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HEALTH CARE REFORM UPDATE

April 23, 2012

Implementation of the Affordable Care Act (ACA)

On April 18th the Department of Health and Human Services (HHS) released a report finding that the competitive bidding program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) had saved Medicare over \$200 million in its first year of implementation and is expected to save over \$40 billion over the next ten years. The program, which requires DMEPOS suppliers to compete to become Medicare contractors, was created but not fully implemented under the Medicare Modernization Act of 2003 and expanded by the ACA. The report can be found [here](#).

Other HHS and Federal Regulatory Initiatives

On April 16th HHS Secretary Kathleen Sebelius announced the creation of the Administration for Community Living. The new entity combines the Administration on Aging, the Office on Disability and the Administration on Developmental Disabilities into a single agency. An HHS news release can be found [here](#).

On April 16th HHS released its second “Open Government Plan.” The 54-page document describes the Department’s plans to increase transparency in its activities. The plan can be found [here](#).

On April 16th the Government Accountability Office (GAO) released a report evaluating the guidance put out by the Federal Trade Commission and Department of Justice regarding antitrust issues that arise in collaborative agreements among health care providers. The GAO interviewed representatives of health plans and health care providers about the guidance issued by the agencies. The report finds that many industry representatives found the guidance to be inadequate. The report can be found [here](#).

On April 16th HHS Office of the Inspector General released a report finding major gaps in the preparedness of nursing homes for natural disasters. The report found that, while most nursing homes have a written emergency plan as required by law, many of the plans lacked important implementation

details. Furthermore, nursing homes' contracts with transportation providers and with local emergency management teams were often insufficient. The report can be found [here](#).

On April 19th the Centers for Medicare and Medicaid Services (CMS) released the results of a national survey of patients' experiences with Medicare-certified home health agencies. The Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey is designed to provide patients with information to allow them to compare home health care providers. A CMS press release can be found [here](#).

On April 20th the Agency for Healthcare Research and Quality (AHRQ) released a new report showing that racial and ethnic disparities in access to care did not improve between 2002 and up until the enactment of the ACA. The AHRQ press release on the report can be found [here](#).

Other Congressional and State Initiatives

On April 16th Mississippi Governor Phil Bryant (R) signed a law requiring a physician who performs abortions in the state to have admitting privileges at a local hospital. The state's only abortion clinic, Jackson Women's Health Organization, has stated that the law could cause it to shut down. A press release from the Governor's office can be found [here](#).

On April 17th Senators Tom Coburn (R-OK) and Richard Burr (R-NC) introduced the Promoting Accountability, Transparency, Innovation, Efficiency and Timeliness at FDA (PATIENTS' FDA) Act. The bill seeks to increase Congressional oversight of the FDA and to recalibrate the FDA's risk-benefit analysis by placing the burden on the FDA to show evidence that a drug or device is not safe. The text of the bill can be found [here](#). A press release from Senator Coburn's office can be found [here](#).

On April 17th Senators Jack Reed (D-RI), Lamar Alexander (R-TN), Patty Murray (D-WA) and Pat Roberts (R-KS) introduced the Better Pharmaceuticals and Devices for Children Act. The bill seeks to incentivize more robust studies of drugs and medical devices intended for children. It renews three major laws—Best Pharmaceuticals for Children Act of 1997, the Pediatric Research Equity Act of 2003, and the Pediatric Medical Device Safety and Improvement Act of 2007—which will expire this year. The text of the bill can be found [here](#). A press release from Senator Reed's office can be found [here](#).

On April 18th the Senate Health, Education, Labor, & Pensions (HELP) Committee and the House Energy & Commerce Subcommittee on Health announced that they will be holding markups of legislation to reauthorize the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee Act (MDUFA) and to create new user fee programs at the FDA. The proposed Senate Bill, as well as several proposed amendments, can be found [here](#). The proposed House bill can be found [here](#).

On April 18th several Democratic Senators introduced a bill that would allow generic drug manufacturers to put additional warning information on their product labeling. The bill is designed to allow consumers to sue generic drug manufacturers for failure to properly warn of the dangers of their drugs. Currently, generic drug manufacturers are required to use the same label as their brand-name counterparts—which the Supreme Court has ruled makes them immune from lawsuits based on the labeling. A press release from Senator Patrick Leahy's office can be found [here](#).

Other Health Care News

On April 16th the National Coalition on Health Care released a new survey finding that, despite the fact that the practice is illegal, more than two million Medicare beneficiaries had used –name drug discount coupons in 2011, potentially costing the program millions of dollars. A press release can be found [here](#).

On April 17th the Supreme Court ruled that generic drug manufacturers may file counterclaims against brand-name manufacturers for submitting inaccurate patent information to the FDA in order to delay the marketing of generic drugs. The Court's decision can be found [here](#).

On April 17th Express Scripts released its annual Drug Trend Report. The report found that spending on prescription drugs grew only 2.7 percent in 2011—the lowest growth rate since the report was initiated. The report can be found [here](#).

On April 18th the centrist think tank Third Way released a new report calling for more cost sharing and other cost control mechanisms in the Tricare program citing the military health program's current unsustainable cost trajectory. The report can be found [here](#).

On April 19th the Commonwealth Fund released a survey finding that more than one quarter of working-age adults experienced at least one gap in their health insurance coverage in 2011—usually as a result of losing or changing jobs. The study also found that adults who experienced coverage gaps were less likely to receive regular preventive care. The survey also found that many of the groups who most benefit from provisions of the ACA that are currently in effect are unaware of those provisions. The survey found that 40 percent of young adults were unaware of the provision allowing them to remain covered under their parents' plans, and 45 percent of respondents who were in poor health were unaware of the law's high-risk insurance pools. The study can be found [here](#).

On April 19th the Urban Institute released a report finding that much of the perceived spending problem in Medicare and Medicaid is driven by growth in enrollment, rather than growth in the cost of health care. The authors emphasize that growth in spending per beneficiary is only slightly higher than growth in GDP. The authors suggest that reforms such as premium support or block grants will be unlikely to achieve better outcomes. The report can be found [here](#).

Hearings & Mark-ups Scheduled

Senate

On April 24th the Senate Finance Committee will hold a hearing on Medicare and Medicaid fraud entitled “Anatomy of a Fraud Bust: From Investigation to Conviction.” More information can be found [here](#).

On April 25th the Senate Health, Education, Labor, & Pensions Committee will hold a markup on legislation to renew MDUFA and PDUFA, and also to create new user fee programs for generic drugs and biosimilars. More information can be found [here](#).

On April 25th the Senate Veterans' Affairs Committee will hold a hearing entitled "VA Mental Health Care: Evaluating Access and Assessing Care." More information can be found [here](#).

House of Representatives

On April 25th the House Oversight & Government Reform Committee will hold a hearing entitled "Is Government Adequately Protecting Taxpayers from Medicaid Fraud?" More information can be found [here](#).

On April 25th the House Energy & Commerce Subcommittee on Health will be holding a markup on the reauthorization of the user fee programs at the FDA. More information is expected to be posted soon to the Committee's [website](#).

On April 24th and 25th the House Energy & Commerce will mark-up a reconciliation package that includes the repeal of several ACA provisions. A Committee memo can be found [here](#).

On April 26th the House Education & the Workforce Committee will hold a hearing with HHS Secretary Kathleen Sebelius on the proposed FY2013 budget for HHS.

On April 26th the House Ways & Means Subcommittee on Oversight will hold a hearing on the impact of limitations on the use of tax-advantaged accounts for the purchase of over-the-counter medication. More information can be found [here](#).