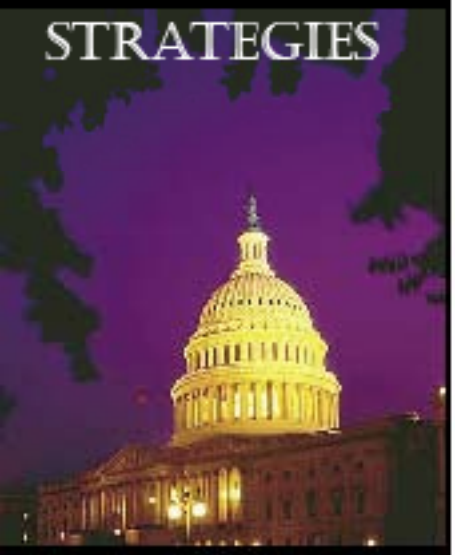
HART HEALTH STRATEGIES



Health Policy Briefing

May 28, 2012

Senate Passes FDA User Fee Legislation; House Returns to FDA Bill and Appropriations

House/Senate Schedule

Before recessing for a week, the Senate voted 96-1 to pass S. 3187, legislation reauthorizing existing and new FDA user fee programs (see below). The Senate also voted down a Republican proposal to repeal the PPACA Prevention and Public Health Fund to pay for a one-year extension of current federal student loan rates. The House returns from recess to take up on Wednesday an FDA reauthorization bill under suspension of the rules (H.R. 5651). Also, up for a vote that day is H.R. 3541, the Susan B. Anthony and Frederick Douglass Prenatal Nondiscrimination Act of 2011 that would, among other things, impose 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. On Thursday, the House is scheduled to take up H.R. 5854, the FY 2013 Military Construction and Veterans Affairs and Related Agencies Appropriations Act and, possibly, H.R. 5325 which provides appropriations for energy and water related agencies. The House Majority Leader also said the House will soon take up legislation to repeal the PPACA 2.3% medical device tax; the House Ways and Means Committee has scheduled a markup on May 31st.

New MedPAC Board Members Named

The GAO Comptroller General has appointed five new members of the Medicare Payment Advisory Commission and reappointed **Glenn Hackbarth** as Chairman. The new members are: **Alice Coombs**, a critical care specialist and anesthesiologist at Milton Hospital and South Shore Hospital in Weymouth, Mass; **Jack Hoadley**, a research professor at the Georgetown University Health Policy Institute; **David Nerenz,** director of the Center for Health Policy and Health Services Research at the Henry Ford Health System in Detroit; **Rita Redberg**, a cardiologist and professor of clinical medicine at the University of California at San Francisco Medical Center; and **Craig Samitt**, president and chief executive officer of Dean Health System Inc., in Madison, Wis.

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Grants for CCER

The Patient-Centered Outcomes Research Institute (PCORI) announced that applications are due by July 31 in regard to primary research funding for the first round of grants to support comparative clinical effectiveness research. About $96 million in grants will be awarded for projects to assess different prevention, diagnosis and treatment options; improve health care systems; compare approaches to communication and dissemination of comparative effectiveness research information; and address and potentially eliminate disparities across patient populations.

Responses to Ways and Means Request for SGR Reform Ideas

Several physician groups have responded to **House Ways and Means Committee Chairman Dave Camp's** request for solutions to the current problems presented by the sustainable growth rate formula under the Medicare physician payment system. The AMA urged Congress to: waive program integrity laws and regulations for physicians who seek to engage in and lead innovative delivery models that promote quality, increase coordination and reduce costs; extend anti-trust protections under the Medicare Shared Savings Program to other providers pursuing innovative contracting arrangements with payers; and help make sure that physicians engaged in new models of care delivery are not precluded from having a meaningful market presence with hospitals and insurers. Also, the Medical Group Management Association suggested that Congress: prevent CMS from backdating penalties under the electronic health record meaningful use requirements and encourage CMS to be more flexible in allowing physicians to experiment with new payment models for delivering and reimbursing health care (such as bundled payments, partial capitation, ACOs, medical homes and other hybrid approaches).

CMS Actuaries Provide New Medicare Projections

The CMS Office of the Actuary released a new set of projections on future Medicare spending which differ from the projections released earlier under the 2012 Medicare Trustee Reports. Stating that the Trustee report projections are unrealistic, e.g. because it was assumed the 31% reduction in physician payment rates would not be waived as has always been the case in the past, the OA said that (1) Medicare Part B costs will increase to 1.87% of GDP by 2020 and 3.58% of GDP by 2080 (assuming SGR cuts are prevented) in contrast to the increases under the Trustee report (i.e. costs increasing to 1.65% of GDP by 2020 and 2.52% of GDP by 2080); and (2) Medicare Part A costs will increase to 9.9% of GDP in 2085 which is 3.6 percentage points higher than shown under the Trustees' report.

Republicans Criticize PPACA Educational Funding

After HHS awarded a $20 million contract to a public relations firm to implement a national campaign to provide education on PPACA initiatives to prevent illness, Republicans criticized the Administration for its so-called election year "propaganda" moves.

Grants for Family Health Information Centers

HHS announced that $4.9 million in grants will be made available to help fund Family-to-Family Health Information Centers supporting care for children with special health needs.

FDA User Fee Reauthorizations Move Forward

As stated above, the Senate sent to the House its version of FDA user fee legislation which: reauthorizes at $693 million for FY 2013 the Prescription Drug User Fee Act (PDUFA); reauthorizes at $595 million for FY 2013 the Medical Device User Fee Act (MDUFA); creates new user fee programs for generic drugs ($299 million for FY 2013-2017) and biosimilar drugs; ensures that named-brand drugs are made available for generic testing; enhances penalties for drug counterfeiting; helps alleviate drug shortages; requires HHS to issue a report on a proposed regulatory framework with respect to medical device regulation and health information technology software prior to issuing final guidance on medical mobile applications; and modernize the FDA inspection process for foreign manufacturing facilities.

During consideration of S. 3187 the following amendments were adopted: Harkin amendments to modify and limit certain exemptions to the Freedom of Information Act and to facilitate the development of recommendations on interoperability standards to inform and facilitate the exchange of prescription information across state lines; a Coburn/Burr amendment to require an independent assessment of the FDA review of drug applications; and a Portman/Schumer amendment to amend the Controlled Substances Act to place synthetic drugs in Schedule I; an amendment which provides whistleblower protections to uniformed employees of the public health service working at FDA; a provision which ensures that adequate information is disseminated to health care providers and payers about the potential benefits and risks of medical products on all patient populations, particularly underrepresented subpopulations, including racial subgroups; a provision which deals with sunscreen testing and labeling; a provision which sets out deadlines for the issuance of certain regulations and to require a GAO report on the implementation of the clinical trial registration and reporting requirements under the Public Health Service Act; a provision which requires the FDA commissioner to report to Congress on issues with respect to small businesses; and another which amends the Controlled Substances Act to make any substance containing hydrocodone a Schedule II drug.

The CBO estimated that the Senate bill would reduce the Federal deficit by $363 million over ten years. The House bill is expected to be changed before final passage to also be revenue neutral or deficit reducing. In general, the House bill, H.R. 5651, includes the following: the Food and Drug Administration Reform Act of 2012; the Biosimilar User Fee Act of 2012; the Generic Drug User Fee Amendments of 2012; the Medical Device User Fee Amendments of 2012; and the Prescription Drug User Fee Amendments of 2012.

Medicaid Screening Program

CMS announced that, from May 30 through October, the agency will be sponsoring a "Provider Screening Innovator Challenge" to induce private sector software vendors to develop Medicaid provider screening applications to help reduce fraud and abuse.

NIH Issues

NIH Director Francis Collins announced that the the National Institutes of Health Pain Consortium has designated 11 health professional schools as Centers of Excellence in Pain Education which will serve as hubs for the development, evaluation and distribution of pain-management curriculum resources for medical, dental, nursing and pharmacy schools. He said "These new centers will translate current research findings about pain management to fill what have been recognized as gaps in curricula so clinicians in all fields can work with their patients to make better and safer choices about pain treatment."

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Recently Introduced Health Legislation

S. 3212 (PRESCRIPTION MEDICATION PATIENT INFORMATION), to require the secretary of health and human services to promulgate regulations regarding the authorship, content, format, and dissemination of patient medication information to ensure patients receive consistent and high-quality information about their prescription medications and are aware of the potential risks and benefits of prescription medications; GILLIBRAND; to the Committee on Health, Education, Labor, and Pensions, May 22.

H.R. 5853 (DRUGS), to prohibit wholesalers from purchasing prescription drugs from pharmacies, and to enhance information and transparency regarding drug wholesalers engaged in interstate commerce; CUMMINGS; to the Committee on Energy and Commerce, May 22.

S. 3226 (TAXATION), to amend the Internal Revenue Code of 1986 to provide an income tax credit for eldercare expenses; KLOBUCHAR; to the Committee on Finance, May 23.

S. 3229 (LONG-TERM CARE), to develop a model disclosure form to assist consumers in purchasing long-term care insurance; KLOBUCHAR; to the Committee on Health, Education, Labor, and Pensions, May 23.

S. 3230 (LONG-TERM CARE), to require issuers of long-term care insurance to establish third-party review processes for disputed claims; KLOBUCHAR; to the Committee on Health, Education, Labor and Pensions, May 23.

S. 3232 (REFORM), to amend the Internal Revenue Code of 1986 and the Patient Protection and Affordable Care Act to extend, expand, and improve the qualifying therapeutic discovery project program; MENENDEZ; to the Committee on Finance, May 23.

S. 3237 (BREAST CANCER), to provide for the establishment of the Commission to Accelerate the End of Breast Cancer; WHITEHOUSE; to the Committee on Health, Education, Labor, and Pensions, May 24.

S. 3242 (MEDICARE), to amend Title XVIII of the Social Security Act to provide Medicare beneficiaries coordinated care and greater choice with regard to accessing hearing health services and benefits; MENENDEZ; to the Committee on Finance, May 24.