



**Jeremy Rabinovitz**, JRabinovitz@mlstrategies.com  
**Alexander Hecht**, AHecht@mlstrategies.com  
**Joseph P. Hammang, PhD**, JPHammang@mlstrategies.com  
**Abby Matousek**, AMatousek@mlstrategies.com  
**David Shirbroun**, DShirbroun@mlstrategies.com

**ML Strategies, LLC**  
701 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004 USA  
202 434 7300  
202 434 7400 fax  
www.mlstrategies.com

Follow us on Twitter @MLStrategies

## HEALTH CARE REFORM UPDATE June 24, 2013

### Leading the News

#### *CMS Releases Guidance on State Alternative Applications for Health Coverage*

On June 18<sup>th</sup>, the Centers for Medicare and Medicaid Services (CMS) released [guidance](#) on state alternative applications for health coverage through the ACA that will determine eligibility for enrollment in Qualified Health Plans (QHPs). In alternative applications, states must:

- Request information necessary for determining eligibility for coverage in a QHP.
- Minimize the burden on the applying household.
- Rely primarily on electronic information, and only request paper documentation when necessary.

#### *Supreme Court Rules Generic Drugmakers Not Liable for Defects*

On June 24<sup>th</sup>, the Supreme Court issued a [5-4 ruling](#) that generic drugmakers cannot be held liable for defective products as the drugs and warning labels must be exactly the same as brand name products. The case, *Mutual Pharmaceutical Co. v. Bartlett*, posited that even though generic companies cannot make changes to the label, they do have the discretion to pull the drug from the market. The majority, led by Justice Alito, found that federal generic law preempts state “failure to warn” law in this case. In two dissenting opinions, justices argued that the responsibility to remove the drug from the market was valid and that Congress’ intent was to preserve a role for state law in drug regulation.

### Implementation of the Affordable Care Act

On June 14<sup>th</sup>, the Jobs and Premium Protection Act ([H.R. 763](#)), which would repeal a tax on health insurance plans, gained the [218 cosponsors](#) necessary to pass the House.

On June 17<sup>th</sup>, Rep. Mark Meadows (R-NC) [introduced legislation](#) to delay implementation of the ACA until all activity by the IRS since the beginning of 2010 is audited.

On June 17<sup>th</sup>, the House Oversight and Government Reform Committee [subpoenaed](#) HHS for information on the CO-OP program of the ACA.

On June 17<sup>th</sup>, the five Democratic members of Pennsylvania’s House delegation [wrote](#) to Governor Tom Corbett (R) to urge him to expand Medicaid in the state.

On June 17<sup>th</sup>, Senators Claire McCaskill (D-MO) and Tom Coburn (R-OK) sent a [letter](#) to colleagues urging a repeal of an ACA provision that they say creates a disparity in the Medicare hospital wage index system.

On June 18<sup>th</sup>, Enroll America launched its “[Get Covered America](#)” campaign to provide uninsured individuals with more information about the ACA enrollment process.

On June 19<sup>th</sup>, Senators Susan Collins (R-ME) and Joe Donnelly (D-IN) [introduced legislation](#) to extend the definition of a full-time worker under the ACA from 30 hours to 40 hours.

On June 19<sup>th</sup>, Republicans on the Senate HELP Committee sent a [letter](#) to FDA Commissioner Margaret Hamburg with questions on why the agency is able to promote the ACA.

On June 20<sup>th</sup>, the Obama administration issued a [state-by-state](#) list of rebates that consumers will receive from insurers across the country that failed to meet ACA efficiency rules.

On June 20<sup>th</sup>, a [95-52 vote](#) in the Maine House of Representatives fell three votes short of overriding Gov. Paul LePage’s (R) veto of Medicaid expansion.

On June 21<sup>st</sup>, four hospital organizations sent a [letter](#) to members of Congress urging for a delay to reductions to the Medicare and Medicaid Disproportionate Share Hospital (DSH) program.

#### **Other HHS and Federal Regulatory Initiatives**

On June 18<sup>th</sup>, CMS issued a [bulletin](#) for state Medicaid agencies on when funding is available for certain administrative costs related to the activities of a state Long-Term Care Ombudsman.

#### **Other Congressional and State Initiatives**

On June 17<sup>th</sup>, former CMS administrator Don Berwick [announced](#) he will run to be governor of Massachusetts.

On June 17<sup>th</sup>, the Senate [unanimously passed](#) a bill to end the ban on organ donations between people who are HIV positive.

On June 18<sup>th</sup>, the Congressional Budget Office (CBO) [projected](#) that immigration legislation currently under consideration in the Senate would result in an additional \$110 billion in health care spending over 10 years.

On June 18<sup>th</sup>, the House [passed](#) a bill that would ban most abortions after 20 weeks. The legislation is expected to die in the Senate, and the White House has threatened to veto.

On June 19<sup>th</sup>, bipartisan [legislation introduced](#) in the Senate and House would allow Medicare to cover prescription drugs for chronic weight management.

On June 19<sup>th</sup>, a [study](#) published in the Journal of Infectious Diseases indicated that the human papillomavirus vaccine reduced the prevalence of HPV among teen girls by more than half.

On June 20<sup>th</sup>, Senate Majority Leader Harry Reid (D-NV) said [sequester cuts to the NIH must be eliminated](#). He said an inconsistency of funds at NIH is discouraging organizations from applying for grants and pursuing vital research.

On June 20<sup>th</sup>, the House Ways and Means Health Subcommittee held a [hearing](#) on the 2013 Medicare Trustees Report.

### **Other Health Care News**

On June 17<sup>th</sup>, Susan G. Komen issued a [press release](#) that Executive Director of the IOM Judith Salerno will serve as the organization's new CEO.

On June 18<sup>th</sup>, former HHS Secretary Tommy Thompson announced the formation of the [Working Group on Pharmaceutical Safety](#), an organization focused on compounding reform.

### **Hearings and Mark-Ups Scheduled**

#### ***Senate***

On June 24<sup>th</sup>, the Senate Homeland Security and Governmental Affairs Committee will hold a [hearing](#) titled "Curbing Prescription Drug Abuse in Medicare."

On June 26<sup>th</sup>, the Senate Finance Committee will hold a [hearing](#) to examine health care quality.

On June 26<sup>th</sup>, the Senate Committee on Aging will conduct a [hearing](#) on respecting patients' wishes and advanced care planning.

#### ***House of Representatives***

On June 26<sup>th</sup>, the House Energy and Commerce Subcommittee on Oversight and Investigations will hold a [hearing](#) titled "Challenges Facing America's Businesses Under the Patient Protection and Affordable Care Act."

On June 26<sup>th</sup>, the House Energy and Commerce Subcommittee on Health will hold a [hearing](#) titled "A 21st Century Medicare: Bipartisan Proposals to Redesign the Program's Outdated Benefit Structure."

On June 27<sup>th</sup>, the House Veterans' Affairs Committee will hold a [hearing](#) to assess the VA's capital investment options to provide veterans' care.

On June 27<sup>th</sup>, the House Committee on Education and the Workforce will conduct a [hearing](#) to address school lunch regulations and the consequences for schools and students.

On June 27<sup>th</sup>, the House Small Business Committee will hold a [hearing](#) on mobile medical app entrepreneurs.

On June 28<sup>th</sup>, the House Energy and Commerce Subcommittee on Health will hold a [hearing](#) titled "Examining Reforms to Improve the Medicare Part B Drug Program for Seniors."