

ML Strategies Update

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Health Care Update

Hobby Lobby decision further complicates ACA implementation: This morning, the U.S. Supreme Court announced its ruling in the much anticipated *Burwell v. Hobby Lobby* case, holding that closely-held companies could not be required to cover contraceptives in employee insurance health plans if the corporation owners have religious objections. The Affordable Care Act (ACA) required all health plans to cover preventive health services for women, which the Institute of Medicine (IOM) subsequently defined to include contraceptive products approved by the Food and Drug Administration (FDA).

Justice Samuel Alito Jr., writing for the majority, stated the 5-4 decision was narrow saying, "we do not hold, as the principal dissent alleges, that for-profit corporations and other commercial enterprises can 'opt out of any law (saving only tax laws) they judge incompatible with their sincerely held religious beliefs…".

However, Justice Ruth Bader Ginsburg wrote in a dissenting opinion that claims under the Religious Freedom Restoration Act (RFRA) were likely to "proliferate, for the court's expansive notion of corporate personhood - combined with its other errors in construing RFRA - invites for-profit entities to seek religion-based exemptions from regulations they deem offensive to their faith."

Congressional Democrats have already begun meeting on possible legislative proposals that would fix the gap created by today's ruling. One possible mechanism suggested by Justice Kennedy would be for the government to directly cover contraceptive coverage as an addition to an employer's health plan. However, it is unlikely that Republicans would agree to such a legislative fix, leaving the Obama Administration to explore other executive branch unilateral options.

Most health policy experts believe that the easiest "fix" would be for the federal government to extend the existing exemption for religiously-affiliated nonprofits to closely held companies. For religiously-affiliated nonprofits such as Catholic hospitals or churches, employers are allowed to refuse coverage for contraceptives, but insurance carriers are required to cover "... without cost sharing, contraception coverage for female employees who wish it." If the Administration went the route of broadening the religiously-affiliated regulation, a change could be made relatively quickly through sub-regulatory guidance such as an issuance of a FAQ document or Fact Sheet.

Implementation of the Affordable Care Act

CMS Seeking Healthcare.gov Contractor: On a pre-solicitation notice, the Centers for Medicare & Medicaid Services (CMS) took a first step to start soliciting bids for a new contractor to revamp Healthcare.gov. The solicitation states that the agency is seeking a contractor who can "provide analysis, design, development, testing, implementation, documentation, services, maintenance and support" for the website.

CMS Awards Additional Funding to Terremark: In a contracting document, CMS has authorized an additional \$45 million for Verizon Terremark. As the contract is slated to be transferred from Terremark to Hewlett Packard in August, the additional funding will only be drawn on if delays or transition issues require Terremark to continue.

CBO on Employer Tax Benefit: A Congressional Budget Office (CBO) analyst provided a presentation on the effects of limiting tax breaks for employer-sponsored health coverage.

GAO Releases Small Group Premiums: The Government Accountability Office (GAO) released a detailed premium analysis for small businesses in 2013, a report requested by Senator Orrin Hatch (R-UT). The report provides an overview of low, median and high price plans by provider network.

CMS Releases Reenrollment Policies: In guidance documents and a press release, CMS outlined the procedure for the second year of Affordable Care Act (ACA) enrollment, stating that consumers would be automatically reenrolled, unless they opt to select new coverage in November.

Other Federal Regulatory Initiatives

White House to Appoint McDonald to VA: President Obama is expected to announce the appointment of Bob McDonald, West Point graduate and CEO of Procter & Gamble, to head the Department of Veterans Affairs.

CMS Sees Progress in Fraud Prevention: A report to Congress released by CMS finds that in year two of its new fraud prevention program, the agency identified twice as many improper Medicare payments.

FDA Using EHRs for Drug Safety Measure: Director of the FDA's Center for Drug Evaluation and Research Janet Woodcock wrote in a blog post that the agency is working to utilize the information gathered via EHRs on prescription drugs and other medical products to monitor and improve safety.

FDA Extends Comment on e-Cig Proposal: The FDA added an additional month for public comment on its proposed rule to regulate e-cigarettes, cigars, and other tobacco products.

CDC Examines Alcohol Related Deaths: The Centers for Disease Control (CDC) released data finding that excessive drinking contributes to 88,000 deaths a year among of people age 20-64. These deaths were due to health effects from drinking too much over time, and health effects from drinking too much in a short period of time, such as violence, alcohol poisoning, and motor vehicle crashes.

ONC on Improving Medical Records: In a blog post by Jodi Daniel, Director of the Office of Policy and Planning with the Office of the National Coordinator for Health IT, the agency described federal programs such as the Blue Button Initiative which can increase patient access to EHRs. Patients engaged in their own medical record can improve the quality of the information in their medical record — helping to spot errors such as outdated information and omissions such as medications prescribed by another provider.

Other Congressional and State Initiatives

Members Introduce MA Bill of Rights: Senators Sherrod Brown (D-OH) and Richard Blumenthal (D-CT), along with and Representative Rosa DeLauro (D-CT), introduced the Medicare Advantage Participant Bill of Rights Act. The legislation is intended to ensure seniors would not lose access to their physician by prohibiting plans from dropping doctors without cause outside of open enrollment.

Representatives Introduce Bill for Complex Conditions: Representatives Joe Barton (R-TX), Kathy Castor (D-FL), and Jamie Herrera Beutler (R-WA) introduced the Advancing Care for Exceptional Kids Act of 2014 (H.R. 4930). The bill would help coordinate care to ensure optimal outcomes for children with medical complexity in Medicaid, while containing costs.

Members Introduce Post-Acute Bill: Senate Finance Chairman Ron Wyden (D-OR) and House Ways and Means Chairman Dave Camp (R-MI) introduced the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The bill seeks to improve post-acute care for Medicare patients by requiring standardized data, improving hospital discharge planning, and reforming post-acute care payments.

Senate HELP Members Query CDC on Anthrax: Bipartisan members of the Senate Health, Education, Labor, and Pensions Committee wrote to CDC Director Tom Frieden, questioning the events that led to 75 CDC employees being exposed to anthrax.

Senators Question Link Between Satisfaction and Opioid Abuse: In a letter to CMS, Senators Chuck Grassley (R-IA) and Diane Feinstein (D-CA) expressed concern that Medicare patient satisfaction surveys may be contributing to opioid abuse.

Representatives Introduce Medial Research Equality Bill: Representatives Jim Cooper (D-TN) and Cynthia Lummis (R-WY) introduced legislation that would require the inclusion and separate analysis of both male and female animals, tissues and cells in basic research conducted and funded by the National Institutes of Health (NIH).

House Passes Public Health Bills: The House passed five bills to reauthorize health programs, the Newborn Screening Saves Lives Reauthorization Act of 2013 (H.R. 1281), the Trauma Systems and Regionalization of Emergency Care Reauthorization Act (H.R. 4080), the Improving Trauma Care Act (H.R. 3548), the Traumatic Brain Injury Reauthorization Act (H.R. 1098), and the Autism CARES Act (H.R. 4631). The Senate HELP Committee marked up the Autism bill the same day.

House E&C Digital Cures Roundtable: The House Energy and Commerce Committee hosted a roundtable on digital health care featuring testimony from panelists who represented health systems, technology companies, providers, and other stakeholders. In general, witnesses praised the Committee for looking into how technology can further innovation in health care and urged Congress to discuss ways in which to further incentivize entrepreneurs to take risks in this space

House E&C Hearing on Medicare Fraud: The House Energy and Commerce Subcommittee on Oversight and Investigations held a hearing, "Medicare Program Integrity: Screening Out Errors, Fraud, and Abuse," to discuss what steps need to be taken to eliminate the waste. Witnesses included officials from CMS, HHS, HHS OIG, and the GAO.

Republican Lawmakers Question FDA Generics Authority: Senate HELP Ranking Member Lamar Alexander (R-TN) and House Judiciary Chairman Bob Goodlatte (R-VA) wrote to the FDA and to the White House questioning whether the FDA has the legal authority to allow generic drug makers to update safety labels without FDA approval.

Other Health Care News

Neurologists' Policy Statement on Telemed: The American Academy of Neurology released a policy statement calling on state and federal legislation to expand telemedicine to those with limited access to care "regardless of location and the health insurance coverage they might have."

ICD-10 Survey Finds Expectation of Revenue Decrease: A study conducted by the American Health Information Management Association and the eHealth Initiative found that close to 40 percent of health providers expect revenues to fall in the year after the switch to ICD-10.

Group Creates ONC Health IT Guide: The Certified Commission for Health Information Technology (CCHIT) launched a new service to assist health IT developers in satisfying regulation requirements of the ONC. The CCHIT guide provides help on clinical quality measures, interoperability, and EHRs.

Report on Remote Monitoring: According to a report by Berg Insight, approximately three million patients were remotely monitored by a device in 2013. The report also predicts that the number of patients using a remote monitoring device will risk to 19.1 million by 2018.

Gallup Finds 5 Percent Newly Insured: A Gallop survey found that five percent of Americans report being newly insured in 2014 and 2.8 percent of the total U.S. population say they got their new insurance through the health exchanges.

Upcoming Hearings and Markups

The Senate and House are in Recess.

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