



## Health Policy Briefing

December 15, 2014

### Senate Extends 113th Congress to Wrangle Over the Passage of FY 2015 Cromnibus

#### *House and Senate Pass FY 2015 Cromnibus*

After the House voted 219-206 to pass H.R. 83, the so-called Cromnibus bill, the Senate voted late Saturday night 56-40 to pass the appropriations measure, thus paving the way for Congress to finally adjourn for the year. Because of the resistance in the Senate to immediately take up the bill after the House passed it on Thursday, Senate Majority Leader Harry Reid (D-NV) gave the chamber additional time to consider the bill and for President Obama to sign it into law by adopting H.J.Res. 131, which allows current federal spending to continue until Wednesday, December 17. In general, H.R. 83 would extend FY 2015 federal funding until September 30, 2015 for all federal agencies with the exception of the Department of Homeland Security (DHS). The funding for DHS would extend only through February 27th which would give the Republican House and Senate the leverage they seek to defund or scale-back the President's executive actions which allow certain undocumented immigrants to remain in the United States and become eligible for various benefits, such as Social Security and Medicare. The \$1.013 trillion in discretionary and non-discretionary spending under the bill is consistent with the Ryan/Murray budget deal which has guided Congress in setting federal spending levels. Various riders were included in the omnibus, some of which were vocally objected to by Democrats, such as one allowing political parties to raise money for party conventions and another which would scale back certain restrictions on bank swap activities under the Dodd/Frank Wall Street Reform Act. Also tucked into the bill was a bipartisan amendment to the Employee Retirement Income Security Act of 1974 (ERISA) which would allow severely underfunded multiemployer pension plans to reduce certain benefits and which would increase Pension Benefit Guaranty Corporation (PBGC) premiums for such plans.

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### *Health-Related Provisions in CRomnibus*

When signed by the President, the omnibus spending bill will provide for the following: \$5.4 billion of the \$6.2 billion requested by the President for Ebola response and preparedness; \$30.1 billion for the National Institutes of Health (NIH), a \$150 million increase, including a \$25 boost for Alzheimer's research; \$3.7 billion for program management at the Centers for Medicare and Medicaid Services (CMS); \$6.9 billion for the Centers for Disease Control and Prevention (CDC), a \$21 million increase; a directive to CMS to provide information about the requirement that home health agencies (HHAs) provide a face-to-face certification from a physician before home health care services for Medicare and Medicaid patients will be covered and a mandate that CMS present a plan on how rebasing is affecting HHAs, on how critical-access hospital rules impact HHAs and on how HHA requirements can be streamlined; a directive that CMS review its previous decision to cover ventricular assist devices upon receipt of new evidence; a directive that the National Institute of Allergy and Infectious Diseases (NIAID), the Biomedical Advanced Research and Development Authority (BARDA) and the CDC hold a workshop within 180 days to develop a comprehensive plan with a timeline and measurable objectives to help develop antibiotics for resistant bacteria; and a directive that CMS educate providers on how to reduce the backlog of appeals of decisions by Medicare Recovery Audit Contractors (RACs). **The legislation also includes the following provisions related to the Patient Protection and Affordable Care Act (PPACA):** it prohibits CMS from providing new funding to subsidize potential revenue losses by health insurers under the law's risk corridor provision (however payments to CMS from insurers whose revenues are higher than expected could still be used to pay for insurer losses); a cut of \$350 million in the Internal Revenue Service (IRS) budget could impede the agency's activities related to the law; a provision prohibiting funds from the law's Prevention and Public Health Fund to be used for other PPACA activities; a provision that would cut funding of the Independent Payment Advisory Board (IPAB) by \$10 million; a directive that CMS report on the cost of PPACA administrative and information technology services, benefit reviews, and enrollment and market reviews; a directive that the U.S. Department of Health and Human Services (HHS) increase the transparency of abortion coverage within federal exchange health-care plans and language directing HHS to quickly respond to claims filed by health-care providers on conscience-clause violations; and an exemption for expatriate health care plans from the PPACA coverage requirements. These provisions trimming PPACA-related activities are but the opening shot by Republicans to go further next year to repeal major portions of the law, including the individual mandate and related tax credits, Medicaid expansion, employer mandate threshold of 30 hours, medical device tax, and the IPAB, etc.

### *Congress Considers Additional Legislation*

The House sent to the President for his signature H.R. 1281, the Newborn Screening Saves Lives Reauthorization Act of 2014, legislation amending the Public Health Service Act to revise and extend through FY 2019 a grant program for screening, counseling, and other services related to heritable disorders that can be detected in newborns. The bill authorizes grants to be used to improve timeliness of newborn screening and provide training to health care professionals on the importance of timely screening and on the sharing of medical and diagnostic information with providers and families. In addition, the CDC is directed to engage in data collection, reporting and other activities to assure the quality of labs involved in such screening and HHS is directed to update the Federal Policy for the Protection of Human Subjects. The Senate sent to the President for his signature the following House-passed bill: **H.R. 4771**, the Designer Anabolic Steroid Control Act of 2014. The Senate is also expected to act before adjournment on the following House-passed bills: **H.R. 5185**, the EARLY Act Reauthorization of 2014, legislation which reauthorizes through FY 2019 the Young Women's Breast Health Education and Awareness Requires Learning Young Act of 2009; **H.R. 5059**, the Clay Hunt Suicide Prevention for American Veterans Act, legislation to direct the Secretary of Defense and the Secretary of Veterans Affairs to provide for the conduct of annual evaluations of mental health care and suicide prevention programs of the Department of Defense and the Department of Veterans Affairs, to review the terms or characterization of the discharge or separation of certain individuals from the armed forces, to require a pilot program on loan repayment for psychiatrists who agree to serve in the Veterans Health Administration of the Department of Veterans Affairs; **H.R. 3979**, the \$513.4 billion National Defense Authorization Act for Fiscal Year 2015; and **H.R. 5771**, legislation extending various tax provisions through December 31, 2014.

## PPACA Health Reform Update

### *House Republicans Use Final Week to Set Up PPACA Changes Next Year*

The House Oversight and Government Reform Committee took MIT Professor Jonathan Gruber to task over the remarks he made in video recordings which both Republicans and Democrats on the committee said were disparaging to the public and “stupid”. Dr. Gruber responded, thusly: “I am not an expert on politics, and my tone implied that I was, which is wrong. In other cases I simply made insulting and mean comments that are totally uncalled for in any situation.” He pleaded ignorance that he was the architect of the health reform law, but Chairman Darrell Issa (R-CA) is apparently not done with his inquiry, in that he obtained a subsequent committee vote to subpoena Dr. Gruber’s statements and other records connected to state and federal activities related to the health care law. Rep. Issa said: “Dr. Gruber repeatedly refused to answer several key questions, including the amount of taxpayer funds he received for his work on Obamacare....The American people deserve not just an apology, but a full accounting, which Dr. Gruber must provide.” The committee also grilled CMS Administrator Marilyn Tavenner about the agency’s admission in mistakenly including nearly 400,000 individuals electing dental only coverage in its estimate of 7.3 million persons enrolled under the PPACA. She apologized but defended the law, stating that “While this mistake was regrettable, it shouldn’t obscure the fact that the Affordable Care Act is working...” Before the open enrollment period ends on December 15th, the President gave a public push for young people to sign up for coverage which he said could cost “less than \$100”. HHS reported that, with respect to those who have accessed the exchanges so far, about 52% were renewals while 48% represent new enrollments. The Senate Republican Conference also took a shot at the law in passing a resolution stating that all Senate Republican staff should get their health benefits through the District of Columbia’s health insurance exchange and not use a special provision under regulations allowing such staff to continue receiving their coverage under the Federal Health Benefits program.

### *PPACA Payments to Stellar Community Health Centers*

HHS announced that it has awarded \$36.3 million to more than 1,000 U.S. health facilities that have significantly improved patient care quality, outcomes, managing care and use of electronic health records (EHRs).

## Medicare/Medicaid/PHSA Corner

### *Request for Comments on House 21st Century Cures Initiative*

The House Energy and Commerce Committee, as part of the committee’s 21st Century Cures initiative, is asking for comments by January 5th on the regulation of in vitro diagnostic test kits and laboratory developed tests (LDTs). The committee asks what it says are important questions regarding possible duplication and other issues with respect to the regulation of LDT’s under the Clinical Laboratory Improvement Amendments (CLIA) and the Food and Drug Act.

## **Medicare/Medicaid/PHSA Corner cont.**

### ***House Energy and Commerce Hearing on Federal Health Costs***

**A**t a hearing held by the House Energy and Commerce Health Subcommittee, Chairman Joe Pitts (R-PA) indicated the possible direction the committee could take next year when he said about Medicare and Medicaid--“These programs need to be strengthened and modernized, not just because millions of Americans depend on them for their health care, but also because out-of-control entitlement spending is crowding out other important priorities...” A witness from the American Action Forum testified that Congress should put limitations on the expansive spending under the PPACA and subject provisions of the law to cost-saving reforms, such as decreasing the eligibility level for individual tax credit premium assistance. He went on to say that the savings could be used to pay for the reform of the current Medicare physician payment sustainable growth rate (SGR) mechanism. Judy Feder, a professor at the Georgetown Public Policy Institute, objected stating that Medicare and Medicaid are not in crisis and that the PPACA has generated Medicare savings.

### ***HHS Grants Immunity to Ebola Vaccine Makers***

**H**HS Secretary Sylvia Mathews Burwell released a declaration under the Public Readiness and Emergency Preparedness Act under which three pharmaceutical entities would be given immunity from legal liability related to the production, testing and distribution of the Ebola vaccines they are developing. The HHS Secretary said that the global community must ensure that legitimate concerns about liability do not hold back the possibility of developing an Ebola vaccine, an essential strategy in the global response to the Ebola epidemic in West Africa.

### ***HHS Updates EHR Interoperability Guidelines***

**T**he National Coordinator for Health IT described an update of HHS’s Federal Health IT Strategic Plan 2015-2020 as an effort to create a competitive and innovative marketplace by helping remove barriers to the electronic exchange of health information. The intent of the plan is for all participating federal agencies to give an assist in increasing health IT adoption; improving users’ outlook on the safety of health IT; expanding electronic health record interoperability; and increasing access to broadband Internet for rural providers.

### ***HHS IG Finds Medicaid Beneficiaries Lack Access***

**T**he HHS Office of the Inspector General released a report in which it was found that: over 50% of providers listed in Medicaid managed care plan networks were unavailable to provide care to plan enrollees; 35% of providers did not even practice at the locations listed by the plans studied; 8% of the listed providers were not even in the plans’ networks; and 8% were not accepting new patients. The OIG recommended that CMS work with states to overcome the various shortfalls in provider access.

### ***MACPAC Discusses CHIP Extension***

**A**t last week’s meeting, the Medicaid and CHIP Payment and Access Commission (MACPAC) discussed the fallout on the access of up to 4 million children to affordable health coverage if Congress fails to extend the program beyond this fiscal year. If CHIP is not extended, then states would be required to move covered children into PPACA exchange plans which might be more expensive and contain different plan benefits. The panel discussed changes to the PPACA that might be necessary to continue children’s coverage, such as lowering premiums, reducing cost sharing and increasing tax credit subsidies. The commission will continue to discuss the issue at its January meeting.

## Medicare/Medicaid/PHSA Corner cont.

### *CMS Star System for Home Health Agencies*

**C**MS announced it has future plans to introduce a five-star rating system for home health agencies to be displayed on its Home Health Compare website. Once proposed, the agency will seek timely comments to enable the star system to be up and running sometime this summer.

### *CMS to Recompete Certain DMEs*

**C**MS announced a “Round 2 Recompete” for seven categories and national mail-order diabetic testing supplies under its competitive bidding process for durable medical equipment in 90 geographic areas. The new bids will be taken from January 22 to March 25 next year.

### *PCORI Grants for Hep C Treatments*

**T**he Patient Centered Outcomes Research Institute (PCORI) has approved up to \$50 million for one to four head-to-head studies aimed at improving treatment options for hepatitis C.

## Health Legislation Recently Introduced

**H.R. 5805 (DRUGS)**, to amend the Federal Food, Drug, and Cosmetic Act with respect to expanding access for breakthrough drugs, and for other purposes; MCCAUL; to the Committee on Energy and Commerce, Dec. 8.

**H.R. 5808 (MEDICARE)**, to amend Title XVIII of the Social Security Act to strengthen rules applied in case of competition for diabetic testing strips, and for other purposes; DEGETTE; jointly, to the committees on Energy and Commerce and Ways and Means, Dec. 8.

**H.R. 5809 (MEDICARE)**, to amend Title XVIII of the Social Security Act to require state licensure and bid surety bonds for entities submitting bids under the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive acquisition program, and for other purposes; TIBERI; jointly, to the committees on Energy and Commerce and Ways and Means, Dec. 8.

**H.R. 5811 (EMERGENCY PERSONNEL)**, to amend the Internal Revenue Code of 1986 to provide a charitable deduction for the service of volunteer firefighters and emergency medical and rescue personnel; MCKINLEY; to the Committee on Ways and Means, Dec. 9.

**H.R. 5815 (MEDICARE)**, to amend Title XVIII of the Social Security Act to provide for pharmacy benefits manager standards under the Medicare prescription drug program to further transparency of payment methodologies to pharmacies, and for other purposes; COLLINS of Georgia; jointly, to the committees on Energy and Commerce, Ways and Means, Armed Services, and Oversight and Government Reform, Dec. 9.

**H.R. 5819 (SCIENTISTS)**, to amend Title IV of the Public Health Service Act to ensure that scientists are being funded at the age when they are most likely to make breakthroughs; HARRIS; to the Committee on Energy and Commerce, Dec. 9.

**H.R. 5820 (SCIENTISTS)**, to amend Title IV of the Public Health Service Act to allocate additional funding through the common fund for research by emerging scientists; HARRIS; to the Committee on Energy and Commerce, Dec. 9.

**H.R. 5823 (MEDICARE)**, to amend Title XVIII of the Social Security Act to create incentives for health-care providers to promote quality health-care outcomes, and for other purposes; MATHESON; jointly, to the committees on Energy and Commerce and Ways and Means, Dec. 9.

**Health Legislation Recently Introduced cont.**

**S. 2996** (DRUGS), to create a limited population pathway for approval of certain antibacterial drugs; BENNET; to the Committee on Health, Education, Labor and Pensions, Dec. 10.

**H.R. 5825** (TAXATION), to amend the Internal Revenue Code of 1986 to prevent foreign diplomats from being eligible to receive health insurance premium tax credits and health insurance cost-sharing reductions, and for other purposes; ROYCE; jointly, to the committees on Ways and Means, Energy and Commerce and Foreign Affairs, Dec. 10.

**H.R. 5835** (TUBERCULOSIS), to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act with respect to making progress toward the goal of eliminating tuberculosis, and for other purposes; GENE GREEN of Texas; to the Committee on Energy and Commerce, Dec. 10.

**H.R. 5840** (NURSES), to amend the Public Health Service Act to authorize the secretary of health and human services to make grants to eligible entities to train elementary and secondary school nurses on how to respond to a biological or chemical attack or an outbreak of pandemic influenza in a school building or on school grounds; ISRAEL; to the Committee on Energy and Commerce, Dec. 10.

**H.R. 5841** (MEDICAID), to establish a grant program to provide states with funds to detect fraud, waste and abuse in Medicaid program under Title XIX of the Social Security Act and to recover improper payments resulting from such fraud, waste and abuse; ISRAEL; to the Committee on Energy and Commerce.

**H.R. 5845** (SUBSTANCE ABUSE), to authorize the attorney general to award grants to address the national epidemics of prescription opioid abuse and heroin use; SENSENBRENNER; to the Committee on the Judiciary, the Committee on Energy and Commerce and the Committee on Education and the Workforce, Dec. 10.

**H.J. RES. 130** (APPROPRIATIONS), making further continuing appropriations for fiscal year 2015, and for other purposes; ROGERS of Kentucky to the Committee on Appropriations, Dec. 10.

**H. RES. 778** (NURSES), supporting the designation of a week as National Federal Nurse Recognition Week; SCHAKOWSKY; to the Committee on Energy and Commerce, Dec. 10.

**H.R. 5853** (MEDICARE): A bill to expand Medicare coverage to eyeglasses, hearing aids, and dental care; GRAYSON 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; Dec.11.

**H.R. 5854** (DRUG IMPORTATION), to allow the importation, distribution, and sale of investigational drugs and devices intended for use by terminally ill patients who execute an informed consent document; GRAYSON to the House Committee on Energy and Commerce; Dec 11.

**H.R. 5860** (TAX), to amend the Internal Revenue Code of 1986 to allow small businesses to use pre-tax dollars for assistance to employees purchasing policies in the individual market and except certain health reimbursement arrangements from group health plan requirements, and for other purposes; BOUSTANY to the House Committee on Ways and Means; Dec 11.

**H.R. 5862** (MATERNAL HEALTH), to provide assistance to improve maternal and newborn health in developing countries, and for other purposes; CAPPs to the House Committee on Foreign Affairs; Dec. 11.

**H.R. 5874** (FDA), to amend the Federal Food, Drug, and Cosmetic Act to increase criminal penalties for the sale or trade of prescription drugs knowingly caused to be adulterated or misbranded, to establish recall authority regarding drugs, and for other purposes; ISRAEL to the House Committee on Energy and Commerce; Dec. 11.

**S. 3004** (TREATMENTS), to promote the development of meaningful treatments for patients; HATCH to the Committee on Health, Education, Labor, and Pensions; Dec. 11.

## Health Legislation Recently Introduced cont.

S. 3006 (VETERANS), to require the Secretary of Veterans Affairs to use existing authorities to furnish health care at non-Department of Veterans Affairs facilities to veterans who live more than 40 miles driving distance from the closest medical facility of the Department that furnishes the care sought by the veteran; MORAN to the Committee on Veterans' Affairs; Dec. 11.

S. 3007 (MEDICAID), to amend title XIX of the Social Security act to extend the application of the Medicare payment rate floor to primary care services furnished under Medicaid and to apply the rate floor to additional providers of primary services; KLOBUCHAR to the Committee on Finance; Dec. 11.