citing a commitment to support primary care, in 2015 CMS will begin payment for managing the care of Medicare patients with two or more chronic conditions outside of a face-to-face visit. The Medicare payment will be approximately $42 but the service can be billed no more frequently than once per month per qualified patient.

In previous regulations, CMS requires that CCM services include:

- Access to care management services 24-hours-a-day, 7-days- a-week, which means providing beneficiaries with a way to make timely contact with health care providers in the practice to address the patient's urgent chronic care needs regardless of the time of day or day of the week
- Continuity of care with a designated practitioner or member of the care team with whom the patient is able to get successive routine appointments
- Care management for chronic conditions including systematic assessment of the patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications
- Creation of a patient-centered care plan document to assure that care is provided in a way that is congruent with patient choices and values
- Management of care transitions between and among health care providers and settings, including referrals to other clinicians, follow-up after a beneficiary visit to an emergency department, and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities.

In the 2015 draft MPFS, CMS proposes to remove the requirement that the clinical staff person must be a direct employee of the practitioner or the practitioner's practice in order to count the clinical staff person's time in providing aspects of CCM services. CMS also proposes to remove the restriction that services provided by clinical staff under general (rather than direct) supervision may be counted only if they are provided outside of the practice's normal business hours. In addition to the criteria established in 2014, CMS proposes a new scope of service requirement for electronic care planning capabilities and electronic health records. Specifically, CMS proposes that CCM services must be furnished with the use of an electronic health record or other health IT or health information exchange platform that includes an electronic care plan that is accessible to all providers within the practice, including being accessible to those who are furnishing care outside of normal business hours, and that is available to be shared electronically with care team members outside of the practice. Practitioners furnishing CCM services beginning in 2015 would be required to utilize an electronic health record certified to at least 2014 Edition certification criteria.

The AAFP will send CMS extensive regulatory comments on this proposed regulation before the comment period closes on September 2, 2014. The final 2015 Medicare physician fee schedule is expected to be released in November.

2. SUMMARY OF OPEN PAYMENT CHANGES WITHIN THE 2015 PROPOSED MPFS

Quite unexpectedly, in the proposed 2015 Medicare Physician Fee Schedule (MPFS) the Centers for Medicare & Medicaid Services (CMS) also included significant changes to the Open Payment program (also known as the "Sunshine Act"), which requires the public reporting of

items of value given to physicians and other providers by the pharmaceutical and medical device industries. The AAFP created a summary of these changes for members.

Citing a need to respond to questions and experience administering the program, CMS proposed four changes to the Open Payments program:

- Delete the definition of "covered device" as it is duplicative of the definition of "covered drug, device, biological or medical supply," which is already defined in regulation.
- Delete the Continuing Education Exclusion in its entirety. CMS asserts that eliminating the exemption for payments to speakers at certain accredited or certifying continuing medical education events will create a more consistent reporting requirement for industry and be more consistent for consumers who access reported data.
- Require the reporting of the marketed name of the related covered and non-covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered or non-covered drug, device, biological or medical supply.
- Require applicable manufacturers to report stocks, stock options, or any other ownership interest as distinct categories.

The AAFP is concerned with the proposed deletion of the Continuing Education Exclusion and will send CMS extensive regulatory comments on this provision before the comment period closes on September 2, 2014.

3. MEDICAID AND CHIP ENROLLMENT NOW TOTALS ALMOST 66 MILLION

CMS announced Friday, July 11, that 920,628 more people enrolled in Medicaid and the Children's Health Insurance Program in May. Officials also adjusted downward by more than half a million the estimate of the programs' total enrollment in April. However, the increase in May brought the total number of people in both programs to about 65.9 million people. That's about 6.7 million people more than the programs had in the three months before the federal open enrollment period started Oct. 1 under the *Affordable Care Act*. That represents an 11.4 percent increase in enrollment. In states that broadened eligibility, enrollment rose by more than 17 percent when compared to the three-month average before Oct. 1. But in those that did not expand Medicaid, enrollment increased by a much smaller 3 percent.

4. SECOND PHASE OF OPEN PAYMENT REGISTRATION STARTS MONDAY

On July 11, CMS announced that July 14 begins the next phase of the Open Payment system:

> *Physicians and teaching hospitals can begin registering in the Open Payments system on July 14. Although registering in the Open Payments system is voluntary, it becomes a mandatory process if physicians and teaching hospitals want the opportunity to review and dispute data submitted by applicable manufacturers and applicable group purchasing organizations (GPOs) prior to public posting on September 30, 2014.*
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> *In order to review or dispute data submitted by industry for the 2013 reporting period, physicians must be registered—and have reviewed any data reported about them—on or before August 27, 2014, the end of the initial 45-day review and dispute period. And with identity verification as part of the registration process, which can take some time, CMS recommends completing the registration process as soon as possible and not waiting until the end of this initial 45-day review and dispute period.*

5. HOUSE COMMITTEE WILL DEBATE PUBLIC HEALTH LEGISLATION

Beginning on Monday, July 14, the Energy and Commerce Committee begin consideration of five bills related to public health:

- H.R. 594, the *Paul D. Wellstone Muscular Dystrophy Community Assistance, Research, and Education Amendments*, authored by Rep. Michael C. Burgess, M.D. (R-TX) and Rep. Eliot Engel (D-NY), would update surveillance, research, and education activities to reflect scientific developments and continue the support of research and patient support initiatives across all forms of Muscular Dystrophy.
- H.R. 669, the *Sudden Unexpected Death Data Enhancement and Awareness Act*, introduced by Rep. Frank Pallone (D-NJ) and Rep. Peter King (R-NY), would provide for activities to help improve the understanding of stillbirth, sudden unexpected infant death, and sudden unexplained death in children.
- H.R. 4290, the *Wakefield Act*, introduced by Rep. Jim Matheson (D-UT) and Rep. Peter King (R-NY), would reauthorize grant programs that support the expansion, improvement, and evaluation of emergency medical services for children.
- H.R. 4771, the *Designer Anabolic Steroid Control Act*, introduced by Rep. Joe Pitts (R-PA) and Rep. Frank Pallone (D-NJ), would classify certain anabolic steroids, substances often found in bodybuilding products and marketed as dietary supplements, as controlled substances.
- H.R. 4250, the *Sunscreen Innovation Act*, introduced by Rep. Ed Whitfield (R-KY) and Rep. John Dingell (D-MI), would streamline the FDA's approval process for new sunscreen ingredients while maintaining strict safety standards. The FDA has not approved a new sunscreen ingredient in nearly two decades. This legislation would require that pending and new applications be completed in a more predictable and transparent manner.

ADMINISTRATION MAKES PUBLIC FEDERAL STRATEGY ON ILLEGAL DRUG USE
The White House released its 2014 National Drug Control Strategy (along with an accompanying Fact Sheet) outlining the steps it plans to take with respect to drug policy. Focuses include curbing the abuse of opioids, stopping drug use before it begins (especially with respect to youth), detecting drugs abuse issues early, making treatment and recovery more accessible, and taking a "Smart on Crime" approach to drug enforcement. The President has requested $25.5 billion in FY 2015 to support this strategy.

6. AAFP SENDS FDA COMMENTS ON FDASIA HIT REPORT
In a letter sent to the Food and Drug Administration (FDA) on July 2, the AAFP commented on the "Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology Report" request for comments. As required by the *Food and Drug Administration Safety and Innovation Act* (FDASIA), in this regulation the FDA, in consultation with the Office of the National Coordinator for Health Information Technology and the Federal Communication Commission, developed the FDASIA Health IT Report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication. In its response, the AAFP urged the agencies to consider how any given piece of clinical decision support software should involve a three-part test in order to be regulated by the FDA. The AAFP letter outlined this test and provided examples.

7. MISSOURI CREATES "ASSISTANT PHYSICIAN" CLASSIFICATION
On July 10, Missouri Governor Jay Nixon (D) signed into law two bills that included the creation of a classification of health care provider, called "Assistant Physician." The law will allow certain medical school graduates who have passed Step 1 and Step 2 of the licensing exam, but have not completed residency training to practice medicine under a restricted license. The license would allow the assistant physician to enter into a collaborative practice arrangement with a

physician for the purpose of practicing primary care and prescribing in rural and under-served areas. The legislation was supported by the Missouri State Medical Association.

8. OREGON INTRODUCES NEW MALPRACTICE MEDIATION PROGRAM

Last week, Oregon debuted a new malpractice mediation program that is aimed at reducing lawsuits and boosting the reporting of medical errors. The program was spearheaded by Gov. Kitzhaber (D) and the result of a compromise between trial lawyers and the Oregon Medical Association. The patient or family could use the program to file a notice over an incident which triggers what is intended to be a confidential discussion in which a provider or health care facility can offer an apology or financial settlement. However, there are concerns and questions over how the program will develop, including whether providers could still be sued after the mediation. The Oregon Patient Safety Commission will be overseeing the new program.

9. REGULATORY BRIEFS

- On June 25 the HHS Office of Inspector General (OIG) issued a Special Fraud Alert addressing laboratory payments to referring physicians and group practices for blood specimen collection, processing, and packaging, and for submitting patient data to a registry or database.
- On July 7, HHS awarded $83.4 million to support primary care residency programs in 60 Teaching Health Centers across the nation. The funding will help train more than 550 residents during the 2014-2015 academic year, increasing the number of residents trained in the previous academic year by more than 200 and helping to increase access to health care in communities across the country.
- On July 8, HHS announced the availability of $100 million from the Affordable Care Act to support an estimated 150 new health center sites across the country in 2015. New health center sites will increase access to comprehensive, affordable, high quality primary health care services.
- On July 9, HHS announced new prospective awardees to test innovative care models, bringing the total amount of funding to as much as $360 million for 39 recipients spanning 27 states and the District of Columbia. These models are designed to deliver better health care and lower costs under the Health Care Innovation Awards program.
- On July 9, the Department of Justice and HHS announced the Elder Justice Roadmap in order to address challenges to elder abuse prevention and prosecution.
- CMS will host several free educational calls, registration is required for each:
    - Open Payments (the Sunshine Act): Registration, Review, and Dispute, July 22, 2:30 PM ET.
    - 2015 Medicare PFS Proposals for PQRS, Value Modifier, EHR Incentive Program, and the Physician Compare Website, July 24, 1:30 PM ET.
    - National Partnership to Improve Dementia Care in Nursing Homes: Improved Care Transitions, August 19, 1:30 PM ET.