



## Health Policy Briefing

July 7, 2014

### Congress Returns to Debate Finishing FY 2015 Appropriations Process & VA Reform

#### *Appropriations and Reform of VA Health Care Access*

Members return this week with little resolved in terms of finalizing all twelve fiscal year (FY) 2015 appropriations bills before the August recess or even before the end of this fiscal year. Although the House of Representatives is set to complete ten of the bills, the House Appropriations Committee has not scheduled a markup of the Labor/Health and Human Services (HHS)/Education or Interior/Environment appropriations bills which remain pending subject to a Republican leadership decision on whether to move on these bills which could attract controversial amendments. It is also unclear whether the Senate Majority Leader will give the go-ahead to **Senate Appropriations Chair Barbara Mikulski (D-MD)** to bring up the “minibus” including the FY 2015 Agriculture/Food and Drug Administration (FDA), Commerce/Justice/Science and Transportation/Housing and Urban Development (HUD) appropriations bills that was pulled before the July 4 congressional recess. Senator Mikulski announced her intent to bring up in committee the Department of Defense appropriations bill by next week, but she apparently remains circumspect about making further progress on the Labor/HHS/Education bill which could attract controversial amendments in the Senate. If the House and Senate conferees can reach agreement on how or whether to pay for the \$44-50 billion cost of the bill, H.R. 3230, which contains provisions to reform the Veterans Health Administration system’s long waiting times and other problems, Congress could point to at least the passage of this bill in this next few weeks as a major achievement. The Senate could also soon act on S. 2449 and go to conference with the House on it’s version of the “Combating Autism” reauthorization legislation.

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## PPACA Health Reform Update

### *HHS OIG Audit Flags PPACA Enrollment Inconsistencies*

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) performed an audit of the internal controls of the federal Patient Protection and Affordable Care Act (PPACA) marketplace and the state marketplaces run by California and Connecticut; the OIG's first of two reports found that the various exchanges failed to properly resolve inconsistencies found in connection with applicants' income, citizenship and other information. HHS reported that more than 2 million inconsistencies still remained during the month of May. Senator Lamar Alexander (R-TN) said the report demonstrates that the Administration was more interested in "appearances" than getting the enrollment job "right". The OIG also said it will perform an audit of the procedures the marketplaces used to determine enrollee eligibility for premium tax credits and cost-sharing reductions and also look into the use of exchange grant funding. Rep. Dave Camp (R-MI), the House Ways and Means Committee Chairman, said the Administration "sent billions of taxpayer dollars out the door" knowing that the government will not be able to fully recuperate the money sent in error. Senator Tom Harkin (D-IA) echoed congressional Democrats' sentiment stating that "With the Administration already improving marketplace operations, now is the time to look ahead...."

### *Supreme Court Issues "Very Specific" Decision to Narrow PPACA Contraceptive Mandate*

The Supreme Court issued a five to four decision in *Burwell v. Hobby Lobby Stores, Inc.* which Justice Samuel Alito, Jr. said is a "very specific" ruling that the PPACA's contraceptive coverage regulations violate the Religious Freedom Restoration Act (RFRA) with respect to only non-publicly-traded closely held corporations. However, in her dissent Justice Ruth Bader Ginsburg said the majority opinion had "startling breadth" giving "commercial organizations" the right to opt out of any general legislation that they deem contrary to their religious beliefs. Justice Anthony Kennedy added that the opinion is simply one which "held that the government hadn't proved that the contraceptive mandate was the least restrictive means of promoting the government's interest". In addition, Justice Alito said the "accommodation" given to non-profit religious organizations by HHS could have also been extended to closely held corporations; however, some such organizations, e.g. the Little Sisters of the Poor, have also objected in court to this regulatory accommodation as also violating their RFRA rights. Several Senators objected to the opinion with Senator Tom Harkin (D-IA) saying that "While the Supreme Court has ruled, this fight is far from over. Along with my colleagues in Congress, I am deeply committed to ensuring that all Americans, men and women alike, can get the health coverage they need, and we will be exploring legislative remedies to ensure that affordable contraceptive coverage remains available and accessible...." Senator Dick Durbin (D-IL) said he will introduce legislation which would require corporations denying insurance coverage to employees pursuant to the Hobby Lobby case to disclose such to current employees and applicants as well. Through his spokesman, the President hinted that he would support legislation to ensure that women keep their mandated coverage and that corrective regulatory action might also be considered.

**Medicare/Medicaid/PHSA Corner*****CMS Proposes Payment Rules for 2015***

**T**he Centers for Medicare and Medicaid Services (CMS) proposed Medicare payment rules for outpatient hospitals which in 2015 would provide for a 2.1% increase and for ambulatory surgical centers which would provide an update of 1.2%. For physicians, CMS said that there would be a “zero update” for January through March next year and that the Administration supports legislation to provide a permanent fix to the current sustainable growth rate (SGR) formula. In addition, CMS intends to have future physician payment changes, beginning for 2016, go through a public notice and comment period before the rules are finalized. The agency also said that “screening colonoscopies” will now include associated anesthesia when performed by an anesthesiologist which will allow beneficiaries to forego a second coinsurance payment for this procedure. In addition, the agency proposed to simplify the requirements for face-to-face encounters when patients transition from acute care settings to home care by eliminating the current narrative requirement and using only the medical records of the certifying physician or discharging facility for eligibility certification purposes. CMS also proposed that payments for home health agencies be reduced by \$58 million or about 0.3% for CY 2015. The agency’s proposed payment change for end-stage renal disease facilities would amount to a 0.3% increase while payments in 2017-18 would be adjusted downward for facilities not meeting specific quality criteria. Comments on the rules, which also include rules for adjusting payments for durable medical equipment (DME) in areas in which competitive bidding does not exist, are due by September 2nd.

***GAO Reports on Price Disparities of Federal Drug Related Programs***

**A** Government Accountability Office (GAO) report requested by Senator Tom Coburn (R-OK) was released in which the agency found that, for a sample of 78 high use and high expenditure brand name and generic drugs, Medicare Part D pays 32% more than Medicaid and that the Department of Defense (DOD) pays 60% more than Medicaid per unit. The differential was said to be mainly related to the amount of post-purchase price adjustments, e.g. refunds, rebates, or price concessions by drug manufacturers, which ranged from 15% for Medicare Part D, 31% for DOD and nearly 53% for Medicaid.

***HHS Makes Disaster Preparedness Awards***

**H**HS announced, pursuant to the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (P.L. 113-5), that it has approved FY 2014 grants totaling \$228.5 million for the hospital preparedness program and \$611.8 for the Public Health Emergency Preparedness program. HHS said the funds were jointly awarded to encourage further cooperation between health care and public health systems to respond to emergencies and manage public health on a daily basis.

***FDA Issues Policies for Compounding Pharmacies***

**P**ursuant to the provisions of P.L. 113-54, the Drug Quality and Security Act (DQSA), the FDA issued final and interim draft guidance documents as well as a proposed rule. Under the proposed rule the FDA would revise the list of drugs that may not be compounded by compounders or outsourcing facilities because they have been withdrawn or removed from the market after they were found to be unsafe or not effective. The final guidance document describes the interim policies that require implementing regulations of the DQSA and the policies the agency will follow in regulating compounding entities under the new law. The draft interim guidance document describes the agency’s expectations regarding compliance with current good manufacturing practice requirements for facilities that compound human drugs and register with the agency as outsourcing facilities.

## Upcoming Health-Related Hearings and Markups

**House Energy and Commerce Health Subcommittee:** will hold a hearing titled “21st Century Cures: Modernizing Clinical Trials.” 10 a.m., 2123 Rayburn; July 9.

**Senate Special Aging Committee:** will hold a roundtable discussion titled “Improving Audits: How We Can Strengthen the Medicare Program for Future Generations.” 2:15 p.m., 216 Hart; July 9.

**House Oversight and Government Reform Subcommittee on Energy Policy, Health Care and Entitlements:** will hold a hearing on *Medicare management*. 10 a.m., 2154 Rayburn; July 10.

**House Veterans’ Affairs Committee:** will hold a hearing titled “Service Should Not Lead to Suicide: Access to VA’s Mental Health Care.” 9:15 a.m., 334 Cannon; July 10.

**House Energy and Commerce Health Subcommittee:** will hold a hearing titled “21st Century Cures: Incorporating the Patient Perspective.” 10 a.m., 2322 Rayburn; July 11.

## Health Legislation Recently Introduced

**S. 2529** (CONTROLLED SUBSTANCE MONITORING PROGRAM), to amend and reauthorize the controlled substance monitoring program under Section 399O of the Public Health Service Act; SHAHEEN; to the Committee on Health, Education, Labor and Pensions, June 25.

**S. 2538** (VIRAL HEPATITIS SURVEILLANCE), to amend the Public Health Service Act to revise and extend the program for viral hepatitis surveillance, education and testing in order to prevent deaths from chronic liver disease and liver cancer, and for other purposes; KIRK; to the Committee on Health, Education, Labor and Pensions, June 26.

**S. 2539** (TRAUMATIC BRAIN INJURY), to amend the Public Health Service Act to reauthorize certain programs relating to traumatic brain injury and to trauma research; HATCH; to the Committee on Health, Education, Labor and Pensions, June 26.

**S. 2546** (EMPLOYER HEALTH BENEFITS), to repeal a requirement that new employees of certain employers be automatically enrolled in the employer’s health benefits; ISAKSON; to the Committee on Health, Education, Labor and Pensions, June 26.

**S. 2549** (DRUG IMPORTATION), to amend the Federal Food, Drug, and Cosmetic Act to allow for the personal importation of safe and affordable drugs from approved pharmacies in Canada; KLOBUCHAR; to the Committee on Health, Education, Labor and Pensions, June 26.

**S. 2552** (MEDICARE), to enhance beneficiary and provider protections and improve transparency in the Medicare Advantage market and for other purposes; BROWN; to the Committee on Finance, June 26.

**S. 2553** (MEDICARE), to amend Title XVIII of the Social Security Act to provide for standardized post-acute care assessment data for quality, payment and discharge planning and for other purposes; WYDEN; to the Committee on Finance, June 26.

**H.R. 4971** (VETERANS’ HEALTH), to direct the secretary of veterans affairs to conduct annual surveys of veterans on experiences obtaining hospital care and medical services from medical facilities of the Department of Veterans Affairs, and for other purposes; O’ROURKE; to the Committee on Veterans’ Affairs, June 25.