



On Path to August Recess, the Senate Passes Appropriations Supplemental

Appropriations Issues

Last week the Senate passed H.R. 4899, the Iraq/Afghanistan war supplemental appropriations measure that the House passed earlier with various domestic health and other spending provisions including an amendment to strengthen the FTC's ability to restrict "pay for delay" payments by brand-name drug manufacturers to their generic competitors to delay the manufacture and marketing of generic drugs. However, to clear the legislation before the weekend, the Senate stripped the House domestic spending provisions, including \$10 billion in school aid and \$1 billion for summer jobs. **House Armed Services Chairman Ike Skelton** broke with **Speaker Pelosi** in urging the Senate to send the war funding portions back to the House (which is expected to again take up the bill this week). The House is also expected to take up H.R. 5822, FY 2011 appropriations for military construction, the Department of Veterans Affairs and related agencies. At the fractious and party-line House Appropriations markup last week, Democrats also approved the so-called 302(b) spending levels for all 12 FY 2011 appropriations bills, including \$176.4 billion for the Labor-HHS-Education bill, a nearly \$7 billion increase over the \$169.63 billion allocated by the Senate and almost \$6 billion more than requested by the Administration. The total spending limit for the 12 bills equals the \$1.121 trillion discretionary spending cap included in "deeming" budget legislation passed by the House earlier this month.

A 3.2% increase was given the Defense, Homeland Security, Military Construction-VA and State-Foreign Operations bills, while the LHHS and other bills were provided a 2.3% increase over last year. New **West Virginia Senator Carte Goodwin** missed out on former senator **Robert Byrd's** appropriations seat but was assigned to the Armed Services, Budget, Rules and HELP committees instead. **Ohio Senator Sherrod Brown** gave up his HELP Committee seat to join the Appropriations Committee.

House Energy and Commerce Subcommittee Markup of Health Legislation

Last Thursday the House E&C Health Subcommittee reported the following health legislation:

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H.R. 5710 would reauthorize the National All Schedules Prescription Electronic Reporting (NASPER) Act (PL 109-60), which provides grants to states to track drug prescriptions; H.R. 5809 would allow a person to deliver, without being registered with the DEA, a controlled substance to an appropriate person for disposal, subject to AG regulations which would also permit long-term care facilities to dispose of controlled substances on behalf of their

patients; H.R. 2923 would require individuals who sell a scheduled listed chemical product, including methamphetamines, at retail to submit to the attorney general a self-certification, including a statement that the individual understands the law's requirements; H.R. 903 would enhance the role of dentists and dental professionals in the nation's disaster response framework; H.R. 1745 would provide liability protections for volunteer practitioners at health centers; H.R. 3199 would provide

grants to state emergency medical service departments to provide for the expedited training and licensing of veterans with prior medical training; H.R. 3470 would authorize funding for pilot programs on reducing infant mortality; and H.R. 5756 would provide for grants and technical assistance to improve services rendered to children and adults with autism, as well as their families.

PPACA Claims Appeal Regulations

Last week the departments of HHS, Labor and Treasury released interim final regulations standardizing and strengthening the process by which consumers can appeal a medical coverage or claims denial by their health insurance company, including the right to appeal to an external third party.

For the first time, individuals will have the right to bring their appeal to an external, independent third party. The rule is effective for plan years beginning on or after September 23, 2010, except for grandfathered plans in place before March 23, 2010.

PPACA Medical Loss Ratio Rules

The NAIC announced that state insurance regulators are attempting to finish by September their recommendations as to how health insurance companies will have to calculate their medical loss ratios, pursuant to the PPACA. HHS will issue loss ratio regulations once the NAIC recommendations are finalized and may consider allowing states to transition into the rules once

released. **Senator John D. Rockefeller IV**, Chairman of the Senate Commerce, Science and Transportation Committee has written the NAIC expressing his concern that the health insurance industry is trying to weaken the MLR requirements.

Medicare Imaging Demonstration Participation Requested

CMS announced that interested parties have 60 days to apply to participate in a Medicare demonstration project to determine the appropriateness of advanced diagnostic imaging services furnished to program beneficiaries, as authorized under section 135(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, Pub. L. No. 110-275). CMS said the goal

of the demo "is to collect data regarding physician compliance with appropriateness criteria selected by HHS under the terms of the statute in order to determine the appropriateness of advanced diagnostic imaging services furnished to Medicare beneficiaries." The demonstration is scheduled to start January 1, 2011 and operate for two years.

House Ways and Means Hearing on EHR “Meaningful Use”

At last week’s Ways and Means Health Subcommittee hearing on electronic health records, **Rep. Wally Herger** criticized the final “meaningful use” regulations and quizzed CMS and the Office of the National Coordinator for Health Information Technology on why the agencies eased requirements for the first stage of “meaningful use” in the final rule. He said that major changes in the rule resulting in decreased thresholds and more flexible criteria for achieving Stage 1 of meaningful use could lead to lower standards

and lower compliance rates. The CMS spokesman said the final rule for the first stage of meaningful use criteria is meant to “get as many providers on board [with HIT adoption] while recognizing that some will need more time” and that future criteria for 2013 and 2015 will point toward higher standards and requirements in the future. **Chairman Pete Stark** said that “The whole purpose of the [Health Information Technology for Economic and Clinical Health Act] is to push providers to do more with health IT and do it faster, but it is also important to

take a balanced approach so that in our zeal to get to our destination, we don’t leave providers on the sidelines....” Also, CMS has released a fact sheet detailing how the final rule will affect Medicaid programs and providers, including further details on state obligations and opportunities in seven areas: eligibility; payments; adopting, implementing, or upgrading certified EHR technology; demonstrating meaningful use of EHR technology; conditions for federal financial participation (FFP) for states; financial oversight; and combating fraud and abuse.

Republican “Hearing” on Generic Pathway

Citing the lack of hearings by the House Energy and Commerce Committee, **Rep. Michael Burgess** held a Republican-led hearing last week during which he urged Congress and the FDA to consider patient

safety issues when establishing an approval pathway for generic versions of biologic drugs. The FDA is expected to begin holding public meetings later this year to solicit comment on how the process should work. **Rep. Burgess** called

on **Chairman Henry Waxman** to begin holding hearings to examine the FDA’s implementation of the biosimilars legislation approved as part of the PPACA.

Participants in 2009 PQRI to Receive Incentive Payments in October

CMS announced that payments to physicians and other eligible Part B providers for successful participation in the 2009 edition of the CMS quality incentive program will not be made

until this October. CMS said that technical issues involved with the processing of submissions and subsequent analyses have delayed payments.

FDA Issues

House Hearing on Regulation of Commercial Genetic Tests--At last week's House Energy and Commerce Subcommittee on Oversight and Investigations hearing, the FDA explained why the agency is taking action to investigate and regulate direct-to-consumer (DTC) genetic tests which the GAO found to be unreliable. The FDA spokesman said that the agency did not take action earlier to regulate the tests because it did not define the tests as "medical devices" used to diagnose or prevent diseases, but that as more of the tests have claimed to "assess high-risk but relatively common diseases and conditions" the FDA determined that agency oversight is essential to ensuring consumer safety. He said that marketing genetic tests directly to consumers can increase the risk of a test because a patient may make a decision that adversely affects his or her health.

FDA/CMS Agreement on Data Sharing--The FDA and CMS have reached agreement, via a five-year memorandum of understanding (MOU), that will allow the two agencies to share information and expertise while preserving the privacy of individual companies and manufacturers. The purpose of the MOU is to promote collaboration, to develop better and more efficient interagency coordination by sharing tools and expertise and to build infrastructure and processes that will pave the way for the sharing of information used to evaluate the safety, efficacy, utilization, coverage, payment and clinical benefit of drugs, biologics and medical devices. It also could become the first step toward parallel reviews of drugs and medical devices.

FDA Rescinds Pediatric Information Rule--The FDA announced, due to "adverse comments," it is withdrawing a rule that requires device companies to submit "readily available" pediatric medical device information as part of premarket approval applications and certain other FDA submissions.

Health Related Hearings This Week

Senate Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, to hold a business meeting July 27 to mark up proposed budget estimates for fiscal year 2011 for Labor, Health and Human Services, Education, and Related Agencies

Senate HELP, hold a business meeting July 28 to consider H.R. 5610, to provide a technical adjustment with respect to funding for independent living centers under the Rehabilitation Act of 1973 in order to ensure stability for such centers.

House Energy and Commerce, Subcommittee on Health, to hold a hearing July 27, "Implementation of the Health Information Technology for Economic and Clinical (HITECH) Act."

House Financial Services to meet July 28 to consider H.R. 3421, Medical Debt Relief Act of 2009.

House Veterans' Affairs, Subcommittee on Oversight and Investigations, to hold a hearing on July 27, "Gulf War Illness: The Future for Dissatisfied Veterans."

S. 3609 (VETERANS' HEALTH), to extend the temporary authority for performance of medical disability examinations by contract physicians for the Department of Veterans Affairs; AKAKA; to the Committee on Veterans' Affairs, July 20.

H.R. 5795 (MEDICARE/MEDICAID), to amend the Social Security Act to provide for coverage of voluntary advance care planning consultation under Medicare and Medicaid, and for other purposes; BLUMENAUER; jointly, to the committees on Energy and Commerce and Ways and Means, July 20.

H.R. 5802 (FUNDING), to repeal a provision of the Patient Protection and Affordable Care Act providing for funds to a health care facility and rescind funds made available under such section; UPTON; to the Committee on Energy and Commerce, July 20.

H.R. 3627 (HIV/AIDS), to ensure that United States global HIV/AIDS assistance prioritizes saving lives by focusing on access to treatment; COBURN; to the Committee on Foreign Relations, July 21.

H.R. 5803 (MEDICARE), to amend Title XVIII of the Social Security Act to protect Medicare beneficiaries' access to home health services under Medicare; MCGOVERN; jointly, to the committees on Ways and Means and Energy and Commerce, July 21.

H.R. 5807 (REPRODUCTIVE HEALTH), to promote optimal

maternity outcomes by making evidence-based maternity care a national priority, and for other purposes; ROYBAL-ALLARD; jointly, to the committees on Energy and Commerce and Ways and Means, July 21.

H.R. 5808 (REFORM PROPOSAL), to amend the Patient Protection and Affordable Care Act to establish a public health insurance option; WOOLSEY; to the Committee on Energy and Commerce, July 21.

H.R. 5809 (CONTROLLED SUBSTANCES), to amend the Controlled Substances Act to provide for take-back disposal of controlled substances in certain instances, and for other purposes; INSLEE; jointly, to the committees on Energy and Commerce and the Judiciary, July 21.

H. RES. 1547 (HIV/AIDS), 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 21.

S. 3662 (MEDICARE/MEDICAID), to provide for enhanced penalties to combat Medicare and Medicaid fraud, a Medicare data-mining system, and a Beneficiary Verification Pilot Program, and for other purposes; GILLIBRAND; to the Committee on Finance, July 22.

H.R. 5841 (VETERANS' HEALTH), to authorize the secretary of veterans affairs to establish public-private partnerships for the treatment

and research of post-traumatic stress disorder; ISRAEL; to the Committee on Veterans' Affairs, July 22.

H.R. 5844 (MEDICARE), to amend Title XVIII of the Social Security Act to provide all Medicare beneficiaries with the right to guaranteed issue of a Medicare supplemental policy and annual open change-in-enrollment periods, and for other purposes; ROTHMAN of New Jersey; jointly, to the committees on Ways and Means and Energy and Commerce, July 22.