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Health Care Law Update: March 9, 2015

Article By:

Alexander Hecht

Senate HELP Begins Innovation for ***Healthier Americans Hearings***: On Tuesday, the Senate ***Health, Education, Labor, and Pensions (HELP)*** Committee will begin the first in what is expected to be a series of hearings on Innovation for Healthier Americans, an initiative that would advance steps to better align public policy to support medical innovation and patient access. The hearing will feature testimony from FDA Commissioner Hamburg and NIH Director Francis Collins and follows a report released in late January which examined the challenges to getting safe treatments, devices and cures to patients more quickly and effectively at the ***Food and Drug Administration (FDA)*** and the ***National Institutes of Health (NIH)***. The Senate HELP initiative is intended to be a companion to the House Energy and Commerce Committee's 21st Century Cures Initiative which is an attempt, led by Chairman Fred Upton (R-MI) to modernize the discovery, development, and delivery of clinical innovations.

340B Hearing Postponed; Written Testimonies Shed Light on Agenda: While the House Energy and Commerce Subcommittee on health hearing to examine the 340B drug pricing program was postponed due to weather last week, witnesses had submitted their testimony, which were initially posted on the Committee website. The testimony has since been pulled; however, we expect the hearing to be rescheduled. The submissions camefrom Diana Espinosa, Deputy Administer of HRSA; Debbie Draper, Director of Health Care atthe GAO; and Anne Maxwell, Assistant Inspector General for Evaluations and Inspections, HHS-OIG.

Notably, testimonies highlight that, in response to the GAO's 2011 report critical of HRSA's 340B oversight, HRSA implemented two of GAO's recommendations: instituting audits of covered entities, and clarifying non-discrimination policies. But two other GAO recommendations: clarifying hospital eligibility requirements, and clarifying the definition of a 340B "patient" have yet to be acted on by HRSA. HRSA planned to address the two unimplemented recommendations in an omnibus regulation that it had intended to issue in June 2014. However, HRSA has now intends to issue "omnibus guidance" in 2015 to addressmultiple areas, including the two remaining recommendations from the 2011 GAO report: (i) clarifying hospital eligibility standards, and (ii) the definition of a 340B "patient."

Implementation of the Affordable Care Act

GAO on AHRQ Research Dissemination: A Government Accountability Office (GAO) report suggests

that the Agency for Healthcare Research and Quality (AHRQ) improve its dissemination of clinical effectiveness research required by the ACA.

GAO Report Faults CMS for HealthCare.gov Issues: A GAO report finds that CMS failed to prepare for the challenges confronted by HealthCare.gov, including high traffic, coding inaccuracies, and a general lack of functionality. GAO also reiterated problems found in former reviews such as inadequate testing and project oversight.

Other Federal Regulatory Initiatives

CMS Blog on Quality Measurement: Centers for Medicare and Medicaid Services (CMS) Deputy Administrator Patrick Conway published a blog post on how the agency will use the review of quality reporting programs to streamline "quality measurement strategies, better understand the measures that have worked well and guide the development and application of measures going forward."

VA Misappropriates Health IT Funds: A Veterans Health Administration review found that the agency's chief business office illegally appropriated $92.5 million from medical support and compliance appropriations in order to develop the Health Care Claims Processing System.

FDA Public Hearing on Generic User Fees: The FDA announced it will hold a public hearing on June 5th to provide an overview of the current status of regulatory science initiatives for generic drugs and will present an opportunity for public input on research priorities in this area. For those who wish to attend or present, requests can be made through May 15th.

Hamburg Testifies on Menu Labeling: Speaking before the House Appropriations Subcommittee on Agriculture, FDA Commissioner Hamburg—who announced she would be leaving the agency at the end of March—said a decision on delaying menu labeling will be up to the next Commissioner.

FDA Released App for Drug Shortages: The FDA released a mobile app for pharmacists and providers to provide information on drug shortages, resolved shortages, and discontinued products.

FDA Approves First Biosimilar: The FDA approved Zarxio as the first biosimilar to be approved in the U.S. Zarxio is biosimilar to Amgen Inc.'s Neupogen, and is approved for the same indications as Neupogen, which is used to help prevent infections during cancer treatments.

New CDC Director for Preparedness: Rear Admiral Stephen C. Redd, MD, will serve as the new director of the Centers for Disease Control's (CDC) Office of Public Health Preparedness and Response (OPHPR). Redd comes to the job from CDC's Influenza Coordination Division and brings with him the expertise and experience of working at CDC for nearly 30 years and serving 29 years in the U.S. Public Health Service Commissioned Corps.

Congressional Initiatives

Lawmakers Weigh in on Patient CARE Act: Senators Richard Burr (R-NC), Senate Finance Chairman Orrin Hatch (R-UT), and House Energy and Commerce Chairman Fred Upton (R-MI) issued a statement on the Center for Health and Economy analysis of the Patient Choice, Affordability, Responsibility, and Empowerment (CARE) Act, which the lawmakers recently introduced. The analysis found that the bill would "lower premiums, improve access to providers, increase medical productivity, and reduce the nation's deficit by hundreds of billions of dollars."

Senators Write to HHS on Subsidy Calculations: Senators Rob Portman (R-OH) and Chuck Grassley (R-IA) wrote to HHS requesting an explanation on how the agency calculates taxpayer subsidies using information on the federal health care exchange.

Senators Request Special Enrollment for Pregnancy: Thirty-seven Democratic Senators wrote to HHS, requesting the agency add pregnancy to the list of qualifying life events to trigger an ACA special enrollment period. Secretary Burwell has previously said that the agency is considering the issue.

Republicans Introduce Employee Wellness Program Bill: Senate and House Republicans introduced the Preserving Employee Wellness Programs Act "to provide legal certainty—and eliminate confusion caused by the Equal Employment Opportunity Commission (EEOC)—for employers offering employee wellness programs that lower health insurance premiums to reward healthy lifestyle choices."

Lawmakers Question Naloxone Costs: Senator Bernie Sanders (I-VT) and Representative Elijah Cummings (D-MD) sent a letter to Amphastar Pharmaceuticals, manufacturer of Naloxone, asking for an explanation of the opioid reversal drug's increasing price.

House Republicans Respond to King v. Burwell Arguments: House Committee Chairmen John Kline (R-MN), Paul Ryan (R-WI), and Fred Upton (R-MI), who attended the oral arguments in the King v. Burwell case, responded to the proceedings, saying "the House Republican working group to develop a plan to replace the president's health care law over the long term and protect Americans affected by the decision in this case."

Lawmakers To Examine Controlled Substance Quotas: Reacting to a recent GAO report, Senators Chuck Grassley (R-IA) and Dianne Feinstein (D-CA) announced the Senate Caucus on International Narcotics Control will be holding a hearing on the quota process that limits the amount of controlled substances available in the U.S.

Other Health Care News

Groups Press Congress on ICD-10: Close to 100 state and specialty medicine groups sent a letter to CMS noting their concerns with the agency's transition plan. Separately, 22 hospital systems wrote Congressional leaders requesting ICD-10 not be delayed again.

Upcoming Congressional Hearings

Senate

On Tuesday, March 10th, the Senate HELP Committee will hold a hearing titled "Continuing America's Leadership in Medical Innovation for Patients."

The House is in recess.

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