



ML Strategies Update

Alexander Hecht, AHecht@mlstrategies.com
Rodney Whitlock, RLWhitlock@mlstrategies.com
Eli Greenspan, EGreenspan@mlstrategies.com
Erin Morton, EKMorton@mlstrategies.com

FOLLOW US ON TWITTER: [@MLStrategies](https://twitter.com/MLStrategies)

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

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Health Care Update

Senate HELP Committee Set for Second Mark Up on Cures Effort

This week, the Senate Committee on Health, Education, Labor and Pensions (HELP) will hold its second legislative mark-up on its counterpart to the House-passed 21st Century Cures Act. While there is genuine bipartisan interest in advancing this effort, which would bring added resources to NIH and the FDA and streamline the development of medical devices and treatments, questions related to funding in the measure are expected to drive the debate at this week's hearing.

The package being considered this week addresses and clarifies a number of issues before the FDA, including the expansion of the priority review voucher program, which would be expanded to include treatments for sickle cell disease as well as pediatric cancers ([S. 1878](#)). A similar measure would create an expedited review process for breakthrough devices ([S. 1077](#)). There's also a measure to accelerate the development of treatments in the event of a global pandemic or biologic attack ([S. 2055](#)). The MEDTECH Act, which would exclude certain devices from being considered a medical device, like devices used for storing financial records, will also be under consideration ([S. 1101](#)). A measure introduced by Senator Johnny Isakson (R-GA) and Senator Bob Casey (D-PA), which would clarify the existing regulations around combination products, specifically how a product is reviewed at the FDA, is slated to be considered as well ([S. 1767](#)). Lastly, the Adding Zika Virus to the FDA Priority Review Voucher Program Act ([S. 2512](#)), would add the Zika virus to the list of eligible diseases for the FDA priority review vouchered program.

The vast majority of measures being considered for this package are bipartisan, but calls for mandatory NIH funding will continue to persist. While Chairman Lamar Alexander (R-TN) and Senator Richard Burr (R-NC) both signaled support for increased funding at the first hearing, little progress has been made on that front, which prompted the Democrats on the committee to band together to introduce [legislation](#) which would direct \$5 billion annually to the FDA over the next five years. Wednesday will be helpful in determining the prospects of the committee's chances in advancing a complete package to the Senate floor before this summer.

ML Strategies will continue following the Senate's efforts in passing a counterpart to the 21st Century Cures Act. For more coverage on this issue, please visit the Mintz Levin [Health Law & Policy Blog](#).

News from the Hill

Finishing CARA Senate Goal This Week: The Senate is expected to finish debating the Comprehensive Addiction and Recovery Act (CARA) this week. In fact, the Senate invoked cloture on the substitute amendment yesterday, clearing an important hurdle and moving the legislation one step closer to passage. While no further votes on amendments are currently scheduled, senators continue to negotiate a package of amendments which could still be voted on this week.

Sens. Murray, Warren Introduce NIH-Funding Bill: As mentioned in our featured story above, Senator Elizabeth Warren (D-MA) introduced legislation with the rest of the Democratic committee members to allocate five billion each year for the next five years as a part of the Senate counterpart to the House-passed 21st Century Cures Act. You may recall that it was Senator Warren who led the charge in the first hearing on a Senate Cures package to include guaranteed funding for NIH in this legislation. Whether or not this bill gets added to the docket for Wednesday's hearing, there is no question that this will eventually come up.

Sen. Cassidy's TRUST IT Act Irks Industry: Senator Bill Cassidy (R-LA), a physician, has a bill that would establish a federal EHR star-rating system, which would assign a star rating for electronic health records (EHR) systems and decertify the lowest performing ones. Some within the industry argue that there are already a number of these systems, and that introducing a new one is not necessary. Given all the work being done on Capitol Hill with the 21st Century Cures initiative, as well as the Senate's early jump on reauthorizing the Generic Drug User Fee Amendments (GDUFA), this proposal will certainly receive some consideration. Fortunately for industry stakeholders, ONC has expressed similar reservations about a federal star-rating system.

Senate Clears Voluntary GMO Labeling Bill: The Senate Committee on Agriculture approved a measure last week that would create a national voluntary labeling standard for products containing genetically engineered foods. The legislation also preempts state law from requiring such labeling.

All Things ACA

ACA Debates Will Continue: While the apocalyptic ACA rhetoric has simmered, there are still reasonable concerns on both sides of the aisle that will need to be addressed in short order. One issue in particular is the composition of the exchanges, which, according to some stakeholders, are not garnering the number of consumers it had predicted, especially among the young and healthy. For more on marketplace enrollment, please view the Kaiser Family Foundation report [here](#).

State Medicaid Agencies Pushing for Permanent Insurance Tax Repeal: Some state Medicaid agencies are voicing support for the one-year delay on the health insurance tax while also pushing for its permanent repeal. In 2017, any efforts to reform the ACA will center on reconsidering the tax provisions, which include the insurance tax, the medical device tax, and the Cadillac tax.

South Dakota Not Moving on Medicaid Yet: While Governor Dennis Daugaard expressed optimism about moving forward on Medicaid expansion, he told reporters last week that he won't push the state legislature to take up this issue this year. Governor Daugaard's term ends January 2019.

Co-Ops Hemorrhaging Cash: Co-Ops in Illinois, Maine, Ohio, and Wisconsin reported losses of about \$270 million in 2015, five times more than what was lost in 2014. The numbers just keep getting worse for the co-ops, with few signs of imminent relief coming from the federal government.

At the Agencies

CMS Talks MACRA Implementation: CMS outlined its goals for implementing the Medicare Access and CHIP Reauthorization Act (MACRA), including supporting multi-payer initiatives; minimizing reporting burdens; and creating more opportunities for providers with varying levels of risk. Understanding CMS' forecasting on these issues is important, and ML Strategies is here to provide further guidance on these issues.

CMS Proposes Beefing Up EHR Surveillance: Last week, CMS released a proposal to strengthen its EHR certification processes. Among the proposals is a “feedback loop,” which should improve communication between providers and vendors. Providers have complained that some features, when installed, have not complied with meaningful use. The proposal will require vendors to correct flaws in EHR systems when reported or face corrective action.

CMS Holds Off on Quantitative Standards: CMS announced that it would hold off requiring insurers to establish minimum quantitative standards when designing their networks for 2017. Insurers will also not be required to offer standardized health plans.

Slavitt Continues Meeting with Providers over MACRA, MIPS: Implementing performance- and value-based systems has been met with scorn from some corners of the industry, which is why CMS Acting Administrator Andy Slavitt has opened his doors, so to speak, to critics of the new systems in an effort to have buy-in from all parties.

AHIP, CMS At Odds over MA Rate Setting: AHIP is gearing up for a battle over Medicare Advantage payment rates, set to be finalized in early April. One issue in particular is how the federal government determines its rates, which are significantly different than those found in a study commissioned by AHIP. The AHIP commissioned analysis, conducted by Oliver Wyman, found that changes to the risk-adjustment formula will result in a 2.1 percent average reduction while the Administration estimated the change would only be 0.6 percent. Expect significant advocacy prior to the rates being finalized.

FDA Reviewing Animation Direct-To Consumer (DTC) Advertising: You might remember the Nasonex bee and other animated figures serving as spokesman for drug products. Last week, the FDA [announced](#) they are seeking comments on research studying how the animation affects comprehension of DTC television advertisements of prescription drugs.

Prescription Drug Crisis

PhRMA Sues Over Ohio Ballot Initiative: PhRMA filed a lawsuit in the Ohio State Supreme Court to stop a drug pricing initiative that would require the state to pay no more for medicines than the VA negotiated rate.

Insurers, Manufacturers Battle Over Hepatitis C: New York’s attorney general is looking into whether insurance companies intentionally restricted access to Hepatitis C drugs over cost. This battle has been fought in a number of states and will likely continue as the drug pricing debates persist.

Opioid Crisis Coverage

CMS Proposes Curbing Opioid Overuse: Last week, CMS released its Medicare Part D Call Letter which proposes to require plans to prevent opioid overuse at the point of sale as soon as 2017. Expect further deliberations as to what constitutes overuse and who gets to decide that metric. The proposal includes soft thresholds, which can be overridden by the pharmacy, and hard thresholds, which are used to block claims sent to plans and cannot be overridden.

In Other News

SCOTUS Rules in Favor of Self-Funded Health Plans: Last week, the Supreme Court ruled in *Gobeille v. Liberty Mutual Insurance* that federal ERISA law protects self-funded health insurers from state requirements to submit claims data. The case centered on a Vermont law which required health insurers to submit certain information and data to an all-payer database. Proponents of the all-payer database argue it would boost transparency leading to potential cost-savings. Justice Stephen Breyer pointed out that, despite the ruling, the federal government could issue regulations that would enable collection at the federal level.

Patient Records – Who Owns Them?: A study conducted by Accenture shows that doctors and patients view who owns their health records much differently. Over 90 percent of patients believe they should have full access to their records while just 18 percent of doctors feel the same way. The divide has actually grown since the time the last survey was conducted.

End-Of-Life Care Debate Not Going Away: The debate over end-of-life care is as delicate as it is contentious, but the debate continues and is gaining steam in some respects. While discussing the issue can be politically sensitive, addressing the issue is not without support or merit.

Hearings

House of Representatives

Recess; No hearings scheduled.

United States Senate

On Wednesday, March 9th, the Senate Committee on Health, Education, Labor, and Pensions will hold an executive session (Senate Cures Hearing). 10AM – [more info](#).

On Thursday, March 10th, the Senate Committee on Finance will hold a hearing titled, “HealthCare.gov: A Review of Operations and Enrollment.” 10AM – [more info](#).

The Last Word

Senate HELP Committee Could Consider Mental Health Next: Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA) are negotiating a mental health package centered on bipartisan legislation introduced by Senators Chris Murphy (D-CT) and Bill Cassidy (R-LA). The negotiations are focused on including key provisions from the Mental Health Reform Act introduced last year by Murphy and Cassidy. Seeing how progress has stalled over Representative Tim Murphy’s (R-PA) mental health package in the House, the Senate effort is viewed as the best hope for making meaningful progress on mental health in 2016. The Administration has also taken a role in shepherding this legislation along, in part because of the reform elements directed at the Substance Abuse and Mental Health Services Administration, which legislators want to make sure has the Administration’s support.

The HELP Committee can pass a package that falls within its jurisdiction, which does not include Medicaid and Medicare. There are pieces of legislation in both the Finance and Judiciary committees which would be of interest to outside stakeholders as the Senate considers a complete package, but it is unclear at this time whether the HELP committee’s actions would further conversations in those committees.

The Finance Committee work on mental health care has focused on the repeal of the institutions for mental disease exclusion, also known as the IMD exclusion. Lifting the restrictions on Medicaid paying for mental health services could cost upwards of \$40 billion over 10 years, according to the Congressional Budget Office. Elements of Majority Whip John Cornyn’s (R-TX) bill, the Mental Health and Safe Community Act, currently in the Judiciary Committee, may also be included in final package as well. However, some say Cornyn’s legislation would make it easier for mental ill individuals to get guns, which Cornyn denies. It remains to be seen whether both sides would pass up an opportunity to advance meaningful mental health legislation in an election year over a so-called gun control provision.

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