



ML Strategies Update

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Health Care Update

FDA Hosts Genome Scientists For Next-Generation Sequencing Conference

Last week, the Food and Drug Administration (FDA) hosted genome scientists from across the nation at its campus in White Oak, Maryland. Two public workshops engaged presenters and audience members on various technical aspects of translating Next-Generation Sequencing (NGS) into clinical practice, including issues related to analytical performance evaluation, bioinformatics strategies, and the use of genetic databases to establish clinical validity of a test. Although at this stage, FDA has not developed a new regulatory framework for NGS that is distinct from the process for more traditional diagnostic tests, the Agency's stated goal is to institute "appropriate oversight, in a way that is more suitable to the complexity and data-richness of this new technology." These activities are being driven by the President Obama's Precision Medicine Initiative, bipartisan and bicameral interest on Capitol Hill, as well as health care market realities that patients and their physicians want to choose the right treatment, at the right time, with hopefully minimal side effects.

Numerous federal agencies have taken steps to implement the Precision Medicine Initiative - which the President announced at the 2015 State of the Union. For example, the National Institutes of Health approved a blueprint for the initiative which seeks to enroll one million volunteers in the next five years to evaluate an individual's risk of developing a disease. The study would look at both genetic and environmental factors. The FDA workshop last week was also in step with the President's initiative.

The two days of NGS workshops gave stakeholders from industry, government, medicine, and academia an opportunity to discuss and find common ground on certain issues that FDA has been examining as it considers appropriate regulatory approaches to NGS platforms and tests. ML Strategies would be happy to provide summaries of the two most recent workshops to interested clients and stakeholders. Complete transcripts are expected to be posted by FDA in 6-8 weeks, [here](#) and [here](#). We will continue to monitor any announcements by FDA about future regulatory actions in the NGS space.

For more coverage, please check out the Mintz Levin [Health Law & Policy Matters](#) blog.

Reconciliation Vote Nears

Senate Reconciliation Rules Complicate ACA Repeal: While the Senate has yet to formally schedule a vote on the reconciliation measure to repeal portions of the Affordable Care Act (ACA), a ruling from the Senate parliamentarian has potentially made the road to the President's desk slightly more difficult.

Under reconciliation, legislation only has to pass the Senate by a simple majority vote, meaning it can avoid a filibuster, on the condition the language adheres to Senate rules. The Senate parliamentarian has reportedly indicated that the repeal of the individual and employer mandates would violate Senate reconciliation rules and require 60-votes to pass. Senate Republicans disagree; however, they are reportedly working on tweaks to the legislation in order for it to satisfy the reconciliation requirements. Reconciliation, as it passed the House, would repeal the individual and employer mandates, the medical device tax, the Cadillac tax, and eliminate the Independent Payment Advisory Board (IPAB), which Congress created to control the costs associated with Medicare. The House-passed measure would also deny Planned Parenthood funding for one year.

Senators Marco Rubio (R-FL), Ted Cruz (R-TX), and Mike Lee (R-UT) have already indicated they will oppose the legislation because it does not go far enough in repealing the ACA. This puts the Republican vote count at 51. Prospects for reconciliation continue to be murky in Senate, due in part to Planned Parenthood language, which has complicated support prospects from moderate Republicans, including Senators Mark Kirk (R-IL) and Kelly Ayotte (R-NH), who are already facing tough reelection battles in their respective states. There have been discussions of removing the Planned Parenthood language to ensure the package can pass the Senate, although it is not a certainty.

Ultimately, while President Obama is sure to veto a reconciliation package that would repeal significant portions of the ACA, if Republicans can get the measure to the President's desk, it would create an optical political messaging point that, theoretically at least, all that is need to ensure a full repeal of the law is a Republican President.

ML Strategies will be following this closely over the coming days and weeks.

Prescription Drug Costs

HHS to Host Drug Pricing Forum This Week: On November 20, 2015, HHS will host an invite-only event to discuss the rising costs of drugs. Please see the Last Word below for more insight and information.

Obama Keeps Attention on Drug Costs: President Barack Obama reiterated his support for enabling the Department of Health and Human Services (HHS) to negotiate drug prices directly with manufacturers. The President is also looking at ways to prevent companies from raising prices of older drugs, a practice that has garnered international criticism this year.

Senate Special Committee on Aging Launches Drug Price Investigation: Last week, Senators Susan Collins (R-ME) and Claire McCaskill (D-MO) launched an investigation into price increases of certain drugs. They sent letters requesting more information from Valeant Pharmaceuticals, Turing Pharmaceuticals, Retrophin, Inc., and Rodelis Therapeutics.

House Democrats Also Announce New Task Force: House Democrats also announced an Affordable Drug Pricing Task Force aimed combating the skyrocketing costs of pharmaceuticals. Members of the group are also urging House Oversight & Government Reform Chairman Jason Chaffetz (R-UT) to launch a formal investigation.

News from the Hill

Rep. Pat Tiberi (R-OH) to Assume Health Subcommittee?: After missing out on the coveted Ways & Means top post, it appears Ohio Rep. Pat Tiberi is eyeing the Health subcommittee chair vacated by now Ways & Means Chairman Kevin Brady.

Mandatory Funding Debate Stalling Senate Innovations Bill: The Senate Committee on Health, Education, Labor, and Pensions (HELP) is still debating its version of the 21st Century Cures Act, which passed the House in July. Funding for NIH and the FDA appears to be holding up progress. With each passing week with no bill introduction, prospects diminish for forward movement on this measure until 2016.

Acting FDA Commissioner Set for Confirmation Hearing: Today, the Senate HELP Committee will vote on the nomination of Robert Califf to serve as commissioner of the FDA. Even if the committee approves Dr. Califf, GOP Nebraska Senator Ben Sasse has vowed to put a hold on all HHS nominations until the agency responds to questions about the Affordable Care Act's co-op issue.

Representative Joe Pitts (PA-16) to Retire: Last week, Representative Pitts, chairman of the Energy and Commerce Health Subcommittee, announced he will not be seeking reelection. Pitts, who has chaired the health subcommittee since 2011, has overseen a number of major pieces of health care-related legislation, and is highly regarded for his work on the committee. Reps. Brett Guthrie (KY-2) and Michael Burgess (TX-26) are the two expected to pursue the position, which is still a year away from being decided most likely.

All Things ACA

Colorado to Vote on Single-Payer System: Last week, state officials in Colorado confirmed an initiative to establish a single-payer system garnered the necessary signatures to land on the ballot in 2016. If proponents secure passage, the state would likely implement the program by utilizing the Affordable Care Act's (ACA) section 1332 waivers.

White House Stands Firm Against Cadillac Tax Repeal: In the face of growing bipartisan support for the repeal of the Cadillac tax, the White House is highlighting some of the positive benefits of the policy. There is talk of including the repeal of the tax in tax extenders legislation set to be unveiled in the coming weeks. The Cadillac tax does not take effect until 2018.

Alabama Considers Medicaid Expansion: Alabama Governor Robert Bentley announced last week that he is considering expanding Medicaid under the Affordable Care Act. There is a long road ahead if Alabama does push forward, but it is a positive step for proponents of the health care law.

Kentucky's New Governor to Walk Back ACA Policies?: Kentucky's newly elected Governor Matt Bevin ran on a platform to dismantle the state's lauded health care exchange, Kynect, as well as overhaul its Medicaid expansion. Only time will tell if he can muster the support to follow through on his plans.

Telemedicine Update

FAST Act Drawing Interest: The Furthering Access to Stroke Telemedicine Act, or FAST Act, as introduced by Rep. Morgan Griffith (R-VA), has picked up 21 new cosponsors since the beginning of September. The same can't be said for Senator Mark Kirk's (R-IL) Senate version, although his lone cosponsor – Senator John Thune (R-SD) - is reportedly close to unveiling a separate piece of telemedicine-related legislation.

Senate Commerce Committee to Markup Telemedicine Legislation: On Wednesday, the Senate Committee on Commerce, Science, and Transportation will markup the Rural Health Care Connectivity Act of 2015. The legislation would extend eligibility to FCC broadband funding for skilled nursing facilities.

States Consider Telemedicine in Medicaid: Connecticut, Florida, and New Jersey are in the process of exploring ways to incorporate telemedicine into their state Medicaid programs. We'll be following this very closely as we close out 2015.

Arkansas Considering Telemedicine Rules: The Arkansas State Medical Board will hold its next meeting December 8 to discuss draft telemedicine rules. You can view those rules [here](#).

Prescribing Controlled Substances via Telemedicine?: The Drug Enforcement Administration (DEA) is considering a measure that would allow for certain doctors to prescribe controlled substances over telemedicine. Given the attention on opioids, this would appear to be an uphill battle for proponents of the proposal.

Opium Crisis Coverage

Eight Senators Applaud CDC Prescribing Guidelines: Eight Senators wrote to CDC Director Thomas Frieden applauding the agency's approach to its released Draft Guidelines for Opioid Prescribing. The final guidelines, to be released next year, are intended to encourage responsible prescribing practices to curb the opioid epidemic. The Senators sending the letter include Sens. Joe Manchin (D-WV), Ed Markey (D-MA), Tammy Baldwin (D-WI), Dianne Feinstein (D-CA), Jeanne Shaheen (D-NH), Richard Blumenthal (D-CT), Bill Nelson (D-FL), and Angus King (I-ME).

House Committee to Markup Opioid Legislation: Today, the House Veterans Affairs Committee will markup draft legislation titled, "The Promoting Responsible Opioid Management and Incorporating Medical Expertise Act."

New Hampshire Legislature to Hold Special Session: New Hampshire Governor Maggie Hassan, also a Democratic candidate for Senate, has called a special session for this week in an effort to address the state's heroin and opioid crisis. The Governor intends to limit [the agenda](#) to issues surrounding the state's efforts to address the opioid crisis.

Hearings

House of Representatives

On Tuesday, November 17, the House Energy and Commerce Subcommittee on Health will hold a hearing titled, "Examining the Regulation of Diagnostic Tests and Laboratory Operations."

On Tuesday, November 17, the House Judiciary Committee will hold a hearing titled, "The State of Competition in the Pharmacy Benefit Manager and Pharmacy Marketplaces."

United States Senate

On Tuesday, November 17, the Senate Committee on Finance will hold a hearing titled, "Physician Owned Distributors: Are They Harmful to Patients and Payers?"

On Tuesday, November 17, the Senate Committee on Health, Education, Labor, and Pensions will hold a hearing titled, "Nomination of Dr. Robert Califf to serve as FDA Commissioner."

The Last Word

Can HHS Pharmaceutical Forum to Accelerate Debate on Drug Costs?: On Friday, HHS will host a forum on the impact of rising pharmaceutical costs. The forum is expected to draw stakeholders from every corner of the industry, including consumers, providers, manufacturers, insurers, and representatives from state and local government. The goal of the forum is to share information on how to address rising drug costs in a way that drives innovation, strengthens incentives, and promotes competition. For a complete overview of the agenda, [click here](#).

There have been numerous reports of price manipulation this year, in addition to polling which suggests the general public wants to see government action on the high costs of drugs. Out-of-pocket costs continue to grow, and the lack of transparency in the process has galvanized the Administration into action. Mintz Levin and ML Strategies have been closely following the rising costs of prescription drugs and will continue to monitor related events in this update and in the Health Law & Policy blog, which can be accessed [here](#).

Stay tuned for further updates.