



Health Policy Briefing

September 12, 2016

CMS to Allow Choice in Level and Pace of MACRA Participation

The Centers for Medicare and Medicaid Services (CMS) announced that health care providers will be allowed to choose the level and pace at which they comply with implementation of the Medicare Access and CHIP Reauthorization Act’s (MACRA) Quality Payment Program, which is set to start on January 1, 2017. Eligible physicians and other clinicians will have multiple options for participation to ensure that they do not receive a negative payment adjustment in 2019. Under the first option, providers can test the Quality Payment Program. As long as some data is reported, providers will avoid a negative payment adjustment and help ensure that their systems are prepared for broader participation in 2018. Providers also have the option of participating for only part of the calendar year. Through reporting for a reduced number of days, physicians could still qualify for a small payment adjustment. Those clinicians who are fully prepared can choose to participate for the full calendar year, which might result in a modest positive payment adjustment. Finally, providers have the option of participating in an advanced alternative payment model (APM) in 2017. Other details about CMS’ plans for the Quality Payment Program will be described in the final rule, expected to be released in November.

Zika Update

The Senate has again rejected a spending bill that included funding to combat the Zika virus on a 52-46 procedural vote, with 60 votes required to end debate on the conference report and move forward on the legislation. Both Democrat and Independent senators unanimously voted against the \$1.1 billion package written by the GOP due to inclusion of language regarding Planned Parenthood. The bill passed the House in June but has now failed in the Senate three times. Zika funding is now expected to be included in the must-pass continuing resolution (CR) to fund the government later this month, and some Senate Republicans have hinted that the Planned Parenthood provisions will be removed. Both Senate Majority Leader Mitch McConnell (R-Ky.) and House Speaker Paul Ryan (R-Wis.) have promised to address Zika funding before the end of September. The U.S. Department of Health and Human Services

Inside

Clinton Releases Plan to Stem the Rise of Generic Drug Prices.....	2
Lawmakers Urge MACRA Flexibility.....	2
Blue Ribbon Panel Makes Cancer Moonshot Recommendations.....	2
Senate Aims to Move on CR This Week.....	3
EpiPen Investigation Launched.....	3
Cures Timeline Pushed to Lame-Duck.....	3
GAO Releases Report on Per Capita Medicaid Caps Policy.....	3
Upcoming Congressional Hearings and Markups.....	4
Recently Introduced Health Legislation.....	4

continued on page 2

continued from page 1

announced last week that it will provide \$350,000 to the American Academy of Pediatrics to expand its capacity to help children affected by Zika. The money will be used to provide technical assistance to clinicians treating children in areas affected by the virus. As of September 7, the Centers for Disease Control and Prevention (CDC) estimates that the current number of Zika cases in the U.S. and its territories stands at 18,833.

Clinton Releases Plan to Stem the Rise of Generic Drug Prices

Democratic presidential nominee Hillary Clinton has released a **plan** aimed at protecting patients from “unjustified” price hikes of lifesaving medications. Clinton would create a federal consumer oversight body to investigate increasing prices of older drugs with limited competition, specifically, “life-saving or critically needed treatments that have long been available; with no meaningful change or improvement in the product (such as when a new acquirer rapidly raises the price); where there is limited or no competition among manufacturers of the treatment.” The board would have enforcement power if it deems a price increase unjustified, and the company would be fined or face increased rebates. The funds would be used to support the development of lower-cost alternatives and increasing the approval of competing treatments. An unjustified price increase would depend on the magnitude of the increase, cost of production, and the value of the treatment. Release of the plan follows recent outrage from the public and lawmakers about the price of EpiPens.

Lawmakers Urge MACRA Flexibility

A bipartisan group of lawmakers from the House Energy and Commerce Committee and House Ways and Means Committee have **written** to U.S. Department of Health and Human Services (HHS) Secretary Sylvia Mathews Burwell requesting a list of flexibilities for practitioners as the administration implements the Medicare Access and CHIP Reauthorization Act (MACRA). Specifically, the members request simplified, streamlined, coordinated requirements; clear pathways to succeed in the Merit-Based Incentive Payment System (MIPS) or the Alternative Payment Model (APM) track; opportunities to move to the APM track and chances to be rewarded for meaningful delivery system reform activities in MIPS and APMs; and appropriate systems to be ready and in place prior to the January 2017 reporting period. The letter was signed by Energy and Commerce Chairman Fred Upton (R-Mich.), Energy and Commerce Ranking Member Frank Pallone, Jr. (D-N.J.), Health Subcommittee Chairman Joseph Pitts (R-Pa.), Health Subcommittee Ranking Member Gene Green (D-Texas), Ways and Means Chairman Kevin Brady (R-Texas), and Ways and Means Ranking Member Sander Levin (D-Mich.), Health Subcommittee Chairman Pat Tiberi (R-Ohio), and Health Subcommittee Ranking Member Jim McDermott (D-Wash.).

Blue Ribbon Panel Makes Cancer Moonshot Recommendations

Blue Ribbon Panel Makes Cancer Moonshot Recommendations – The Cancer Moonshot Blue Ribbon Panel presented **10 recommendations** to the President’s National Cancer Advisory Board last week at the direction of Vice President Biden. With the goal of accelerating cancer research, the Panel calls for

- Creation of a network for direct patient engagement;
- Organization of a cancer immunotherapy clinical trials network;
- Therapeutic target identification to overcome drug resistance;
- Formation of a national cancer data ecosystem for sharing and analysis;
- Improving understanding of fusion oncoproteins in pediatric cancer;
- Symptom management research;
- Implementation of evidence-based approaches to prevention and early detection;
- Retrospective analysis of biospecimens from patients treated with standard of care;
- Generation of human tumor atlases; and
- Development of new enabling cancer technologies.

Senate Aims to Move on CR This Week

Senate Majority Leader Mitch McConnell (R-Ky.) has said that he will begin work on a short-term spending measure that will last through December 9 as early as this week. This plan puts him in opposition with the conservative House Freedom Caucus members who support a longer continuing resolution (CR) lasting through early 2017. But with many incumbent senators at risk of losing their seat this election season, McConnell's plan of moving quickly on a ten-week CR would allow members to return home to campaign earlier than originally scheduled. Lawmakers have through September 30 to come to an agreement that keeps the federal government operating.

EpiPen Investigation Launched

The Senate Homeland Security Subcommittee on Investigations announced the opening of an inquiry into recent increases of the price of EpiPens. The announcement was made by Subcommittee Chairman Rob Portman (R-Ohio) and Ranking Member Claire McCaskill (D-Mo.). The manufacturer of the epinephrine autoinjector, Mylan, has recently taken steps to increase discounts for the device and introduce a generic version onto the market. These efforts, however, have done little to stem the outrage over the 400 percent EpiPen price hike that has taken place in recent years.

Cures Timeline Pushed to Lame-Duck

Senate passage of a medical innovation package is likely going to be pushed to the lame-duck session of Congress following the elections. House Energy and Commerce Committee Chairman Fred Upton (R-Mich.), who led passage of the companion House bill known as the 21st Century Cures Act (H.R. 6), recently acknowledged that there is not enough time to complete work in the Senate before the chamber breaks for election recess. The timeline on the bill has already been delayed multiple times as lawmakers negotiate an agreement on how to pay for new funding for the National Institutes of Health (NIH). Upton said he remains confident that the bill would become law before the end of this Congress.

GAO Releases Report on Per Capita Medicaid Caps Policy

The Government Accountability Office (GAO) has posted a [report](#) explaining considerations for implementing a per capita cap in the Medicaid program. This approach would limit the amount of federal Medicaid funding states could receive per enrollee. Should policymakers decide to pursue a per capita cap, the agency believes they should consider the issues of coverage and flexibility, allocation of funds across states and over time, accountability, and the broader effects that changes to Medicaid financing could have on the federally financed health care system as a whole. The GAO also cautions policymakers about the limitations of both enrollee and expenditure data from the Centers for Medicare and Medicaid Services (CMS), as well as other available federal data sources, to be used for the purpose of developing a per capita cap amount and allocating those funds. The report was requested by Senate Finance Committee Chairman Orrin Hatch (R-Utah) and House Energy and Commerce Committee Chairman Fred Upton (R-Mich.), who favor the policy as a means to limit cost-growth in the program.

Upcoming Congressional Hearings and Markups

House Energy and Commerce Subcommittee on Health markup of H.R. 4365, Protecting Patient Access to Emergency Medications Act of 2016; H.R. 1192, National Diabetes Clinical Care Commission Act; H.R. 1209, Improving Access to Maternity Care Act; H.R. 1877, Mental Health First Aid; H.R. 2713, Title VIII Nursing Workforce Reauthorization Act of 2015; 5:00 p.m., 2123 Rayburn Bldg.; September 12

House Energy and Commerce Subcommittee on Health and Subcommittee on Oversight and Investigations hearing titled "The Affordable Care Act on Shaky Ground: Outlook at Oversight;" 10:00 a.m., HVC-210; September 14

House Ways and Means Health Subcommittee hearing titled "Exploring the Use of Technology and Innovation to Create Efficiencies, Higher Quality, and Better Access for Beneficiaries in Health Care;" 10:00 a.m., 1100 Longworth Bldg.; September 14

Senate Veterans Affairs Committee hearing titled "The Future of the VA: Examining the Commission on Care Report and VA's Response;" 2:30 p.m., 418 Russell Bldg.; September 14

House Energy and Commerce Subcommittee on Commerce, Manufacturing, and Trade hearing titled "Disrupter Series: Advanced Robotics;" 10:30 a.m., 2322 Rayburn Bldg.; September 14

Senate Homeland Security and Governmental Affairs Committee hearing titled "The State of Health Insurance Markets;" 10:00 a.m., 342 Dirksen Bldg.; September 15

House Veterans' Affairs Committee field hearing titled "An Assessment of Deficiencies at the Northport VA Medical Center;" 9:00 a.m. (local time), Northport VA Medical Center, Auditorium, 79 Middleville Road, Northport, NY 11768; September 20

Recently Introduced Health Legislation

H.R.5934 (introduced by Rep. John Katko): To amend the Controlled Substances Act to add certain synthetic substances to schedule I, and for other purposes; Energy and Commerce, Judiciary; September 6

H.R.5932 (introduced by Rep. Tammy Duckworth): To amend title 38, United States Code, to eliminate copayments by the Department of Veterans Affairs for medicines relating to preventive health services, and for other purposes; Veterans Affairs; September 6

H.R.5942 (introduced by Rep. Todd C. Young): To amend title XVIII of the Social Security Act to establish a demonstration program to provide integrated care for Medicare beneficiaries with end-stage renal disease, and for other purposes; Energy and Commerce, Ways and Means; September 7

H.R.5960 (introduced by Rep. Renee Ellmers): To amend title XXVII of the Public Health Service Act to make publicly available, through 2021, the amount of premium rate increases of health insurance plans in advance of such increases taking effect, and for other purposes; Energy and Commerce; September 8

H.R.5958 (introduced by Rep. Curt Clawson): Making supplemental appropriations for fiscal year 2016 for Zika response and preparedness; Appropriations, Budget; September 8

H.R.5956 (introduced by Rep. Katherine Clark): To amend the Public Health Service Act to better address substance use and substance use disorders among young people; Energy and Commerce; September 8

H.R.5951 (introduced by Rep. Morgan H. Griffith): To amend title XVIII of the Social Security Act to prohibit prescription drug plan sponsors and MA-PD organizations under the Medicare program from retroactively reducing payment on clean claims submitted by pharmacies; Energy and Commerce, Ways and Means; September 8

H.Res.850 (introduced by Rep. Tim Murphy): Recognizing suicide as a public health problem and expressing support for designation of September as “National Suicide Prevention Month”; Energy and Commerce; September 8

H.R.5981 (introduced by Nydia M. Velazquez): To amend the Public Health Service Act to improve the provision of medical services to aliens present in the United States; Energy and Commerce; September 9

S.3298 (introduced by Sen. Jeanne Shaneen): A bill to amend the Federal Food, Drug, and Cosmetic Act to require the label of any drug containing an opiate to prominently state that addiction is possible; Health, Education, Labor, and Pensions; September 7

S.3297 (introduced by Sen. Tom Cotton): A bill to amend the Internal Revenue Code of 1986 to provide an exemption to the individual mandate to maintain health coverage for certain individuals whose premium has increased by more than 10 percent, and for other purposes; September 7

S.3296 (introduced by Sen. John McCain): A bill to amend the Internal Revenue Code of 1986 to provide an exemption to the individual mandate to maintain health coverage for individuals residing in counties with fewer than 2 health insurance issuers offering plans on an Exchange; September 7

S.3290 (introduced by Sen. Marco Rubio): A bill to mitigate risks of the Zika virus to members of the Armed Forces and Department of Defense civilian personnel stationed in or deployed to areas affected by or that may soon be affected by the Zika virus, to authorize the Secretary of Defense to transfer funds to counter or control the Zika virus, and for other purposes; Armed Services; September 7

S.3305 (introduced by Sen. Chuck Grassley): A bill to amend title XVIII of the Social Security Act to require the use of electronic visit verification systems for home health services under the Medicare program; Finance; September 8

S.3302 (introduced by Sen. Barbara Boxer): A bill establishing the Centers for Disease Control and Prevention Emergency Response Fund for the Director of the Centers for Disease Control and Prevention to provide assistance for a public health emergency, and for other purposes; Health, Education, Labor, and Pensions; September 8