



Health Policy Briefing

March 3, 2014

President’s Budget Release This Week Will Likely Ramp Up Debate on SGR Reform Cost

Budget Debate to Ensure

On Tuesday, March 4th the President will release his budget recommendations for fiscal year (FY) 2015-2024 and several committees of jurisdiction will hold hearings this week to take measure of whether or not the Administration’s priorities will be considered this budget season. With the President recommending increased “investment” for domestic programs while backing off his recommendations made last year to reduce Social Security and other federal cost of living adjustments (COLAs), the House is likely to call most of his recommendations “dead on arrival”. Republican skirmishing over veterans’ legislation in the Senate last week, which delayed final consideration, is a presage of a Republican wish list to find domestic spending offsets for military and other spending priorities. Republicans in the House and Senate appear to be more inclined to push for a reconciliation bill than do Democrat leaders. Amid the budget debate, the House and Senate leaders are under pressure to come up with a compromise on the means to offset the cost of reforming the Medicare sustainable growth rate (SGR) physician payment

reform, H.R. 4015 and S. 2000, that the Congressional Budget Office (CBO) now says would cost \$138.4 billion in the FY 2014-2024 11-year period.

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Health-Related Legislative Actions

Last week the House passed H.R. 899, the Unfunded Mandates Information and Transparency Act, legislation that amends the Unfunded Mandates Reform Act (UMRA) to, among other things, require federal agencies to consult with private corporations before proposing any new rules and allow points of order against rules that increase the direct cost of private sector mandates (e.g. those included under the PPACA); and amends the Congressional Budget Act of 1974 to require CBO, at the request of a committee Chairman or Ranking Member, to conduct analyses into the direct cost of promulgated rules on state, local, and tribal governments. The House Energy and Commerce Subcommittee on Health voted to send to the full committee the following bills: H.R. 3548, the Improving Trauma Care Act of 2013; H.R. 1281, the Newborn Screening Saves Lives Reauthorization Act of 2013; H.R. 1528, the Veterinary Medicine Mobility Act of 2013; and H.R. 4080, the Trauma Systems and Regionalization of Emergency Care Reauthorization Act. The approval in the Senate HELP Committee of Vivek Murthy as the next Surgeon General will allow Democrats to move his nomination to a vote in the full Senate, pending a fight with Senator Rand Paul who has placed a hold on his nomination. Of note, the longest-serving member of congress, Rep. John Dingell (D-MI), announced that this term will be his last, thus ending his tour-de-force in health legislation. Also, House Majority Leader Eric Cantor (R-VA) announced that the House will take up H.R. 4118, the Suspending the Individual Mandate Penalty Law Equals Fairness Act, on Wednesday or Thursday.

PPACA Health Reform Update

HHS Announces More Relief under PPACA, Republicans Counter

The Administration announced additional relief for individuals and businesses who have attempted to access health insurance coverage under the various exchanges. The Centers for Medicare and Medicaid Services (CMS) issued guidance, “CMS Bulletin to Marketplaces on Availability of Retroactive Advance Payments of the PTC and CSRs in 2014 Due to Exceptional Circumstances”, under which individuals who have had difficulty in enrolling in state exchanges experiencing technical difficulties would still be eligible to receive federal tax credit subsidies on a retroactive basis even though they enrolled outside of the marketplace structure. House Energy and Commerce Committee Republicans said the rule is a blatant violation of the Patient Protection and Affordable Care Act (PPACA) that could lead to additional fraud. The Internal Revenue Service (IRS) also announced “Health Care Tax Tips” on their website to assist individual taxpayers on understanding their eligibility for and extent of tax subsidies, their obligation to obtain health coverage or be penalized and their coverage options. Although the IRS has given small businesses some relief under the law with respect to their obligation to offer coverage to their full-time workers (e.g. by only having to offer coverage to 70% in 2015 and 95% in 2016), Speaker John Boehner (R-OH) and other Republican leaders again lashed out at the law citing a report by the CMS Office of the Actuary which includes estimates that the premiums for about 11 million individuals in group health plans (and about 65% of the smallest plans) which are subject to the PPACA’s restrictive rating requirements will increase while only 6 million will experience premium decreases. Nonetheless, House Democrats have also gone on the offensive with a CBO/Joint Committee on Taxation cost estimate of the Republican-sponsored bill, H.R. 2575 that passed the House Ways and Means Committee, which estimates the cost of the legislation to be about \$73.7 billion, cause one million people to lose their employer-based health insurance and increase the number of people receiving coverage through Medicaid, CHIP or the exchanges by between 500,000 and one million persons. House Democrats were also supportive of the supposed plans by the Department of Labor to issue regulations that would make it harder for self-insured health plans, particularly for smaller employers, to obtain so-called “stop-loss” insurance which serves to contain the catastrophic risk of self-insuring for such employers. Republicans at the House Education and the Workforce Health, Employment, Labor and Pensions Subcommittee hearing were more supportive of the current self-insurance marketplace for small plans in stating that the federal government should stay out of a market that is working. In other actions that could have a significant impact on the Administration’s use of discretion in implementing the PPACA, the House Judiciary Committee held hearings on legislation, soon to be marked up, which would curtail such discretion. Among the measures that may be considered are: H.R. 3857, which would allow the House or Senate, with a 60% vote majority, to proceed with an expedited court challenge to an executive action determined to be a violation of the Constitution; H.Res. 442, which would call on the House to sue the Administration over delays in the PPACA, among other things; and H.R. 3973, that would require the Attorney General to issue reports to Congress if the Administration declines to enforce a federal law.

Medicare/Medicaid/PHSA Corner

House Scrutinizes Medicare Part D Drug Class Changes

At a hearing held by the House Energy and Commerce Subcommittee on Health, Rep. Phil Gingrey (R-GA) said that the proposed CMS regulations that would remove “protected class” status for three of six Medicare Part D drug categories would “destroy Medicare Part D as we know it.” Bipartisan letters were recently sent to U.S. Department of Health and Human Services (HHS) Secretary Kathleen Sebelius objecting to the changes. Nonetheless, the CMS witness said that even with the changes “extensive beneficiary protections” would remain. Also, Rep. Henry Waxman (D-CA), who previously announced his retirement, said he supports several of the provisions of the proposed regulations, including one related to preferred pharmacies, although he said CMS should “rethink” the proposal on protected classes.

Senate HELP Committee Hearing on Mental Health

At a Senate HELP Committee hearing, Chairman Tom Harkin (D-IA) expressed concern that the use of antipsychotic drugs among children increased 800% from 1993 to 2010 while the use of alternatives, such as behavioral and psychological treatments, increased only slightly. Physicians who testified said that it is important to know more about the long-term effects of the use of such drugs and urged Congress to fund research on alternatives to such drug treatments. Mentioned was legislation introduced by Senators Tammy Baldwin (D-WI) and Rob Portman (R-OH), S. 1992—the Quality Foster Care Services Act, which defines therapeutic foster care and provides that it can be included as reimbursable medical assistance.

CMS Asks for Comments on DMEPOS

CMS is seeking public comments before proceeding with the nationwide implementation of the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program. Comments are sought: on the factors the agency would use in developing a methodology to adjust DMEPOS fee schedule amounts or other payment amounts in non-competitive bidding areas based on DMEPOS competitive bidding payment information; on the means to simplify the payment rules and improve beneficiary access to items and services under the competitive bidding programs for certain DME and enteral nutrition products; and on lump-sum purchases, capped rental payment rules, beneficiary-owned equipment and continuous bundled monthly payments.

HHS Asks for Comments on National HAI Plan

HHS gave notice that it is seeking comments by March 27 on the National Action Plan to Prevent Health Care Associated Infections (HAI), specifically on the new targets the agency is proposing for the first phase of its HAI action plan. HHS said that the proposed targets for each of the infections identified in the plan will reflect improvement efforts over a five-year period with a baseline of January 2015.

FDA Urges Greater Penalties for Importing Unapproved Drugs

At a House Energy and Commerce Oversight and Investigations Subcommittee hearing, the Food and Drug Administration (FDA) testified that “the criminal penalty for the risky and inherently dangerous practice of importing unapproved foreign drugs is simply not sufficient to deter the criminal element” and should be increased. Subcommittee Chairman Tim Murphy (R-PA) said the drug counterfeiting penalties have not been updated since 1938, intimating that perhaps Congress may soon look into changing the law.

Medicare/Medicaid/PHSA Corner cont.***FDA Reports on 501(k) Premarket Notification***

The FDA released a report mandated by the FDASIA in which the FDA states it will generally follow the recommendations of device manufacturers in determining when a change to a device will warrant a new 510(k) submission. The agency said a new proposed policy that would update 1997 guidance will clarify the kinds of changes that trigger the need for a new 510(k) submission, such as specific kinds of labeling changes, changes to the technology used in the device, changes in performance specifications, manufacturing changes and changes in the materials used in the manufacturing process.

Upcoming Health-Related Hearings and Markups

House Energy and Commerce Health Subcommittee: will hold a hearing titled “Examining Concerns Regarding FDA’s Proposed Changes to Generic Drug Labeling;” 2:00 p.m., 2123 Rayburn Bldg.; March 3. -- POSTPONED

House Energy and Commerce Subcommittee on Health: will hold a hearing titled “Keeping the Promise: How Better Managing Medicare Can Protect Seniors’ Benefits and Save Them Money;” 10:00 a.m., 2123 Rayburn Bldg.; March 4.

Senate Finance Committee: will hold a hearing on the President’s FY 2015 budget; 10:30 a.m., 215 Dirksen Bldg.; March 5.

House Budget Committee: will hold a hearing on the President’s FY 2015 budget; 2:00 p.m.; 210 Cannon Bldg.; March 5.

House Ways and Means Committee: will hold a hearing on the President’s FY 2015 budget; 9:30 a.m.; 1100 Longworth Bldg.; March 6.

House Small Business Subcommittee on Contracting and Workforce: will hold a hearing on the health care law and its impact on the self-employed; 10 a.m., 2360 Rayburn; March 6.

Health Legislation Recently Introduced

S. 2035 (MENTAL HEALTH), to provide funding to the National Institute of Mental Health to support suicide prevention and brain research, including funding for the Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Initiative; BEGICH; to the Committee on Health, Education, Labor and Pensions, Feb. 24.

S. 2037 (MEDICARE), to amend Title XVIII of the Social Security Act to remove the 96-hour physician certification requirement for inpatient critical access hospital services; ROBERTS; to the Committee on Finance, Feb. 24.

H.R. 4075 (MENTAL HEALTH), to provide funding to the National Institute of Mental Health to support suicide prevention and brain research, including funding for the Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Initiative; BARBER; to the Committee on Energy and Commerce, Feb. 25.

H.R. 4077 (ANTITRUST LAWS), to ensure and foster continued patient safety and quality of care by clarifying the application of the antitrust laws to negotiations between groups of health-care professionals and health plans and health-care insurance issuers; CONYERS; to the Committee on the Judiciary, Feb. 25.

H.R. 4080 (TRAUMA CARE), to amend Title XII of the Public Health Service Act to reauthorize certain trauma care programs, and for other purposes; BURGESS; to the Committee on Energy and Commerce, Feb. 25.

H. RES. 489 (ALZHEIMER'S DISEASE), expressing the sense of Congress regarding the need to facilitate and promote a robust response to the looming global crisis of Alzheimer's disease and other forms of dementia; SMITH of New Jersey; jointly, to the committees on Foreign Affairs and Energy and Commerce, Feb. 25.

H.R. 4067 (HOSPITALS), to provide for the extension of the enforcement instruction on supervision requirements for outpatient therapeutic services in critical access and small rural hospitals through 2014; JENKINS; jointly, to the committees on Energy and Commerce and Ways and Means, Feb. 18.

S. 2046 (MEDICARE), to amend Title XVIII of the Social Security Act to provide Medicare beneficiaries coordinated care and greater choice with regard to accessing hearing health services and benefits; BROWN; to the Committee on Finance, Feb. 26.

H.R. 4101 (TRICARE), to amend Title 10, U.S. Code, to ensure that a TRICARE beneficiary receives written notice of any change to benefits received by the beneficiary under TRICARE, and for other purposes; ELLMERS; to the Committee on Armed Services, Feb. 26.

S. 2064 (REFORM), to provide for the repeal of certain provisions of the Affordable Care Act that have the effect of rationing health care; ROBERTS; to the Committee on Finance, Feb. 27.

S. 2069 (TAX CREDITS), to amend the Internal Revenue Code of 1986 to expand and modify the credit for employee health insurance expenses of small employers; BEGICH; to the Committee on Finance, Feb. 27.

H.R. 4104 (TAXATION), to amend the Internal Revenue Code of 1986 to make permanent the 7.5 percent threshold for the medical expense deduction for people 65 or older; NEGRETE MCLEOD; to the Committee on Ways and Means, Feb. 27.

H.R. 4106 (CLINICAL PRACTICE GUIDELINES/MEDICAL MALPRACTICE), to provide for the development and dissemination of clinical practice guidelines and the establishment of a right of removal to federal courts for defendants in medical malpractice actions involving a federal payor, and for other purposes; BARR; jointly, to the committees on Energy and Commerce and the Judiciary, Feb. 27.

H.R. 4108 (CHILDREN'S HEALTH), to establish a grant program for nebulizers in elementary and secondary schools; JACKSON LEE; jointly, to the committees on Education and the Workforce and Energy and Commerce, Feb. 27.

H. RES. 493 (RARE DISEASES), expressing support for the designation of Feb. 28 Rare Disease Day; CARSON of Indiana; to the Committee on Energy and Commerce, Feb. 27.