



Senate Passage of “FMAP” Legislation Brings House Back Tuesday for Votes

Congressional Schedule

After passing legislation last week to provide enhanced funding for the Federal Medical Assistance Percentages (FMAP), House Speaker Nancy Pelosi announced the House will reconvene this Tuesday to vote on the legislation. The Senate is scheduled to adjourn this week (after approving Elena Kagan as the 112th Supreme Court justice last week) and return for a September 13-October 8 session. The first order of business is expected to be a small business “jobs” bill and an amendment by Senator Mike Johanns (R-NE) which would repeal a provision of the Patient Protection and Affordable Care Act (PPACA) health reform that would expand IRS 1099 reporting for small businesses. Although a unanimous consent request in the Senate to take up the new Defense Authorization legislation was blocked, this legislation, including authorization of numerous health spending programs, also is likely to be considered a priority. The Senate also will convene the week of November 15, recess for the Thanksgiving week and reconvene on November 29 to finish up any lame-duck business (which will likely include an “omnibus” bill to finish FY 2011 appropriations measures and consideration of the recommendations of the Presidential Deficit Reduction Commission).

States to Receive Extension of Enhanced Medicaid Funding

Last week the Senate voted 61-39 to pass H.R. 1586,

an aviation bill revised to provide for an extension of enhanced Medicaid funding (i.e., FMAP) first provided under the American Recovery and Reinvestment Act of 2009 (ARRA), the stimulus legislation. The \$26.1 billion substitute amendment would provide states with \$16.1 billion in a phase-out of the increased FMAP as follows: a 3.2% increase in the second quarter of FY 2011 and a 1.2% increase in the third quarter of FY 2011 with a slightly larger increase based on state unemployment rates. The House will vote Tuesday on the bill which is paid for by offsets that include a \$1.5 billion cut in renewable-energy loan guarantees, reductions in food stamp benefits and

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\$2 billion in savings due to changes in the calculation of the Medicaid average manufacturer price (AMP) which would create an exception to the current AMP exclusion for an inhalation, infusion, instilled,

implanted, or injectable drug that is not generally dispensed through a retail community pharmacy. The bill would also provide \$10 billion for state and local governments to prevent the layoff of more than 100,000 teachers and other public

employees. Republicans remain generally opposed to the bill, challenging the idea that the offset from the food stamp reductions will actually materialize.

HHS Report Says PPACA Will Reduce Medicare Beneficiary Costs

Last week the U.S. Department of Health and Human Services (HHS) released a report, *Affordable Care Act Update: Implementing Medicare Costs Savings*, stating that the provisions of the PPACA relating to Medicare will reduce projected Medicare spending about \$8 billion over the next two years and about \$575 billion over the next 10 years and also save beneficiaries \$200 a year in Part B premiums by 2018. Specifically the report states: “Without reform, Medicare spending was projected to grow at an average annual rate of 6.8 percent, reaching an annual cost of roughly \$978 billion by 2019....As a result of these reform measures, projected annual growth in Medicare spending has been reduced to 5.3

percent, reaching \$852 billion by 2019—a ten-year savings of over \$575 billion and a reduction of 13 percent in 2019 over previous baseline spending.” Republicans were not convinced, with **Senator Charles Grassley**, Ranking Republican for the Senate Committee on Finance, issuing a statement that “The White House continues to try to persuade people that cutting more than half a trillion dollars from Medicare to fund an unsustainable new entitlement program is somehow a good thing for Medicare beneficiaries.” He said that it is “intellectually dishonest” to count Medicare savings even though the funds are being used to fund an expansion of coverage.

DOL EBSA Withdraws ERISA Regulation Narrowing Preemption

Last week the Employee Benefits Security Administration (EBSA) announced that it intends to withdraw a proposed regulation to define a welfare benefit plan under the Employee Retirement Income Security Act (ERISA) which would have the effect of narrowing the preemption of state law and allow state and local government

laws mandating employer health benefits coverage to survive under the federal law. In light of the enactment of the PPACA and the recent court case allowing a San Francisco “play or pay” health mandate law to proceed, the U.S. Department of Labor (DOL) will likely now review whether further regulation in this area is necessary or appropriate.

Part D Drug Manufacturers Must Agree to Donut-Hole Discounts

Last week, the Centers for Medicare and Medicaid Services (CMS) released the agreement that drug manufacturers must sign by September 1st which describes the discounts which must be provided to Medicare Part D enrollees whose spending extends into the so-called donut-hole coverage gap. The agreement implements the PPACA requirement for discounts of about 50% for brand-name drugs and biologics and includes: additional time for quarterly invoice payments by manufacturers to plan sponsors within 38 days of receipt through the Third Party Administrator; provision of manufacturers with the claims-level data needed to validate invoices,

but without violating patient privacy; and a dispute resolution and appeals process. In related news, HHS announced that the PPACA expansion of the 340B Drug Pricing Program will make discounts (in the range of 20-50%) of out-patient drugs available to children’s hospitals, free-standing cancer centers, critical access hospitals, rural referral centers and sole community hospitals. The Health Resources and Services Administration (HRSA) said the number of facilities participating in the 340B program is expected to increase from 14,000 to nearly 20,000, including 1,500 newly eligible hospitals.

Virginia Challenge to PPACA Individual Health Insurance Mandate to Proceed

Last week **Federal District Judge Henry Hudson** rejected the federal Department of Justice (DOJ) motion to dismiss **Virginia Attorney General Ken Cuccinelli's** challenge to the constitutionality of the PPACA's individual mandate. In rendering his opinion, the judge said "neither the U.S. Supreme Court nor any circuit court of appeals has squarely addressed [the question of whether there is constitutional authority to regulate] a person's decision not to purchase a product, notwithstanding its effect on interstate commerce." He also said the suit was not barred by

the federal Anti-Injunction Act, which provides that "no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person." The White House emphasized that the ruling was procedural, not a decision on the merits.

In related news, **Judge James Shelfer**, of the Florida Circuit Court, 2nd Judicial Circuit, Leon County, ordered removed from the November ballot a proposed Florida state constitutional amendment that would prohibit any law or rule from forcing persons to buy health

insurance. Ballot supporters, however, said they would appeal the ruling and seek to expedite the matter to the Florida Supreme Court in time to have the issue decided before the September 2 ballot printing deadline.

DOJ also has argued that the challenge to PPACA by **Florida Attorney General Bill McCollum** be dismissed. The National Federation of Independent Business and a group of 20 other state attorneys general filed a brief arguing that the DOJ arguments that the suit be dismissed are flawed.

PPACA Unpopular in Missouri

Last week more than 71% of those voting in a Missouri primary voted for the Missouri Health Care Freedom Act, "Proposition C," which is intended to assert the state's authority in

an attempt to block the PPACA's federal insurance coverage mandate on Missouri residents and prohibit enforcement of the mandate against state residents who do not choose to be covered under health

insurance. In response, **Senate Majority Leader Harry Reid** said "the more that people learn about this bill, the more they like it."

Medicare Trustees' Cite Improved Part A Finances Due to PPACA

Last week the Medicare Trustees issued their annual report stating that the \$575 billion in Medicare spending reductions under the PPACA would increase the life of the Hospital Insurance Trust Fund from 2017 projected last year to 2029. However, they warned that some of the savings could evaporate, since they depend on improved productivity by providers such as hospitals to meet lower Medicare reimbursement rates that will require substantial changes in how the health care system operates. They also reported that the 75-year actuarial deficit for the trust fund is 0.66% of taxable payroll, down from 3.88% projected in the 2009 report and that the test for near-term financial adequacy was not met since the Part A trust fund balance will fall below one year's projected expenditures beginning in 2012. In response, **House Republican Minority Leader**

John Boehner retorted, "In fact, the chief Medicare actuary has already blown the whistle on the Obama Administration for attempting to pass off cuts as 'savings' within Medicare when, in fact, the money is being used to establish a new federal entitlement and massive new bureaucracies. Democrats are raiding Medicare, not saving it." The Medicare Actuary stated that his office estimates that the "productivity adjustments" assumed under the Trustees' report would generate \$233 billion of the \$575 billion in Medicare savings over 10 years per the PPACA. A CMS Office of the Actuary report states that based on the historical evidence "actual health provider productivity is very unlikely to achieve improvements equal to the economy as a whole over sustained periods...."

Medicare Limits Blood Disorder Treatment to CED Only

In another final decision memo, CMS said that the available evidence does not demonstrate that the use of allogeneic hematopoietic stem cell transplantation (HSCT) improves health outcomes in Medicare

beneficiaries with myelodysplastic syndromes (MDS) and is therefore, not covered as being “reasonable and necessary.” However, CMS said the available evidence suggests that allogeneic HSCT for MDS is reasonable and necessary

under Coverage with Evidence Development (CED) and proposed that the treatment be covered by Medicare in the context of a prospective controlled clinical study that meets specific standards.

HRSA to Provide \$159M for Training Health Care Professionals

HS announced that \$159 million in grants will be awarded for training nurses, geriatricians and minority health care professionals as the PPACA expands the demand for

health services. HRSA will award \$106 million for various levels of nurse education; about \$30 million to train professionals in specialized care for the elderly; and \$23.6 million for Centers of Excellence

programs that train minority students in various kinds of health professions.

Medicare Expansion of Coverage of PET Scans

In a final decision memo, CMS said it will change a national coverage decision (NCD) from April 2009 that established an absolute limitation of only one FDG (fluorodeoxyglucose) PET (positron emission tomography) study for “beneficiaries who

have solid tumors that are biopsy proven or strongly suspected based on other diagnostic testing when the beneficiary’s treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor.”

FDA Issues

FDA Increases Fees on Drug Industry—The Food and Drug Administration (FDA) has issued notice on the increased amount of certain drug manufacturer application user fees to be collected by the FDA for FY 2011, including a fee on the facilities where drugs are made. The fees include: \$1.5 million for an application requiring clinical data (compared with \$1.4 million in FY 2010); \$771,000 for an application not requiring clinical data or a supplement requiring clinical data (compared with \$702,750 in FY 2010); \$497,200 for establishment fees (compared with \$457,200 in FY 2010); and \$86,520 for product fees (compared with \$77,720 in FY 2010).

CDC Issues

HIV/AIDS Prevention Grants--The Centers for Disease Control and Prevention (CDC) has awarded \$42 million in grants to 133 community-based organizations to support HIV/AIDS prevention efforts. Specifically, the grants will be used to: implement prevention programs for people with HIV and those in high-risk groups; increase HIV testing and knowledge of HIV status in at-risk communities; and monitor program effectiveness and behavioral outcomes.

H.R. 5923 (REFORM PROPOSALS), to amend the Patient Protection and Affordable Care Act to repeal certain limitations on tax health care benefits; PAULSEN; to the Committee on Ways and Means, July 29.

H.R. 5926 (MEDICARE), to amend Title XVIII of the Social Security Act to provide for Medicare coverage of comprehensive Alzheimer's disease and other dementia diagnosis and services in order to improve care and outcomes for Americans living with Alzheimer's disease by increasing detection, diagnosis, care, and planning; MARKEY of Massachusetts; jointly, to the committees on Energy and Commerce and Ways and Means, July 29.

H.R. 5936 (REFORM PROPOSALS), to repeal limitations imposed by the Patient Protection and Affordable Care Act on health-related tax benefits under the Internal Revenue Code of 1986 and to treat high deductible health plans as qualified health plans under such act; REICHERT; jointly, to the committees on Ways and Means and Energy and Commerce, July 29.

H.R. 5939 (ABORTION), to prohibit taxpayer funded abortions and to provide for conscience protections, and for other purposes; SMITH of New Jersey; jointly, to the Committee on the Judiciary, and in addition to the committees on Energy and Commerce and Ways and Means,

July 29.

H.R. 5950 (MEDICARE), to amend Title XVIII of the Social Security Act to count a period of observation status in a hospital exceeding 24 hours toward satisfying the three-day inpatient hospital requirement for coverage of skilled nursing facility services under Medicare; COURTNEY; jointly, to the committees on Ways and Means and Energy and Commerce, July 29.

H.R. 5961 (HEALTH DEMONSTRATION PROGRAMS), to require the secretary of health and human services to establish a demonstration project to award grants to, and enter into contracts with, medical-legal partnerships to assist patients and their families to navigate health-related programs and activities; MAFFEI; to the Committee on Energy and Commerce, July 29.

S. 3680 (FAMILY AND MEDICAL LEAVE), to amend the Family and Medical Leave Act of 1993 to permit leave to care for a same-sex spouse, domestic partner, parent-in-law, adult child, sibling, or grandparent who has a serious health condition; DURBIN; to the Committee on Health, Education, Labor, and Pensions, July 30.

H.R. 5986 (PUBLIC HEALTH), to require the submission of a report to the Congress on parasitic disease among poor Americans; JOHNSON of Georgia; to the Committee on Energy and Commerce, July 30.

H.R. 5996 (VETERANS' HEALTH), to direct the secretary of veterans affairs to improve the prevention, diagnosis, and treatment of veterans with chronic obstructive pulmonary disease; STEARNS; to the Committee on Veterans' Affairs, July 30.

H.R. 6000 (HEALTH CARE COVERAGE), to provide for criminal liability for the denial of health care coverage of a treatment or an individual, and for other purposes; GRAYSON; jointly, to the committees on Energy and Commerce and the Judiciary, July 30.

H.R. 6001 (COBRA), to amend the Internal Revenue Code of 1986 to provide for the establishment of tax-free COBRA premium payment accounts, and for other purposes; PITTS; to the Committee on Ways and Means, July 30.

H.R. 6005 (MEDICARE/ MEDICAID), to amend titles XVIII and XIX of the Social Security Act to provide for the temporary treatment of certain electronic health records as certified EHR technology for purposes of health information technology payment incentives under Medicare and Medicaid; BURGESS; jointly, to the committees on Energy and Commerce and Ways and Means, July 30.

H.R. 6012 (DIABETES), to direct the secretary of health and human services to review uptake and utilization of diabetes screening

benefits and establish an outreach program with respect to such benefits, and for other purposes; SPACE; to the Committee on Energy and Commerce, July 30.

H.R. 6017 (PUBLIC HEALTH), to amend the Public Health Service Act to ensure that the federal government has independent, peer-reviewed scientific data and information to assess short-term and long-term direct and indirect impacts on the health of oil spill clean-up workers and vulnerable residents resulting from the Deepwater Horizon oil spill, and for other purposes; CAPPS; to the Committee on Energy and Commerce, July 30.

H.R. 6032 (CHIROPRACTORS), to amend the Public Health Service Act to authorize appointment of doctors of chiropractic to regular and reserve corps of the Public Health Service Commissioned Corps, and for other purposes; GENE GREEN of Texas; to the Committee on Energy and Commerce, July 30.

H.R. 6072 (MEDICARE/MEDICAID), to amend titles XVIII and XIX of the Social Security Act to clarify the application of EHR payment incentives in cases of multi-campus hospitals; SPACE; jointly, to the committees on Ways and Means and Energy and Commerce, July 30.

H.R. 6074 (MEDICARE/MEDICAID), to amend titles XVIII and XIX of the Social Security Act to enhance quality under Medicaid through nursing facility survey system

improvements; STUPAK; jointly, to the committees on Ways and Means and Energy and Commerce, July 30.

H. RES. 1575 (DISEASE AWARENESS) expressing support for designation of the third week of October as Male Breast Cancer Awareness Week; GINNY BROWN-WAITE of Florida; to the Committee on Oversight and Government Reform, July 29.

H. RES. 1580 (PRESCRIPTION DRUGS) raising the awareness of the need to secure prescription medications and expressing support for designation of Sept. 10 as National Lock Your Meds Day; ROE of Tennessee; to the Committee on Oversight and Government Reform, July 29.

H. RES. 1591 (MINORITY HEALTH) recognizing the Black Barbershop Health Outreach Program's contribution to the national fight against health disparities through education, community involvement, research, and culturally relevant strategies that seek to improve health outcomes in Black communities across the country; HASTINGS of Florida; to the Committee on Energy and Commerce, July 30.

H. RES. 1600 (PHYSICIAN ASSISTANTS) supporting the critical role of the physician assistant profession and supporting the goals and ideals of National Physician Assistant Week; MCCOLLUM; to the Committee on Energy and Commerce, July 30.

H. RES. 1603 (DISEASE AWARENESS) expressing support

for designation of September 2010 as National Craniofacial Acceptance Month; ROSS; to the Committee on Oversight and Government Reform, July 30.

S. 3684 (DISEASE AWARENESS), to establish the Cavernous Angioma CARE Center (Clinical Care, Advocacy, Research and Education) at the University of New Mexico, and for other purposes; UDALL of New Mexico; to the Committee on Health, Education, Labor, and Pensions, Aug. 2.

S. 3686 (APPROPRIATIONS), original bill making appropriations for the Department of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending Sept. 30, 2011, and for other purposes; HARKIN; from the Committee on Appropriations; placed on the calendar, Aug. 2.

S. 3690 (DRUGS), to provide for additional quality control of drugs; BENNET; to the Committee on Health, Education, Labor, and Pensions, Aug. 4.

S. 3697 (PEDIATRIC DISEASES), to amend the Federal Food, Drug, and Cosmetic Act to improve the priority review voucher incentive program relating to tropical and rare pediatric diseases; BROWNBACK; to the Committee on Health, Education, Labor, and Pensions, Aug. 4.

S. 3698 (MENTAL HEALTH), to amend the Public Health Services Act to provide for integration of mental health services and mental health treatment outreach teams,

and for other purposes; COLLINS; to the Committee on Health, Education, Labor, and Pensions, Aug. 4.

S. 3703 (DISEASE AWARENESS), to expand the research, prevention, and awareness activities of the Centers for Disease Control and Prevention and the National Institutes of Health with respect to pulmonary fibrosis, and for other purposes; MURRAY; to the Committee on Health, Education, Labor, and Pensions, Aug. 4.

S. 3708 (MEDICARE/MEDICAID), to amend titles XVIII and XIX of the Social Security Act to clarify the application of EHR payment incentives in cases of multi-campus hospitals; SCHUMER; to the Committee on Finance, Aug. 5.

S. 3709 (MENTAL HEALTH), to amend the Public Health Services Act and the Social Security Act

to extend health information technology assistance eligibility to behavioral health, mental health, and substance abuse professionals and facilities, and for other purposes; WHITEHOUSE; to the Committee on Finance, Aug. 5.

S. 3711 (DISEASE AWARENESS), to amend the Public Health Service Act to direct the secretary of health and human services to establish, promote, and support a comprehensive prevention, education, research, and medical management referral program for viral hepatitis infection that will lead to a marked reduction in the disease burden associated with chronic viral hepatitis and liver cancer; KERRY; to the Committee on Health, Education, Labor, and Pensions, Aug. 5.

S. 3723 (ABORTION), to prohibit taxpayer funding of insurance plans or health care programs that cover abortion; COBURN; to the Committee on Health, Education,

Labor, and Pensions, Aug. 5.

S. 3737 (MEDICAL IMAGING SERVICES), to amend the Public Health Service Act and Title XVIII of the Social Security Act to make the provision of technical services for medical imaging examinations and radiation therapy treatments safer, more accurate, and less costly; ENZI; to the Committee on Health, Education, Labor, and Pensions, Aug. 5.

S. 3751 (STEM CELL RESEARCH), to amend the Stem Cell Therapeutic and Research Act of 2005; HATCH; to the Committee on Health, Education, Labor, and Pensions, Aug. 5.