



Health Policy Briefing

July 21, 2014

Heading to August Recess Congress Stalemates on Appropriations, VA and PPACA Bills

Senate Rejects Overturning Supreme Court Hobby Lobby Decision

The Senate, on a vote of 56-43, rejected a move to consider H.R. 2578, the “Protect Women’s Health from Corporate Interference Act”, which **Sen. Patty Murray (D-WA)** offered in an attempt to overturn the Supreme Court ruling which allows non-publicly traded for-profit corporations to disregard the PPACA’s “preventive health services” related to birth control for women. She said that “Women should call the shots when it comes to their health-care decisions: Not their boss, not the government, not anyone else—period...” In response to their opposition of the Murray bill, Republicans cited the introduction of S. 2605; legislation introduced by **Senator Kelly Ayotte (R-NH)** which states that “an employer cannot block an employee from legal access to her FDA-approved contraceptives...”

House Poised to Vote on Resolution Authorizing Court Action on PPACA

Last week the House Rules Committee held a hearing on the resolution promoted by Republican leaders which would authorize the House to bring suit against executive agency actions to delay the Patient Protection and Affordable Care Act’s (PPACA) employer mandate and related penalties for non-compliance. The proposed civil action seeks injunctive relief regarding the “failure of the President” or any other Administration

continued on page 2

Inside

- Appropriations/Budget Matters.....2
- Conferees on VA Reform Legislation Remain Divided..2
- House Energy and Commerce Advances Health Bills...2
- House Republicans Remain Skeptical of PPACA Implementation.....3
- Hobby Lobby Decision Spurs New PPACA Disclosure Rule.....3
- Medicare FFS Under Fire at Senate Finance Committee Hearing.....3
- Senate Hearing Focuses on Preventable Mistakes in Hospitals.....4
- House Energy and Commerce “21st Century Cures” Panel Focuses on Technology.....4
- House Members Urge that Pathologists Be Exempt from Meaningful Use.....4
- CMS Announces Efforts to Restructure QIO Program/Aid State Medicaid Programs.....4
- House Members ask FDA for Changes to Generic Drug Labeling Rule.....5
- House E&C Subcommittee Oversight of CDC Anthrax Scare.....5
- Upcoming Health Related Hearings and Markups.....5
- Health Legislation Recently Introduced.....6

continued from page 1

official “to act in a manner consistent with their duties under the Constitution and laws of the United States” with respect to the implementation of any provision of the PPACA. Chairman Pete Sessions (R-TX) said that the Constitution does not give the President the authority to change laws by himself and that the suit is needed to restore the U.S. system of “checks and balances”. Rep. Louise Slaughter (D-NY) said the measure is “preposterous” and any suit is unlikely to survive in the courts. George Washington University law professor Jonathan Turley defended the House’s standing to bring the suit, stating that since the President can sue states, and states can sue to preserve their power, the legislative branch should in turn be able to do the same to preserve its powers. However, Simon Lazarus, the Senior Counsel for the Constitutional Accountability Center, disagreed stating that “exercising presidential judgment in carrying laws into execution is precisely what the Constitution requires.” The hearing is but a prelude to a potential vote on the resolution next week before the beginning of the August recess. Of note, the House fiscal year (FY) 2015 Financial Services bill would also restrict Administration spending to implement presidential executive orders.

Appropriations/Budget Matters

The House passed H.R. 5016, the FY 2015 Financial Services appropriations bill, which shortchanges the President’s budget request for the enforcement of provisions under the PPACA. The bill also specifically prohibits the U.S. Department of Health and Human Services (HHS) from transferring funds to the Internal Revenue Service (IRS) as well as prohibits the IRS from implementing the PPACA’s individual mandate. After the House takes up the FY 2015 Energy/Environment appropriations bill, the only remaining bill to be addressed would be the FY 2015 Labor/HHS/Education appropriations measure. While the Senate Appropriations Committee did pass its version of the FY 2015 Defense appropriations, this may be the only measure that advances to a House/Senate conference. It appears likely that all unresolved FY 2015 appropriations, including HHS, will become subject to a continuing resolution (CR) to be considered in September after the August congressional recess. Of note, at a House Budget Committee hearing, Congressional Budget Office (CBO) Director Doug Elmendorf said his agency projected federal FY 2014 spending on Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP) will amount to about 4.8% of gross domestic product (GDP), a figure which is expected to rise to 8% by 2039 (a reduction from previous projections). He said he was uncertain as to the cause for the slowdown in health care costs, but that a sluggish economy has contributed. He also said that the PPACA will result in some savings, in particular stemming from the law’s cuts to Medicare and Medicaid.

Conferees on VA Reform Legislation Remain Divided

Last week House Democrats attempted to instruct the House conferees on the Veterans Affairs (VA) reform legislation (H.R. 3230) to accept the Senate’s provision which would authorize the VA to execute 26 leases for major medical facilities at specific locations and dollar amounts to help decrease the current long waiting times that veterans face. The resolution was defeated on a 201-213 vote which leaves at least this issue, the extent of private care opt-out and the CBO estimated cost of the bill (\$38 billion) as major hurdles which conferees will have to scale before a compromise is next brought to a vote in the two chambers. Of note, at a Senate Veterans Affairs Committee hearing the Acting VA Secretary Sloan Gibson testified that contracting out more medical services would leave the agency in an even less able position to meet the demands for VA internal services.

House Energy and Commerce Advances Health Bills

The House Energy and Commerce Committee approved by voice vote, for consideration in the House, the following reauthorization bills: H.R. 594, for muscular dystrophy research and assistance programs; H.R. 669, for sudden infant death; and H.R. 4290, for emergency medical services for children (EMSC). The committee also voice voted H.R. 4771, legislation reclassifying certain anabolic steroids; and H.R. 4250, legislation intended to streamline FDA approval of sunscreen products. This week the Senate HELP Committee will take up legislation to reauthorize the following programs: S. 531, for physical activity guidelines; S. 2405 and S. 2406, for trauma care programs; and S. 2539, for traumatic brain injury research. The committee will also consider legislation relating to muscular dystrophy (S. 315) and EMSC (S. 2154).

PPACA Health Reform Update

House Republicans Remain Skeptical of PPACA Implementation

At a House Energy and Commerce Health Subcommittee hearing, Chairman Joe Pitts (R-PA) said that the Administration is “taking a ‘shovel the money out the door first, verify later’ approach when it comes to exchange subsidies...” and that it is “simply unacceptable that CMS [Centers for Medicare and Medicaid Services] does not yet have the internal controls necessary to validate Social Security numbers, citizenship, national status, income and employer-sponsored coverage.” Rep. Bill Cassidy (R-LA) said this may result in tens of thousands of undocumented immigrants getting unwarranted subsidies. However, a witness from the Office of Inspector General (OIG) Office of Audit Services testified that the agency’s audits did not find conclusive evidence that subsidies or tax credits were ever granted to applicants who didn’t deserve them or that subsidies were miscalculated as a result of application errors. The OIG audit report did say, nonetheless, that there were inconsistencies when the exchanges were unable to verify self-attested applicant information with the data received through the federal data hub and other sources. The office is expected to investigate whether subsidies were paid inaccurately and report back next spring. It apparently remains to be seen whether a fully operational verification system will be in place before the next open season begins in October.

Hobby Lobby Decision Spurs New PPACA Disclosure Rule

The Departments of Labor, HHS and Treasury issued guidance which requires that employer plans subject to the Employee Retirement Income Security Act of 1974 (ERISA) send out notices to employees if plan coverage is changed mid-year to eliminate PPACA women’s preventive services relating to contraceptive coverage which is allowed in accordance with the recent decision by the Supreme Court in the Hobby Lobby Stores, Inc. case. The decision allows non-publicly traded for-profit corporations to disregard the PPACA’s preventive health services related to birth control for women.

Medicare/Medicaid/PHSA Corner

Medicare FFS Under Fire at Senate Finance Committee Hearing

At a Senate Finance Committee hearing, Ranking Republican Orrin Hatch (R-UT) stated that the Medicare Payment Advisory Commission (MedPAC) “has long said that fee-for-service Medicare creates silos—incentivizing providers to deliver more care, not necessarily higher quality, coordinated care.” Chairman Ron Wyden (D-OR) said the way health care is now delivered has to change and that managing chronic illness represents “the biggest challenge” facing Medicare and the entire U.S. health-care system. The witness from Emory Healthcare appeared to agree, stating that the current fee-for-service model makes it more profitable to prescribe and complete procedures than to coordinate care, the extra costs of which are not reimbursed under Medicare. Senator Hatch also called into question whether Accountable Care Organizations (ACOs) created under the PPACA are actually improving the quality of care and saving money through coordinated care. Of note, a Government Accountability Office (GAO) report released last week found that payments to physicians under Medicaid fee-for-service and managed care for services such as office visits and emergency care were generally lower than payments from private insurers.

Medicare/Medicaid/PHSA Corner cont.

Senate Hearing Focuses on Preventable Mistakes in Hospitals

At a Senate Health, Education, Labor and Pensions (HELP) Primary Health and Aging Subcommittee hearing, Chairman Bernie Sanders (I-VT) reported on an article maintaining that there are more than 440,000 deaths a year stemming from preventable medical errors that take place in the nation's hospitals. Senator Sheldon Whitehouse (D-RI) said that in his opinion the fundamental problem in the U.S. health-care system is its inefficiency. Witnesses said that federal action may be needed to help improve patient safety and reduce preventable deaths. A professor at the Harvard School of Public Health, Dr. Ashish Jha, testified that safety decisions are driven by individual officials and hospitals and that policy changes be made to incent them to increase safety measures. Another witness pointed out that Medicare payments remain the same for hospitals, regardless of their safety record. Other witnesses suggested that an independent national patient safety board be created to help reform the system.

House Energy and Commerce “21st Century Cures” Panel Focuses on Technology

At a House Energy and Commerce hearing jointly convened by the Subcommittees on Communications and Technology and on Health as part of the committee's 21st Century Cures efforts, Rep. Greg Walden (R-OR) praised the “technological revolution ongoing in the health-care space” and Rep. Frank Pallone (D-NJ) said that it has been demonstrated that technology can improve patient outcomes, bring down costs and help reduce costly readmissions. Witnesses described: how so-called cloud computing could expand the abilities of health researchers and companies to find new biomedical treatments and cures, if the Health Insurance Portability and Accountability Act (HIPAA) is modernized; the need for electronic health records interoperability to allow health systems and devices to better exchange data; and the need for all of a patient's physicians, providers and insurers to be involved in such data exchange to ensure better outcomes and cost savings through patient-centric coordinated care. It was also recommended that Congress update the Food, Drug and Cosmetic Act (FDCA) to establish guidelines defining categories of health IT according to the potential risk to the patient and the opportunity for clinical intervention. On another issue, Rep. Marsha Blackburn (R-TN) said that she and other House Republicans were disappointed with the response received from the Office of the National Coordinator for Health Information Technology (ONC) with respect to their concerns that the agency overstepped its regulatory authority in proposing the establishment of a new Health IT Safety Center.

House Members Urge that Pathologists Be Exempt from Meaningful Use

Reps. Tom Price (R-GA), Ron Kind (D-WI) and 88 other House members sent a letter to CMS requesting that pathologists be exempted through 2017 from the federal electronic health record incentive program, given that they do not work directly with patients.

CMS Announces Efforts to Restructure QIO Program/Aid State Medicaid Programs

CMS said that, as part of the second phase to restructure the not-for-profit Quality Improvement Organization Program, the agency has awarded 14 data-driven contracts to Quality Innovation Networks-Quality Improvement Organizations (QIN-QIOs) to help implement quality of care improvements throughout the care spectrum. CMS also announced a new \$100 million technical support initiative, the Medicaid Innovation Accelerator Program (IAP), which is designed to help improve the health of and health care for Medicaid beneficiaries by enhancing state efforts to accelerate new payment and service delivery reforms. In another initiative CMS issued new guidance for Medicare Advantage and Part D prescription drug plans which relieves them from a requirement to give prior authorization on all drugs for beneficiaries enrolled in hospice facilities. Instead, CMS said it will encourage plans to place prior authorization requirements on just four categories—analgesics, anti-nauseants, laxatives and anti-anxiety drugs.

House Members ask FDA for Changes to Generic Drug Labeling Rule

In a letter sent to the FDA, House Oversight and Government Reform Committee Chairman Darrell Issa (R-CA) and other committee Republicans criticized the Food and Drug Administration's (FDA) proposed ruling which would allow generic drug manufacturers to independently update product labeling with newly acquired safety information before the FDA's review of the change (in the same manner as for manufacturers of brand name drugs). They asked for further information on the process and communications involved in the process, stating "Given the intent of the rule is to create an environment for increased litigation, the Committee finds it troubling that the FDA consulted only with trial lawyers, but no other major stakeholder likely to be affected..."

House E&C Subcommittee Oversight of CDC Anthrax Scare

The House Energy and Commerce Oversight and Investigations Subcommittee grilled Dr. Thomas Frieden, Director of the Centers for Disease Control and Prevention (CDC) about the agency's lapses in safely handling anthrax and other deadly viruses. Chairman Tim Murphy (R-PA) said the potential exposure of CDC personnel to the deadly anthrax toxin, as well as the contamination of influenza strains with a deadly flu virus, was inexcusable. The CDC Director said the lapses were "unacceptable", that the cause was due to "an insufficient culture of safety" and that he will convene a high-level working group within the agency and an external advisory group of outside experts to help establish safety protocols.

Upcoming Health-Related Hearings and Markups

House Energy and Commerce Health Subcommittee: will hold a hearing titled "21st Century Cures: Examining Barriers to Ongoing Evidence Development and Communication;" 3:00 p.m., 2123 Rayburn Bldg; July 22.

Senate HELP Committee: will hold an executive session to consider health and income security bills, including S. 315, Paul D. Wellstone Muscular Dystrophy Community Assistance, Research, and Education (MD-CARE) Amendments of 2013, S. 2154, Emergency Medical Services for Children Reauthorization Act of 2014, S. 2405, Trauma Systems and Regionalization of Emergency Care Reauthorization Act; S. 2406, Improving Trauma Care Act of 2014, and S. 2539, Traumatic Brain Injury Reauthorization Act of 2014; 10:00 a.m., 430 Dirksen Bldg; July 23.

House Energy and Commerce Health Subcommittee: will hold a roundtable discussion on "the rise of personalized medicine and advances on science and technology;" 10:00 a.m., 2123 Rayburn Bldg; July 23.

House Ways and Means Oversight Subcommittee: will hold a hearing on the health care overhaul law's premium tax credit; 10:30 a.m., 1100 Longworth Bldg; July 23.

House Ways and Means Health Subcommittee: will hold a hearing on the status of Medicare Advantage under the health care law; 10:00 a.m., 1100 Longworth Bldg; July 24.

Health Legislation Recently Introduced

H.R. 5097 (VETERANS' HEALTH), to direct the secretary of veterans affairs to allow certain veterans to participate in the Patient-Centered Community Care program; BOUSTANY; to the Committee on Veterans' Affairs, July 14.

H.R. 5098 (MEDICARE/ MEDICAID), to amend the Internal Revenue Code of 1986 to temporarily exempt from the employer health insurance mandate certain Medicare and Medicaid providers; DAINES; to the Committee on Ways and Means, July 14.

H.R. 5102 (MEDICARE), to amend Title XVIII of the Social Security Act to repeal the requirement for employer disclosure of information on health care coverage of employees who are Medicare beneficiaries, and for other purposes; LEWIS; jointly, to the committees on Ways and Means and Energy and Commerce, July 14.

S. 2605 (WOMEN'S HEALTH), to preserve religious freedom and a woman's access to contraception; AYOTTE; to the Committee on Finance, July 15.

S. 2607 (VETERANS' HEALTH), to extend and modify the pilot program of the Department of Veterans Affairs on assisted living services for veterans with traumatic brain injury, and for other purposes; BOOKER; to the Committee on Veterans' Affairs, July 15.

H.R. 5110 (MEDICARE), amend Title XVIII of the Social Security Act to repeal rebasing of payments for home health services, as required under the PPACA, and to replace such rebasing with a Medicare home health value-based purchasing program, and for other purposes; WALDEN; jointly, to the committees on Ways and Means and Energy and Commerce, July 15.

H.R. 5113 (MEDICAID/ MEDICARE), to amend Title XIX of the Social Security Act to end the increased federal funding for Medicaid expansion with respect to inmates' hospital care under the Affordable Care Act, to apply the savings towards a 2015 Medicare Advantage stabilization program to help protect seniors' choices, and for other purposes; COFFMAN; jointly, to the committees on Energy and Commerce and Ways and Means, July 15.

S. 2618 (FAMILY AND MEDICAL LEAVE), to amend the Internal Revenue Code of 1986 to provide a credit to employers who provide paid family and medical leave; FISCHER; to the Committee on Finance, July 16.

H.R. 5124 (DISEASE SURVEILLANCE), to amend the Public Health Service Act to reauthorize a sickle cell disease prevention and treatment demonstration program and to provide for sickle cell disease research, surveillance, prevention and treatment; DANNY K. DAVIS of Illinois; to the Committee on Energy and Commerce, July 16.

S. 2622 (MAMMOGRAPHY), to require breast density reporting to physicians and patients by facilities that perform mammograms, and for other purposes; FEINSTEIN; to the Committee on Health, Education, Labor and Pensions, July 17.

S. 2625 (CONTRACEPTIVES), to establish certain duties for pharmacies to ensure provision of Food and Drug Administration-approved contraception, and for other purposes; BOOKER; to the Committee on Health, Education, Labor and Pensions, July 17.

S. 2627 (FAMILY AND MEDICAL LEAVE), to amend the Internal Revenue Code of 1986 to provide a credit to employers who provide paid family and medical leave; FISCHER; to the Committee on Finance, July 17.

H.R. 5153 (VETERANS' HEALTH), to direct the secretary of veterans affairs to reimburse non-Department of Veterans Affairs medical providers for the provision of certain hospital care and medical services to veterans, and for other purposes; GABBARD; to the Committee on Veterans' Affairs, July 17.

H.R. 5136 (MEDICAID), to direct the secretary of health and human services to establish a demonstration project under Medicaid under Title XIX of the Social Security Act under which payment may be made to states for expenditures for medical assistance with respect to substance use disorder treatment services, and for other purposes; FUDGE; to the Committee on Energy and Commerce, July 17.

Health Legislation Recently Introduced cont.

H.R. 5145 (MAMMOGRAPHY), to require breast density reporting to physicians and patients by facilities that perform mammograms, and for other purposes; DELAURO; to the Committee on Energy and Commerce, July 17.

H.R. 5147 (MARKETPLACE ENROLLMENT), to provide certain uninsured individuals a special enrollment period after tax filing in 2015 for enrollment in qualified health plans offered through an exchange, and for other purposes; KIRKPATRICK; to the Committee on Energy and Commerce, July 17.

H. RES. 673 (HIV/AIDS TESTING), supporting the goals and ideals of National Clinicians HIV/AIDS Testing and Awareness Day, and for other purposes; WATERS; to the Committee on Energy and Commerce, July 17.

H.RES. 674 (PUBLIC HEALTH), expressing the sense of the House of Representatives that sedentary lifestyles are a public health issue and supporting the designation of a “National Get Vertical Day” to recognize the importance of preventing physical inactivity and encouraging adults to live physically active lifestyles; BISHOP of Georgia; to the Committee on Energy and Commerce, July 17.