



## FDA User Fee Bill on Schedule; Congress/ POTUS Await Supreme Court PPACA Decision

### *FDA User Legislation Scheduled for Enactment*

Under suspension of the rules, the House passed, with an amendment, the previously passed Senate bill, S. 3187, which reauthorizes the Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee Act (MDUFA), authorizes new user fees for generic and biologic drugs, contains the Generating Antibiotic Incentives Now (GAIN) Act providing additional exclusivity periods and priority review by the FDA for manufacturers developing new antibiotics for a serious and life-threatening infection, and bans certain synthetic drugs (e.g. bath salts) among other provisions. The Senate Majority leader has scheduled a cloture vote in the Senate for early this week with enactment expected before the upcoming week-long July 4th recess. Early passage of the legislation will enable the FDA to administer the law before the current user fee authorization expires on September 30th.

### *Appropriations*

On Wednesday the House is scheduled to take up H.R. 5973, the FY 2013 Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Act. The House Appropriations Committee also passed the FY 2013 Financial Services spending bill which includes restrictions on transferring funds between HHS and the IRS for PPACA purposes

as well as a restriction on PPACA federal health insurance exchanges from using federal funds for administrative costs related to abortion.

### *Other Notable Health Legislation*

The House passed H.R. 3668, legislation which increases the penalties against individuals and companies involved in selling counterfeit prescription drugs. The bill's passage sets up a formal or informal conference with the Senate's bill, S. 1886. Also, facing a month-end deadline to freeze student loan interest rates at 3.4% for another year, Senate leaders have apparently reached an agreement to extend the loan rate and pay for the \$6 billion cost of the legislation. It remains to be seen to what extent the final offsets will include PPACA or other health-related cuts which the House included in the bill previously sent to the Senate.

### *Inside*

Supreme's to Rule on PPACA This Week	2
PPACA Health Insurance Premium Rebates	2
PCORI Grants	2
Community Health Center Grants	2
Medicaid Eligibility Rules under PPACA	2
House W&M's Hearing on MedPAC Report	3
Recently Introduced Health Legislation	3

## Supreme's to Rule on PPACA This Week

**A**lthough today is the last scheduled day for the Court to sit to issue decisions before the summer recess, it is likely additional decision dates will be added. The Supreme Court begins announcing its decisions at 10AM. Regardless, the White House and Congress are gearing up to react to the court's decision on the constitutionality of the individual mandate and other provisions of the PPACA. House Republican leaders warned their members against "spiking the ball" if the court strikes down some or all of the law. Regardless of the decision, it is expected that

House Republicans will schedule another vote to repeal the PPACA or whatever remains of the law after the Supreme Court decision. Their intent to replace the PPACA with "step by step" reforms will likely be delayed until after the November elections. **Minority Leader Nancy Pelosi** responded as follows: "It is a sad day when Republicans continue to cheer against health benefits Americans are already enjoying, while running out the clock on the economy and pursuing policies that are dangerous to a thriving middle class. No one, except perhaps House Republicans, actually

believes they 'are focused on the economy.'" The Supreme Court decision will also unleash the stays on the numerous other federal cases involving the PPACA, including among other suits: the constitutionality of the Independent Payment Advisory Board; whether First Amendment rights are violated by the PPACA's mandate for religiously affiliated hospitals and other organizations to provide contraception and other services they say violate their religious values; and whether the law unconstitutionally prevents the expansion of doctor owned hospitals.

### PPACA Health Insurance Premium Rebates

**H**HS announced that health insurance companies will rebate \$1.1 billion to about 12.8 million policyholders as a result of the requirement that insurers pay up when they do not meet the minimum loss ratio (MLR) under the PPACA. The continued status of such rebates remains in doubt pending the Supreme Court decision.

### PCORI Grants

**T**he Patient-Centered Outcomes Research Institute announced that the two-year \$30 million in Pilot Project Program awards will be divided among projects in 24 states and the District of Columbia. The program is intended to support the collection of data that can be used to advance patient-centered CER research.

### Community Health Center Grants

**H**HS announced that \$128.6 million in PPACA Health Center New Access Point grants will be awarded to 219 community health centers. HRSA said the grants will create 5,640 jobs for doctors and other health professionals.

### Medicaid Eligibility Rules under PPACA

**C**MS said it is requesting public comment on new modified adjusted gross income tests mandated under the PPACA for determining expanded Medicaid eligibility in 2014. The expanded Medicaid eligibility standards under the PPACA will allow states to enroll those with incomes up to 133% of the federal poverty level, regardless of categorical status.

## House W&M's Hearing on MedPAC Report

**A**t a House Ways and Means Health Subcommittee Hearing to review the annual MedPAC report, the MedPAC Chairman, **Glenn Hackbarth**, defended the commission's recommendation to restructure Medicare by combining the Part A and B deductibles, replacing coinsurance with copays that vary by type of service and provider, levying a surcharge on Medigap

coverage and placing a cap on out-of-pocket beneficiary spending. Although the Subcommittee Chairman, **Wally Herger**, said Congress should be open to any and all solutions to fixing the financial challenges posed by Medicare, two other Republican members, **Reps. Sam Johnson and Dave Reichert** expressed concerns that the Medigap fee would force some beneficiaries to delay essential care.

**H.J. Res. 112 (TAXATION)**, disapproving the rule submitted by the Internal Revenue Service relating to the health insurance premium tax credit; DESJARLAIS; to the Committee on Ways and Means, June 18.

**S. 3313 (VETERANS' HEALTH)**, to amend Title 38, United States Code, to improve the assistance provided by the Department of Veterans Affairs to women veterans, to improve health care furnished by the department, and for other purposes; MURRAY; to the Committee on Veterans' Affairs, June 19.

**H.R. 5979 (MEDICAID)**, to amend Title XIX of the Social Security Act to reform payment to States under the Medicaid program; CASSIDY; to the Committee on Energy and Commerce, June 20.

**S. 3325 (MENTAL HEALTH)**, to authorize the secretary of health and human services, acting through the administrator of the Substance Abuse and Mental Health Services Administration, in coordination with the secretary of education, to carry out a five-year demonstration program to fund mental health First Aid training programs at 10 institutions of higher education to improve student mental health;

BEGICH; to the Committee on Health, Education, Labor and Pensions, June 21.

**H.R. 5989 (BEHAVIORAL HEALTH/MEDICAID)**, to increase access to community behavioral health services for all Americans and to improve Medicaid reimbursement for community behavioral health services; MATSUI; to the Committee on Energy and Commerce, June 21.

**H.R. 5994 (MEDICARE/MEDICAID)**, to provide a demonstration project under which Medicare and Medicaid beneficiaries are provided the choice of health benefits coverage and access to a debit-style card for the purpose of purchasing qualified health benefits coverage and paying for other health care expenses; NUNES; jointly, to the committees on Energy and Commerce and Ways and Means, June 21.

**H.R. 5996 (MENTAL HEALTH)**, to authorize the secretary of health and human services, acting through the administrator of the Substance Abuse and Mental Health Services Administration, in coordination with the secretary of education, to carry out a five-year demonstration program to fund mental health

First Aid training programs at 10 institutions of higher education to improve student mental health; ALTMIRE; jointly, to the committees on Energy and Commerce and Education and the Workforce, June 21.

**H.R. 5998 (PREVENTIVE HEALTH)**, to amend Title IX of the Public Health Service Act to revise the operations of the U.S. Preventive Services Task Force; BLACKBURN; jointly, to the committees on Energy and Commerce and Ways and Means, June 21.

**H.R. 6006 (MEDICAID)**, to amend Title XIX of the Social Security Act to permit states the option to provide Medicaid coverage for low-income individuals with HIV; ENGEL; to the Committee on Energy and Commerce, June 21.

**H.R. 6011 (MEDICARE)**, to amend Title XVIII of the Social Security Act to improve Medicare benefits for individuals with kidney disease, and for other purposes; LEWIS of Georgia; jointly, to the committees on Energy and Commerce and Ways and Means, June 21.