GOVERNMENT AFFAIRS WEEKLY

AAFP Division of Government Relations — 2021 Massachusetts Avenue, NW — Washington, DC 20036

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IN THIS REPORT…

NEXT WEEK IN WASHINGTON…

* On Wednesday from 1 - 3pm ET, CMS will host a call on the Medicare Physician Feedback and Value Modifier Programs. Further details found in the Regulatory Briefs.

1. CONGRESS FAILS TO FORESTALL SGR PAYMENT CUT

On Tuesday, December 20, the House of Representatives rejected the 2-month extension of the SGR included in the payroll tax cut legislation by a vote of 229-193. The House called for a conference committee to work out the differences before January 1. However, the leaders of the Senate had understood that the House would agree to the short-term extension to have more time to negotiate a year-long SGR measure. As a result, the Senate adjourned after it provided bipartisan approval (by a vote of 89-10) to the 2-month measure.

The Centers for Medicare and Medicaid Services (CMS) has announced (see below) that it has instructed the Medicare carriers to hold payment for services billed on or after January 1 until at least January 17. The purpose of this is to give Congress additional time to work out its differences before the reduction in the payment rate will be applied to physician payment.

On Tuesday, December 13, the House of Representatives passed the *Middle Class Tax Relief and Job Creation Act* (HR 3630) by a vote of 234 to 193. In addition to proposals to extend the pay-roll tax cut and Unemployment Insurance (UI) programs, the bill included a proposal to provide two years of Medicare SGR relief with one-percent increases in each year.

The AAFP, along with most of the physician organizations, did not support the House bill. While the two-year extension and modest updates would provide needed stability for physicians, the financing mechanism that would hold the cost of the SGR provision to $39 billion would result in a 2014 payment cut of 37 percent and increase the cost of repealing the SGR by more than $60 billion to a total of greater than $350 billion.

The AAFP continues to ask that Congress come together in a bipartisan manner and repeal the SGR once and for all, provide a period (3-5 years) of specified payment rates, with a higher rate for primary care physicians. The House tax bill would make that goal less attainable, especially in the light of a challenging fiscal climate.

Guidance from CMS

Attention Health Professionals: Information Regarding the Holding of 2012 Date-of-Service Claims for Services Paid Under the 2012 Medicare Physician Fee Schedule

The negative update under current law for the 2012 Medicare Physician Fee Schedule is scheduled to take effect on January 1, 2012, eight business days from today. Consequently, as on numerous occasions in the past, the Centers for Medicare & Medicaid Services (CMS) will instruct its Medicare claims administration contractors to hold claims containing 2012 services paid under the Medicare Physician Fee Schedule for the first 10 business days of January (i.e., January 1, 2012, through January 17, 2012). The hold should have minimal impact on provider cash flow because, under current law, clean electronic claims are not paid sooner than 14 calendar days (29 days for paper claims) after the date of receipt.

Medicare Physician Fee Schedule claims for services rendered on or before December 31, 2011, are unaffected by the 2012 claims hold and will be processed and paid under normal procedures and time frames.

The Administration is disappointed that Congress has failed to pass a solution to eliminate the sustainable growth rate (SGR) formula-driven cuts, and has put payments for health care for Medicare beneficiaries at risk. We continue to urge Congress to take action to ensure these cuts do not take effect.

CMS will notify you on or before January 11, 2012, with more information about the status of Congressional action to avert the negative update and next steps regarding the claims hold.

2. CONGRESS PROTECTS PRIMARY CARE TRAINING IN FINAL SPENDING BILL

The Senate on Saturday, December 17 passed (67 to 32) the final fiscal year 2012 spending bill, averting a government shutdown and providing appropriations until October 1, 2012. The House had adjourned Friday for the weekend after passing the same spending package (HR 2055) known as the “megabus” appropriations bill on a vote of 296 to 121.

The $915 billion in discretionary spending appropriated under by the megabus falls under the $1.043 trillion spending limit required by the *Budget Control Act (BCA)*. The Department of Health and Human Services was allotted $69.7 billion (a $700 million cut from the FY 2011 comparable level), and all HHS programs will be subject to a further 0.189 percent rescission.

Before the across-the-board cut, the megabus agreement provides $233.7 million for all of the Title VII health professions programs, an $18.9 million (6.9 percent) cut below the FY 2011 appropriation. HR 2055 provides level funding for Title VII Section 747 Primary Care Training of nearly $40 million. This is far below the President’s budget request of nearly $140 million.

Other Title VII programs were cut in the FY 2012 megabus which reduces the Title VII diversity programs by nearly $10 million. The Centers of Excellence are cut by 6.1 percent to nearly $23 million, and the Health Careers Opportunity Program (HCOP) is cut by 31.8 percent to 15 million. HCOPs were targeted for elimination in both the House and Senate freestanding FY 2012 spending bills (HR 3070, S 1599). The megabus also cut the Area Health Education

Centers program by nine percent to $30 million. The Geriatrics line was cut by about 10 percent to $31 million.

The appropriation for the National Health Service Corps program was eliminated down from the FY 2011 level of $24.8 million. However, the NHSC trust fund provided in the Affordable Care Act makes $295 million available in FY 2012, which leaves the program well short of the $431 million comparable level from FY 2011. Overall, the Health Resources and Services Administration was funded at $6.5 billion (a $41 million reduction from the FY 2011 level.)

The President is expected to sign the megabus package which also includes the following:

- Agency for Healthcare Research and Quality - cut by $3 million (0.8 percent) to a total of $369.1 million;
- Office of Rural Health - a $2 million bump up for a total of $139.8 million;
- CMS - $3.9 billion for program management (a $241 million increase);
- CDC - $6.1 billion (a $38 million increase, including $80 million for the Preventive Health and Health Services Block Grant proposed for elimination by the President);
- NIH - $30.7 billion (a $299 million increase);
- SAMHSA - $3.5 billion (a $27 million reduction); and
- Children's Graduate Medical Education (CHGME) was retained at the FY 2011 level of $268.4 million despite the President's budget request that it be eliminated.

3. NEW MEXICO HEALTH EXCHANGE RECEIVES MAJOR FEDERAL GRANT

On November 29, 2011 the New Mexico Office of Health Care Reform received their official Notice of Award from the Centers for Medicare and Medicaid Services (CMS) for the establishment of a Health Insurance Exchange in the state. The state was awarded $34.3 million towards the incorporation of their insurance exchange that will include allowing the Patient Centered Medical Home (PCMH) and primary care extension for the Qualified Health Plans (QHP) to be offered as part of the exchange. Of New Mexico's 400,000 uninsured citizens, as many as 250,000 will qualify for a subsidized premium to put towards the purchase of a QHP on the Exchange beginning in January 2014. In addition, another 175,000 patients will qualify for Medicaid through expansion of the program.

4. SENATE COMMITTEE APPROVES EPIDEMIC PREPAREDNESS MEASURE

On Wednesday, December 14, the Senate HELP Committee approved the *Pandemic and All-Hazards Preparedness Reauthorization Act* (S. 2405). The committee under unanimous consent approved an amendment by Senator Barbara Mikulski (D-MD) creating an advisory committee at HHS on children & disasters (to continue the work of the National Commission on Children & Disasters). Some key features of the bill include:

- The addition of the Medical Countermeasure Strategic Investor, which would authorize creation of an independent entity to provide technical and business advice, as well as venture capital, for novel medical countermeasures;
- More flexibility in the FDA Regulatory Management Plans such as a longer time frame and the ability to prioritize which products receive a plan;
- Border states will now have to define border-specific issues in preparedness plans;
- Clarification of the pre-event emergency use authorization language, including removing obstacles to approval of those products.

5. MEDICARE RELEASES PROPOSED "SUNSHINE" REGULATION

On December 14, CMS released the proposed "Medicare, Medicaid, Children's Health Insurance Program Transparency Reports and Reporting of Physician Ownership or Investment Interests". Also known as the "Sunshine" rule, the CMS press release describes the intent is to increase public awareness of financial relationships between drug and device manufacturers

and health care providers. If finalized without change, it requires manufacturers of drugs, devices, biologicals, and medical supplies covered by Medicare, Medicaid, or the CHIP to report to CMS payments or other transfers of value they make to physicians and teaching hospitals. The proposed rule would also require manufacturers and group purchasing organizations (GPOs) to disclose to CMS physician ownership or investment interests.

Violators of the reporting requirements will be subject to civil monetary penalties, capped at $150,000 annually for failing to report, and $1,000,000 for knowingly failing to report.

Key dates associated with these proposed requirements are:

- CMS is proposing that data collection will not begin on Jan. 1, 2012 and that manufacturers and GPOs do not need to begin data collection until final regulations are issued.
- CMS will accept comments on the proposed rule until Feb. 17, 2012, and will respond to them in a final rule to be published in 2012.
- Depending on the timing of the final rule, CMS is proposing that manufacturers and GPOs will be required to submit a partial year on Mar. 31, 2013.
- Once the data has been submitted, CMS will aggregate manufacturer submissions at the individual physician and teaching hospital level, provide them with a 45-day period to confidentially review and, if necessary, correct the data, and make the data publicly available by Sep. 30, 2013. For each year thereafter, CMS must publish the data for the preceding calendar year by June 30th.

Publicly available reports would include the physician's name, business address, specialty and National Provider Identifier (NPI), date of payment, associated covered item, form of payment, and nature of payment. CMS provided "nature of payment" categories to include consulting fees, compensation for services other than consulting, honoraria, gift, entertainment, food, travel (including the specified destinations), education, research, charitable contribution, royalty or license, current or prospective ownership or investment interest, direct compensation for serving as faculty or as a speaker for a medical education program, grant, or any other nature of the payment or other transfer of value (as defined by the Secretary).

CMS proposes to exclude from reporting requirements:

- Transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year.
- Product samples that are not intended to be sold and are intended for patient use.
- Educational materials that directly benefit patients or are intended for patient use.
- The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.
- Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.
- A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.
- Discounts, including rebates.
- In-kind items used for the provision of charity care.
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.
- In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

- In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.
- In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.
- Transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient.

The AAFP is currently reviewing the regulation and will provide comments to CMS prior to February 17.

6. AAFP OBJECTS TO MEDICARE CHANGES TO PEDIATRIC DEVELOPMENTAL CODE

In a letter sent December 20 to CMS, the AAFP expressed concern that CMS with little notice or discussion changed the status indicator on code 96110 from "A" (Active) to "X" (Statutory Exclusion) and removed the previously-published relative value units (RVUs) from inclusion on the 2012 Medicare physician fee schedule. The CPT Editorial Panel revised the descriptor for code 96110 from "developmental testing; limited," to "developmental screening" and the revised descriptor's inclusion of the term "screening" resulted in CMS's decision to consider this code statutorily excluded from payment. CMS created and appropriately valued a supplemental HCPCS Level II "G" code (G0451) for 2012, however the AAFP argued CMS misunderstood the term "screening" and advised CMS to change the status indicator of code 96110, back to status indicator "A". The AAFP urged CMS to refrain from implementing the new G code, G0451 due to the unnecessary confusion it will cause. If CMS refuses this suggestion, the AAFP advocated that CMS at a minimum change the status indicator for code 96110 to "N" (noncovered) and publish the RVUs for this code on the Medicare physician fee schedule so that state Medicaid agencies and private payers who do cover 96110 can rely on the RVUs in the Medicare physician fee schedule to help set their payment levels.

7. ESSENTIAL HEALTH BENEFITS "BULLETIN" DISAPPOINTS AAFP

On December 16, the U.S. Department of Health & Human Services issued a press release and posted a bulletin that solicits comments before January 31, 2012 on a proposed approach to define the "essential health benefits" as required by Section 1302 of the *Affordable Care Act*. This section requires HHS to define these benefits within the following categories:

- Ambulatory patient services
- Emergency services
- Hospitalization
- Maternity and newborn care
- Mental health and substance use disorder services, including behavioral health treatment
- Prescription drugs
- Rehabilitative and habilitative services and devices
- Laboratory services
- Preventive and wellness services and chronic disease management, and
- Pediatric services, including oral and vision care.

In the bulletin, HHS indicates that states have the option to select a benchmark plan by choosing one of the following:

- One of the three largest small group plans in the state by enrollment;
- One of the three largest state employee health plans by enrollment;
- One of the three largest federal employee health plan options by enrollment;
- The largest HMO plan offered in the state's commercial market by enrollment.

If states choose not to select a benchmark, HHS proposes that the default benchmark will be the small group plan with the largest enrollment in the state. In a statement issued after release of the bulletin, the AAFP expressed concern that HHS chose not to guarantee primary care and preventive services be included as essential health benefits for state-based exchanges in 2014. The AAFP committed to working with HHS, the states, and prospective exchange entities to continue developing their benefit packages so that the state-based exchanges offer a reliable and comprehensive range of services.

8. CMS ANNOUNCES 32 PIONEER ACOS WILL START ON JAN. 1, 2012

On December 19, the Centers for Medicare & Medicaid Services announced that 32 organizations were selected to participate in the Pioneer Accountable Care Organization (ACO) Model and will begin in the new year. According to CMS, the Pioneer ACO Model is designed for health care organizations and providers that are already experienced in coordinating care for patients across care settings and allows these groups to move more rapidly from a shared savings payment model to a population-based payment model on a track consistent with, but separate from, the Medicare Shared Savings Program. CMS estimates that the initiative could save up to $1.1 billion over five years. The 32 Pioneer ACOs underwent a rigorous competitive selection process by the Innovation Center, including extensive review of applications and in-person interviews. Selected Pioneer ACOs include physician-led organizations and health systems, urban and rural organizations, and organizations in various geographic regions of the country, representing 18 States and the opportunity to improve care for about 860,000 Medicare beneficiaries. The first performance period of the Pioneer ACO Model will begin January, 1st 2012. CMS released a fact sheet that includes the name and "service area" of the 32 organizations participating in the Pioneer ACO Model:

1. Allina Hospitals & Clinics, Minnesota and Western Wisconsin
2. Atrius Health Services, Eastern and Central Massachusetts
3. Banner Health Network, Phoenix, Arizona Metropolitan Area (Maricopa and Pinal Counties)
4. Bellin-Thedacare Healthcare Partners, Northeast Wisconsin
5. Beth Israel Deaconess Physician Organization, Eastern Massachusetts
6. Bronx Accountable Healthcare Network (BAHN), New York City (the Bronx) and lower Westchester County, NY
7. Brown & Toland Physicians, San Francisco Bay Area, CA
8. Dartmouth-Hitchcock ACO, New Hampshire and Eastern Vermont
9. Eastern Maine Healthcare System, Central, Eastern, and Northern Maine
10. Fairview Health Systems, Minneapolis, MN Metropolitan Area
11. Franciscan Health System, Indianapolis and Central Indiana
12. Genesys PHO, Southeastern Michigan
13. Healthcare Partners Medical Group, Los Angeles and Orange Counties, CA
14. Healthcare Partners of Nevada, Clark and Nye Counties, NV
15. Heritage California ACO, Southern, Central, and Costal California
16. JSA Medical Group, a division of HealthCare Partners, Orlando, Tampa Bay, and surrounding South Florida
17. Michigan Pioneer ACO, Southeastern Michigan
18. Monarch Healthcare, Orange County, CA
19. Mount Auburn Cambridge Independent Practice Association (MACIPA), Eastern Massachusetts
20. North Texas Specialty Physicians, Tarrant, Johnson and Parker counties in North Texas
21. OSF Healthcare System, Central Illinois
22. Park Nicollet Health Services, Minneapolis, MN Metropolitan Area
23. Partners Healthcare, Eastern Massachusetts
24. Physician Health Partners, Denver, CO Metropolitan Area

25. Presbyterian Healthcare Services – Central New Mexico Pioneer Accountable Care Organization, Central New Mexico
26. Primecare Medical Network, Southern California (San Bernardino and Riverside Counties)
27. Renaissance Medical Management Company, Southeastern Pennsylvania
28. Seton Health Alliance, Central Texas (11 county area including Austin)
29. Sharp Healthcare System, San Diego County
30. Steward Health Care System, Eastern Massachusetts
31. TriHealth, Inc., Northwest Central Iowa
32. University of Michigan, Southeastern Michigan

9. CMS LAUNCHES INDEPENDENCE AT HOME DEMONSTRATION PROJECT

On December 20, the Centers for Medicare & Medicaid Services (CMS) announced the Independence at Home demonstration project. As outlined in Section 3024 of the *Affordable Care Act*, this effort tests a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes to applicable beneficiaries. Participants will be accountable for providing comprehensive, coordinated, continuous, and accessible care to high-need populations at home and coordinating health care across all treatment settings.

Medical practices eligible to participate in the Demonstration must include physicians or nurse practitioners who have experience delivering home-based primary care. Up to 50 practices will be selected and each must serve at least 200 Medicare fee-for-service beneficiaries with multiple chronic conditions and functional limitations. Participation in the demonstration is voluntary for up to 10,000 Medicare patients with chronic conditions.

In a related CMS fact sheet, the agency indicates that, "applications and letters of intent, if applicable, are due on February 6, 2012" and notes that questions may be emailed to IndependenceAtHomeDemo@cms.hhs.gov.

10. REGULATORY BRIEFS

- On December 12, the Centers for Disease Control and Prevention released A Framework for Patient-Centered Health Risk Assessments (HRAs). The *Affordable Care Act* requires the addition of a HRA to the 2012 Annual Wellness Visit, however the CDC specifies that the framework is a guidance document intended to inform the development of HRAs and is not mandatory. The AAFP will release further educational information for physicians regarding the 2012 Annual Wellness Visit.
- On December 13, the Centers for Medicare & Medicaid Services released the final rule implementing the Consumer Operated and Oriented Plan (CO-OP) program.
- Also on December 13, the Obama Administration announced recovery of over $5.6 billion in fraudulent payments in fiscal year 2011. As part of this announcement, CMS announced additional steps to identify and prevent prescription drug fraud and abuse in the Medicare Part D program.
- On December 14, the U.S. Department of Health & Human Services announced $218 million in funds for 26 state, regional, national, or hospital system organizations. As a piece of the Partnership for Patients initiative, these funds will be used to help identify solutions already working to reduce healthcare acquired conditions, and work to spread them to other hospitals and health care providers. In addition, the Hospital Engagement Networks' will be funded with $500 million from the CMS Innovation Center.
- On December 14, HHS highlighted the one-year anniversary of the release of the Strategic Framework on Multiple Chronic Conditions.

- On December 14, HHS released data indicating that the *Affordable Care Act* has helped 2.5 million young adults stay on their parents' insurance plans through age 26. This policy took effect in September 2010.
- On December 15, CMS announced the first results for a new "value-based purchasing" program for dialysis facilities. Nearly 70 percent of dialysis facilities that were evaluated under the program will receive no payment reduction in payment year (PY) 2012, while the remaining 30 percent will receive reductions ranging from 0.5 percent to 2.0 percent depending on their final performance scores.
- The Centers for Disease Control and Prevention (CDC) announced a series of webinars regarding the National Healthy Worksite Program, which is an initiative to establish and evaluate comprehensive workplace health programs to improve the health of workers and their families. Registration is required for each webinar, all times EST:
    - December 20, 2–3 pm;
    - January 13, 12–1 pm;
    - January 20, 12–1 pm; and
    - January 20, 3–4 pm.
- On December 21 from 1 – 3pm, CMS will host a national conference call titled, "Payment Standardization and Risk Adjustment for the Medicare Physician Feedback and Value Modifier Programs." As discussed in the final 2012 Medicare physician fee schedule (MPFS), CMS provides confidential feedback reports to physicians and physician group practices about the resource use and quality of care they provide to their Medicare patients. Section 3007 of the *Affordable Care Act* requires CMS to apply a Value Modifier, which compares the quality of care furnished to the cost of that care, to physician payment rates under the MPFS starting with specific physicians and physician groups in 2015 and expanding to all physicians by 2017. Registration is required.
- Before December 27, CMS is accepting nominations for potential members to join the recently renamed Hospital Outpatient Panel (formally known as the Advisory Panel on Ambulatory Payment Groups). Membership has been expanded to 19 seats and CMS seeks 6 new members. More information on the application process can be found online.
- On January 24 from 9-5p ET in Washington, DC, the Office of Minority Health within the U.S. Department of Health and Human Services will hold their Meeting of the Advisory Committee on Minority Health. This meeting is open to the public but preregistration is required.
- On January 25, 2012 from 1 – 2:30pm ET, CMS will conduct the National Medicare Education Program (NMEP) Webinar.