



House Approves FDA User Fee Legislation and Schedules PPACA Repeal Efforts

House-Passed FDA User Fee Reauthorizations Move to Conference

The House passed its version of FDA user fee legislation (H.R. 5651) on a vote of 387-5 which sets up a conference with the Senate on its reauthorization bill (S. 3187). CBO estimates the House bill would result in \$1.5 billion in user fees and reduce the federal deficit by \$114 million over 2012-2017 while the Senate bill would reduce the deficit by \$363 million over ten years. In general, for FY 2013-2017 the House bill would:

- ◆ reauthorize PDUFA (setting FY 2013 fee revenue at \$713;
- ◆ the comparable Senate bill number is \$693 million);
- ◆ reauthorize MDUFA (setting FY 2013-2017 fee revenue at \$595, the same as in the Senate bill);
- ◆ authorize new generic drug and biosimilars user fee programs; and, among other things,
- ◆ provide new incentives for the development of antibiotics and provisions to address drug shortages.

House Passes FY 2013 MilCon/VA Appropriations Bill

The House voted 407-12 to pass the \$146.4 billion FY 2013 Military Construction and Veterans Affairs and Related Agencies Appropriations Act which is about 1% less than

the President's request. The bill, H.R. 5854, includes \$41.4 billion for medical services, including \$6.2 billion for mental health programs; \$250 million to support rural health services; \$220 million for traumatic brain injury treatment; and \$73 million for suicide prevention programs. The bill would also withhold 75% of funds available for a VA/DOD integrated health records program until administrators submit a data standardization schedule and annual spending report to Congress. The Administration is expected to oppose all House-passed appropriations bills in an effort to get the House to abandon the House-passed budget resolution which would shrink federal discretionary spending from the level set under the Budget Control Act.

Prenatal Nondiscrimination Act of 2011 Fails in House

The House voted down the Susan B. Anthony and Frederick Douglass Prenatal Nondiscrimination Act of 2011 under the suspension-

continued page two

Inside

PPACA Insurer Reporting Rule/QHSs Rule	2
IRS Delays MLR Date	2
Hearings on PPACA Effects on Hiring	3
CMS Initiative to Reduce Nursing Home Drug Use	3
Medical Home DEMO Expansion Possible	3
Recently Introduced Health Legislation	3

from page one

of-the-rules process which requires a two-thirds vote (246-168).

Among other things, the legislation would have imposed certain criminal penalties on anyone who knowingly or knowingly attempts to perform an abortion knowing that the abortion is sought based on the sex, gender, color or race of the child or the race of a parent.

Upcoming Schedule in House

The House will proceed with votes on additional appropriations bills this week, including the energy-water bill and, possibly, the homeland security and legislative branch bills. The following week the stage is set for action on an omnibus PPACA-related bill which includes several measures that the House Ways and Means Committee passed last week. The first, H.R. 436, would repeal the PPACA medical device tax (passed on a 23-11 vote); a second bill, H.R. 5842,

would repeal the ban on the use of tax-free money in flexible spending arrangements (FSAs) and health savings accounts (HSAs) to purchase over-the-counter medicines without a prescription (passed on a 24-9 vote); and another bill, H.R. 1004, would allow up to \$500 of unspent money in FSAs to be returned to account holders (passed on a 23-6 vote). To offset the cost of the omnibus bill, it is expected that the House Rules Committee will add a provision which increases revenue by about \$44 billion by requiring individuals to return to the Treasury any PPACA premium assistance tax credits which are made in error.

The House Ways and Means Committee also approved a bill (H.R. 5858) on a 21-7 vote that would encourage more use of health savings accounts by permitting individuals to get the saver's credit currently allowed for retirement accounts to be used for HSAs. The bill would also allow

retirees aged 55-65 to use HSA amounts to pay for group health insurance premiums.

Unclear as of now is the Republican strategy for further amending the PPACA in the event the Supreme Court strikes down by the end of June the PPACA individual mandate or other parts of the law.

Congressional leaders also continue to spar over the means to offset the cost of extending the reduced interest rate for Stafford student loans. The Senate rejected the House pay-for which would repeal the funding for the PPACA Prevention and Public Health Fund. Republicans have offered several other pay-for options, one of which would track the Obama budget proposal to phase down the Medicaid provider tax threshold from the current 6% to 3.5% over FY 2015 to FY 2017.

PPACA Insurer Reporting Rule/ QHSs Rule

HHS issued a proposed rule under which the three largest small group health insurance plans in each state would have to report information "to collect sufficient information on potential benchmark plans' benefits to enable plans seeking to offer coverage in the individual or small group markets in 2014" to know what benefits will be included in the essential health benefits (EHB) benchmark. Also HHS proposed the first of a two-phased means of accrediting entities to implement standards for "qualified health plans" (QHPs) that will be sold in health insurance exchanges beginning in 2014. Comments are due within 30 days.

IRS Delays MLR Date

The IRS issued Notice 2012-37 to extend previous interim guidance and transition relief for health insurers regarding implementation of the PPACA minimum loss ratio rule. The relief extends through the first taxable year beginning after the end of this year. Comments are due by September 10th.

Hearings on PPACA Effects on Hiring

The House Education and the Workforce Subcommittee on Health, Employment, Labor and Pensions held a hearing last week to gather information on how small businesses might react to the various provisions of the health reform law and efforts to reduce health care costs. Several business witnesses testified that

the law is likely to force them to reduce benefits or otherwise accept the increase in business health plan costs which would stymie their hiring of new employees. Others testified that the employer mandate and state-based health insurance exchanges mandated by the PPACA will help expand coverage and lower costs in

larger insurance pools. Another witness testified that the PPACA 60% minimum actuarial value plan requirement and related IRS guidance will make it harder for employers to adopt high-deductible health plans such as health savings accounts and health reimbursement arrangements.

Medical Home DEMO Expansion Possible

CMS provided notice that the agency is seeking information on the regulatory burden associated with the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration project in an effort to determine whether the demo should be expanded under Medicare.

CMS Initiative to Reduce Nursing Home Drug Use

CMS announced a new “Partnership to Improve Dementia Care” to improve the proper use of antipsychotic medication for nursing home residents and reduce the use of such drugs in nursing homes by 15% by year-end. The partnership includes the federal government, states, nursing homes and advocacy groups. The partnership may be expanded to other providers, including hospitals, in the future.

Recently Introduced Health Legislation

H.R. 5858 (HEALTH SAVINGS ACCOUNTS), to amend the Internal Revenue Code of 1986 to improve health savings accounts, and for other purposes; HERGER; which was referred to the Committee on Ways and Means, May 29.

H.R. 5866 (MEDICAL DEVICES), to enhance Food and Drug Administration oversight of medical device recalls, to provide for the conditional clearance of certain medical devices, and for other purposes; BRALEY of Iowa; to the Committee on Energy and Commerce, May 30.