



CMS Releases Long Awaited MACRA Proposed Regulations

Last week, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule to further implementation of the Medicare Access and CHIP Reauthorization Act (MACRA). This legislation repealed the sustainable growth rate (SGR) formula and was passed by Congress last year. CMS' rule spells out the path toward physician use of either the Merit-Based Incentive Payment System (MIPS) or an Alternative Payment Model (APM). The release of the proposed rule was welcomed by bipartisan leadership on the House Energy and Commerce Committee, who helped author and pass MACRA. Chairman Upton and Ranking Member Pallone said they look forward to reviewing the proposed rule and continuing to be a part of the discussion.

Wakefield Nomination Stalled By Abortion Concerns

Mary Wakefield's nomination to be Deputy Director of the U.S. Department of Health and Human Services (HHS) was dropped from an executive session panel of the Senate Finance Committee to approve federal nominees. While her nomination was once uncontroversial, it is reported that Republicans have decided to delay further action in response to HHS not conducting a sufficient investigation into a California agency's decision requiring all health insurers in the state to cover abortions. Republicans argue that the California decision is a violation of the Weldon amendment, a federal law preventing discrimination against health insurers which do not cover abortions.

Zika Update

Congress has left town for a one week recess without reaching an agreement on funding levels and a legislative path forward for moving an emergency funding bill to combat the Zika virus. Democrats and the Administration are pushing for funds in the amount of \$1.9 billion, and legislation has been introduced in both chambers to fully fund that request (H.R. 5044/S. 2843). But Senate appropriators are trying to negotiate a compromise closer to \$1.1 billion. This amount is thought to be

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somewhat less likely to attract resistance from fiscal conservatives in the House. Some House Republicans are demanding that emergency spending for Zika be offset by matching cuts elsewhere in the federal budget. Although House Majority Leader Kevin McCarthy (R-Calif.) has said that the \$589 million the White House has transferred from the administration's Ebola response to Zika should be sufficient for fiscal year (FY) 2016, House Appropriations Chairman Harold Rogers (R-Ky.) has said that work has already begun on a House Zika funding bill. While Democrats have thus far not disrupted the regular appropriations process by attaching emergency funds, this remains a possibility moving forward. Officials from the administration, including HHS Secretary Sylvia Mathews Burwell and Dr. Tony Fauci, Director of the National Institute for Allergy and Infectious Diseases (NIAID) have said that without supplemental funding, some aspects of the government's response to Zika, such as the development of diagnostic tests and an experimental Zika vaccine, could be delayed.

Congressional Letters to CMS Regarding Part B Rx Payment Model

Republicans on the Senate Finance Committee have sent a **letter** to Acting Administrator for the Centers for Medicare and Medicaid Services (CMS) Andy Slavitt calling into question the unprecedented scope of the agency's proposed Part B drug payment model. The lawmakers write that they sincerely hope that the proposed rule is withdrawn. Senate Finance Democrats have sent their own **letter** to Mr. Slavitt, expressing concerns about the proposed model. But unlike their Republican colleagues, the signers of the letter are not asking CMS to do away with the proposal entirely. "Any proposed changes to the Part B program must be carefully considered to prevent any disruptions in care for Medicare beneficiaries, particularly those with serious and complex conditions," the letter states. The lawmakers ask CMS to resolve the following issues before moving forward with the model: beneficiaries' access to Part B medications and quality of care; potential impact of the proposed model on site of service; and the proposed model's interaction with existing delivery and payment reform models. A similar letter is being circulated by Rep. Richard E. Neal (D-Mass.) in the House. Republicans in the House, lead by Reps. Tom Price (R-Ga.), John Shimkus (R-Ill.), and Charles Boustany (R-La.) are circulating a letter calling on CMS to withdraw the proposed rule. The deadline for co-signing the letter is today and at the writing of this article, the letter already has been co-signed by well over half of the House, including several democrats. Meanwhile, Rep. Larry Bucshon (R-Ind.) and Rep. Bob Dold (R-Ill.) introduced a bill (H.R. 5122) that would halt the implementation of the Part B model altogether. The administration continues to defend the program and signals that it will move forward.

AHRQ Gets New Director

Dr. Andrew Bindman has been named as the new director of the Agency for Healthcare Research and Quality (AHRQ). Bindman is a primary care physician and health policy researcher at the University of California at San Francisco. He has served as a senior advisor in the Centers for Medicare and Medicaid Services (CMS) where he used data analytics to accelerate health care transformation in Medicaid.

Legislation Would Create Cybersecurity Office within HHS

Rep. Billy Long (R-Mo.) and Rep. Doris Matsui (D-Calif.) have introduced legislation aimed at improving cybersecurity within the U.S. Department of Health and Human Services (HHS). The HHS Data Protection Act (H.R. 5086) would mandate that the president appoint a chief information security officer by October 1 of this year. It would also call for the Secretary to submit a report to Congress one year after the legislation's enactment on the new officer's plan to oversee and coordinate information security. The legislation comes in response to a report by the House Energy and Commerce Committee that found "pervasive and persistent deficiencies" across the agency's information security programs.

Energy and Commerce Advances Opioid Legislation to the Floor

Last week, the House Energy and Commerce Committee advanced 12 pieces of legislation related to the prescription drug and heroin abuse epidemic:

- H.R. 4641, to provide for the establishment of an inter-agency task force to review, modify, and update best practices for pain management and prescribing pain medication, and for other purposes
- H.R. 4978, the Nurturing and Supporting Healthy Babies Act
- H.R. 1818, the Veteran Emergency Medical Technician Support Act of 2015
- H.R. 4981, the Opioid Use Disorder Treatment Expansion and Modernization Act
- H.R. 4969, the John Thomas Decker Act
- H.R. 4599, the Reducing Unused Medications Act of 2016
- H.R. 4976, the Opioid Review Modernization Act
- H.R. 4982, Examining Opioid Treatment Infrastructure Act of 2016
- H.R. 3250, the DXM Abuse Prevention Act of 2015
- H.R. 3680, the Co-Prescribing to Reduce Overdoses Act of 2015
- H.R. 3691, the Improving Treatment for Pregnant and Postpartum Women Act of 2015
- H.R. 4586, Lali's Law

While the bills were largely approved with bipartisan support, debate did arise over Democratic attempts to attach \$1 billion in emergency funding to combat the opioid crisis. There was also disagreement about the expansion of the cap for physicians to prescribe buprenorphine from 100 patients to 250 patients. Several Democrats on the Committee spoke in favor of abandoning the caps altogether, and introduced amendments to increase the limit to 300 patients and 500 patients. These partisan amendments were each voted down by roll call vote. There was also debate regarding the so-called "cut go" rules that require new or increased spending be offset by a reduction in current spending. The Committee amended H.R. 4586, H.R. 3680, and H.R. 3691 to be cut-go compliant, reducing the funding contained in each bill. Completion of the markup sets up a floor vote for the week of May 9, after the House returns from recess.

Senators Request Feedback on MU Legislation

Sens. John Thune (R-S.D.), Lamar Alexander (R-Tenn.), Mike Enzi (R-Wyo.), Pat Roberts (R-Kans.), Richard Burr (R-N.C.), and Bill Cassidy (R-La.) have **written** to the U.S. Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) requesting feedback on recently introduced legislation to address implementation of the meaningful use program. The legislation would shorten the reporting period for eligible physicians and hospitals from 365 days to 90 days, relax the all-or-nothing nature of the current program, and extend flexibility in applying for a hardship exemption from meaningful use requirements.

Upcoming Congressional Meetings and Hearings

Senate Finance Committee hearing on "Can Evidence Based Practices Improve Outcomes for Vulnerable Individuals and Families?" 10:00 a.m., 215 Dirksen Bldg.; May 10

Recently Introduced Health Legislation

H.R. 5044 (introduced by Rep. Lowey): A bill making supplemental appropriations for fiscal year 2016 to respond to Zika virus; to the Committee on Appropriations, and in addition to the Committee on the Budget, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; April 25

H.R. 5045 (introduced by Rep. Ellmers): A bill to impose a moratorium on the implementation of a proposed Medicare local coverage determination on lower limb prostheses; to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; April 25

H.R.5048 (introduced by Rep. Frank C. Guinta): A bill to require a study by the Comptroller General of the United States on Good Samaritan laws that pertain to treatment of opioid overdoses, and for other purposes; to the House Committee on the Judiciary; April 26

H.R.5052 (introduced by Rep. Kevin McCarthy): A bill to direct the Attorney General and the Secretary of Health and Human Services to evaluate the effectiveness of grant programs that provide grants for the primary purpose of providing assistance in addressing problems pertaining to opioid abuse, and for other purposes; to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; April 26

H.R.5057 (introduced by Rep. William R. Keating): A bill to amend title 38, United States Code, to provide for a continuing education requirement for employees of the Department of Veterans Affairs authorized to prescribe medication; to the House Committee on Veterans' Affairs; April 26

H.R.5068 (introduced by Rep. Billy Long): A bill to amend the Public Health Service Act to establish the Office of the Chief Information Security Officer within the Department of Health and Human Services; to the House Committee on Energy and Commerce; April 26

H.RES.703 (introduced by Rep. Elliot Engel): A resolution expressing support for designation of November 2016, as "National Bladder Health Month"; to the House Committee on Oversight and Government Reform; April 26

H.RES.705 (introduced by Rep. Alcee L. Hastings): A resolution expressing support for designation of June as "National Men's Cancer Awareness Month"; to the House Committee on Energy and Commerce; April 26

H.R.5073 (introduced by Rep. Steve Cohen): A bill to establish EUREKA Prize Competitions to accelerate discovery and development of disease-modifying, preventive, or curative treatments for Alzheimer's disease and related dementia, to encourage efforts to enhance detection and diagnosis of such diseases, or to enhance the quality and efficiency of care of individuals with such diseases; to the House Committee on Energy and Commerce; April 27

H.R.5088 (introduced by Rep. Jackie Speier): A bill to prevent abusive billing of ancillary services to the Medicare program, and for other purposes; to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; April 28

H.R.5091 (introduced by Rep. Jeff Denham): A bill to amend title 38, United States Code, to reinstate the requirement for an annual report on the capacity of the Department of Veterans Affairs to provide for specialized treatment and rehabilitative needs of disabled veterans; to the House Committee on Veterans' Affairs; April 28

H.R.5095 (introduced by Rep. Katherine M. Clark): A bill to amend the Public Health Service Act to authorize the Secretary of Health of Human Services to award grants to States (or collaborations of States) to establish, expand, or maintain a comprehensive regional, State, or municipal system to provide training, education, consultation, and other resources to prescribers relating to patient pain, substance misuse, and substance abuse disorders, and for other purposes; to the House Committee on Energy and Commerce; April 28

H.R.5100 (introduced by Rep. Tony Cardenas): A bill to amend title XIX of the Social Security Act to protect at-risk youth against termination of Medicaid eligibility while an inmate of a public institution; to the House Committee on Energy and Commerce; April 28

H.R. 5122 (introduced by Rep. Bucshon): A bill to prohibit further action on the proposed rule regarding testing of Medicare part B prescription drug models; to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; April 29

H.R. 5127 (introduced by Rep. Griffith): A bill to amend the Federal Food, Drug, and Cosmetic Act to extend the exclusivity period for certain drug products developed or labeled so as to reduce drug abuse, and for other purposes; to the Committee on Energy and Commerce; April 29

H.R. 5128 (introduced by Rep. Roby): A bill to direct the Secretary of Veterans Affairs to establish a grant program to improve the monitoring of mental health and substance abuse treatment programs of the Department of Veterans Affairs; to the Committee on Veterans' Affairs; April 29

H.R. 5133 (introduced by Rep. Hardy): A bill to improve rural health services, including by requiring the Department of Health and Human Services to conduct an annual study on such services, and for other purposes; to the Committee on Energy and Commerce, and in addition to the Committee on Agriculture, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; April 29

H.R. 5142 (introduced by Rep. Walberg): A bill to amend the Public Health Service Act to provide for the sharing of health information concerning an individual's substance abuse treatment by certain entities; to the Committee on Energy and Commerce; April 29

H.R. 5145 (introduced by Rep. Bilirakis): A bill to amend title XIX of the Social Security Act to exclude abuse-deterrent formulations of prescription drugs from the Medicaid additional rebate requirement for new formulations of prescription drugs, and for other purposes; to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; April 29

H.R. 5149 (introduced by Rep. Coffman): A bill to amend title 38, United States Code, to provide for the circumstances under which the Secretary of Veterans Affairs shall provide reimbursement for emergency ambulance services; to the Committee on Veterans' Affairs; April 29

H.R. 5161 (introduced by Rep. Mullin): A bill to amend title 38, United States Code, to expand the qualifications for licensed mental health counselors of the Department of Veterans Affairs; to the Committee on Veterans' Affairs; April 29

H.R. 5162 (introduced by Rep. O'Rourke): A bill to amend title 38, United States Code, to authorize the Secretary of Veterans Affairs to disclose to non-Department of Veterans Affairs health care providers certain medical records of veterans who receive health care from such providers; to the Committee on Veterans' Affairs; April 29

H. Res. 712 (introduced by Rep. Murphy of Pennsylvania): A resolution expressing support for the designation of May 2016 as ``Mental Health Month''; to the Committee on Energy and Commerce; April 29

H. Res. 715 (introduced by Rep. Holding): A resolution expressing support for designation of April 2016 as ``National Congenital Diaphragmatic Hernia Awareness Month''; to the Committee on Energy and Commerce; April 29

H. Res. 717 (introduced by Rep. Yoder): A resolution recognizing the importance of cancer research and the contributions of scientists, clinicians, cancer survivors and other patient advocates across the United States who are dedicated to finding a cure for cancer, and supporting the designation of May 2016 as ``National Cancer Research Month''; to the Committee on Energy and Commerce; April 29

S. 2858 (introduced by Sen. Franken): A bill to amend part D of title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate for lower prices for Medicare prescription drugs; to the Committee on Finance; April 27

S. 2861 (introduced by Sen. Rounds): A bill to require the Secretary of Defense to review and monitor prescribing practices at military treatment facilities of pharmaceutical agents for the treatment of post-traumatic stress; to the Committee on Armed Services; April 27

S. 2863 (introduced by Sen. Franken): A bill to amend title XIX of the Social Security Act to remove limitations on Medicaid benefits for persons in custody pending disposition of charges; to the Committee on Finance; April 27

S. 2864 (introduced by Sen. Wyden): A bill to amend title XVIII of the Social Security Act to prevent catastrophic out-of-pocket spending on prescription drugs for seniors and individuals with disabilities; to the Committee on Finance; April 27

S. 2866 (introduced by Sen. Manchin): A bill to amend the Public Health Service Act to provide for the sharing of health information concerning and individual's substance abuse treatment by certain entities; to the Committee on Health, Education, Labor, and Pensions; April 27

S.2871 (introduced by Sen. John Thune): A bill to establish the position of Choice Program Ombudsman within the Office of Inspector General of the Department of Veterans Affairs to manage complaints regarding the provision of hospital care and medical services under section 101 of the Veterans Access, Choice, and Accountability Act of 2014; to the Committee on Veterans' Affairs; April 28

S.2872 (introduced by Sen. Shelley Moore Capito): A bill to require the Government Accountability Office to submit to Congress a report on neonatal abstinence syndrome (NAS) in the United States and its treatment under Medicaid; to the Committee on Finance; April 28

S.2873 (introduced by Sen. Orrin G. Hatch): A bill to require studies and reports examining the use of, and opportunities to use, technology-enabled collaborative learning and capacity building models to improve programs of the Department of Health and Human Services, and for other purposes; to the Committee on Health, Education, Labor, and Pensions; April 28

S.2874 (introduced by Sen. Christopher S. Murphy): A bill to amend title XIX of the Social Security Act to protect the enrollment of incarcerated youth for medical assistance under the Medicaid program, and for other purposes; to the Committee on Finance; April 28

S.2883 (introduced by Sen. Sherrod Brown): A bill to amend title 38, United States Code, to extend the requirement of the Secretary of Veterans Affairs to submit a report on the capacity of the Department of Veterans Affairs to provide for the specialized treatment and rehabilitative needs of disabled veterans; to the Committee on Veterans' Affairs; April 28

S.2896 (introduced by Sen. John McCain): A bill to eliminate the sunset date for the Veterans Choice Program of the Department of Veterans Affairs, to expand eligibility for such program, and to extend certain operating hours for pharmacies and medical facilities of the Department, and for other purposes; to the Committee on Veterans' Affairs; April 28

S.2899 (introduced by Sen. John Thune): A bill to remove Federal barriers to combating mosquito-borne transmission of the Zika virus and promote public health, and for other purposes; to the Committee on Environment and Public Works; April 28