



ML Strategies Update

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Health Care Update

Confusion Persists in Anticipation of 340B “Mega-Rule”: The 340B drug discount program continues to be one of the most scrutinized and anticipated areas of health policy regulation going into the summer. The 340B program provides discounts between 20 and 50 percent off the cost of pharmaceuticals to providers, such as hospitals and community health centers. While the program was initially created to provide affordable access to providers serving overwhelmingly needy communities, the ACA’s expansion of eligible providers to critical access hospitals (CAHs) and children’s hospitals, among others, has drawn the intense scrutiny of lawmakers and drug manufacturers alike.

As [we discussed previously](#), the U.S. District Court in Washington D.C. recently reversed an attempt by the Department of Health and Human Services (HHS) to create exceptions to the ACA ban on expanding the 340B discounts to “orphan drugs” and cited the lack of authority for HHS to expand the drug discount program in that manner. Last week, HHS communicated that it was continuing to evaluate whether to appeal the court’s decision or whether interpretive guidance might be released to further clarify. This comes at a time where stakeholders from all sides have been heavily focused on an upcoming 340B “mega rule” that was nearing finalization at the time of the recent court ruling.

The upcoming rule, which is expected as early as this month, is expected to provide critical guidance governing several aspects of the 340B Program, including the basic issue of how to define a “patient” for 340B. If HHS delays the rule to pursue a judicial appeal, stakeholders could find themselves in a position of interpreting the original court opinion as a license to discontinue the 340B discount in certain cases, pitting drug manufacturers and providers in a high stakes fight over the now \$7 billion drug discount program.

Implementation of the Affordable Care Act

CMS Allows SHOP Delays: CMS will allow [18 states](#) utilizing the Small Business Health Options Program (SHOP) to delay providing the “employee choice” option until 2016. “Employee choice” allows an employer to offer several different plans and insurers to their employees.

CMS Announces Support for Navigators: CMS [announced](#) the availability of \$60 million in funding to support Navigators in federally-facilitated and State Partnership Marketplaces in 2014-2015, with applications due by July 10, 2014. Navigators will be required to maintain a physical presence in their service area and to submit weekly and monthly progress reports to CMS.

AHIP Proposal for ACA Changes: America's Health Insurance Plans (AHIP) released a [proposal](#) recommending several changes to the ACA, including offering a lower cost catastrophic plan to everyone on the exchanges, instituting voluntary policies insurers could adopt to help consumers switch between plans, and transparency for consumers about their plans.

Other Federal Regulatory Initiatives

PCORI Beginning Clinical Trials: NIH Director Francis Collins [announced](#) that the Patient-Centered Outcomes Research Institute (PCORI) will begin running clinical trials through their network in September 2015. PCORI takes data from patients' electronic health records and uses it in a variety of studies to improve the use of different drugs and procedures.

HHS OIG Finds CMS Does Not Accurately Review EHRs: According to an Office of the Inspector General [report](#), Medicare contracted fraud detectors use the same system to review paper health records and electronic health records (EHRs). Despite the increased use of EHRs they have not updated their techniques to better identify fraud.

VA Says Staff Bypasses Electronic Scheduling: According to a [review](#) by the Department of Veterans' Affairs, eight percent of staff at the VA Health Administration reported they tracked patient appointment requests in a way other than through the computerized scheduling system.

FDA Posts Track and Trace Guidance: On June 10th, the FDA posted initial [guidance](#) on implementing Drug Quality and Security Act prescription drug track and trace requirements. The guidance provides the recommendations for identification of suspect products and notification of illegitimate products.

Health IT Group Supports Facilitating Exchange of Substance Abuse Records: In a public listening [session](#) held by the Substance Abuse and Mental Health Services Administration (SAMHSA) on the confidentiality of patients' substance abuse records, the Executive Director of the Health IT Now Coalition stated the group's support for suggested changes that would reduce the privacy protections on those records.

Other Congressional and State Initiatives

Senate Labor-HHS Bill Advanced: The Senate Appropriations Subcommittee on Labor-HHS advanced FY2015 funding [legislation](#). The bill provides \$156,773,000,000 in base discretionary budget authority, the same as the FY 2014 level. Full committee consideration scheduled for June 12th was postponed.

House Energy & Commerce Advances Public Health Bills: On June 10th the House Energy and Commerce Committee advanced three bills by voice vote: [H.R. 4299](#), the Improving Regulatory Transparency for New Medical Therapies Act, [H.R. 4709](#), the Ensuring Patient Access and Effective Drug Enforcement Act, and [H.R. 4631](#), the Autism Collaboration, Accountability, Research, Education and Support (CARES) Act.

White House Opposes Withholding FDA Funding: The White House issued a [statement](#) of administration policy (SAP) on June 10th detailing its opposition to the House-passed appropriations bill for Agriculture, Rural Development, FDA and related agencies. The bill includes a provision withholding \$20 million from the FDA until it issues final guidance on abuse-deterrent formulations of opioids.

Banning E-Cigs on Airplanes: Seven Democratic Senators [wrote](#) to Transportation Secretary Foxx urging him to finalize a ban on the use of e-cigarettes on airplanes. The letter notes that while many major carriers have decided to prohibit the use of electronic cigarettes, federal regulations still allow these products to be used during flight.

Republican Leaders Press HHS on Risk Corridors: House Energy and Commerce Committee Chairman Fred Upton (R-MI) and Senate Budget Committee Ranking Member Jeff Sessions (R-AL) [wrote](#) to HHS Secretary Burwell questioning the legal authority of HHS to issue payments to health insurance providers through the ACA's risk corridor program.

House E&C Examines 21st Century Cures: The House Energy and Commerce Subcommittee on Health held a second [hearing](#) examining the role incentives for drug and device development play in advancing 21st century cures.

Senate Passes VA Reform Legislation: On June 11th, the Senate passed the Veterans' Access to Care through Choice, Accountability, and Transparency Act of 2014 ([H.R. 3230](#)) in a 93 to 3 vote. The bill would increase veteran access to health care by facilitating the hiring of new physicians, providing resources to lease new facilities, and allowing veterans to access care through non-VA providers. Earlier in the week the House unanimously [passed](#) a similar version of the bill.

House E&C Hearing on Health Care Access: The House Energy and Commerce Subcommittee on Health held a [hearing](#) to examine the ACA and equal health care access in which witnesses discussed the difference between coverage and access.

House W&M Joint Hearing on Income Verification: The House Ways and Means Oversight Subcommittee and the Health Subcommittee held a joint [hearing](#) on the verification system for income and eligibility for tax credits under the ACA. In his [opening statement](#), Chairman Boustany (R-LA), Oversight Subcommittee Chairman, said the hearing was intended to explore the improper administration of tax credits, and taxpayer rights.

Other Health Care News

NHPCO Reports on Part D Problems: The National Hospice and Palliative Care Organization (NHPCO) [reported](#) that many patients in hospice are experiencing difficulties with the procurement of their non-terminal illness prescriptions because of the Medicare Part D Prescription Drug policy. Medicare Part D is attempting to prevent duplicate medication charges for hospice patients; in the process it is adding many complications to the prescription approval process.

Research Shows Growing Health IT Market: [Data](#) from Transparency Market Research forecasts that the global health IT market could reach \$53.2 billion by 2019—with the market growing by 7.1 percent over 2013 to 2019.

NPC on Specialty Drugs: the National Pharmaceutical Council released a [paper](#) asserting that insurers should not impose more than a “modest” cost sharing on high value drugs, such as specialty medicines. The report advises insurers use cost sharing to encourage patients to use these drugs.

Study on “In-Network” Physicians: In a [study](#) of claims data filed through employer-sponsored health plans in the 30 largest US cities, Health IT company Castlight Health released found wide price variations for four health care services for “in-network” physicians within the same city.

Brookings Report on “Innovation Districts”: The Brookings Institution released a [report](#) on innovation districts, finding that these settings allow for the training of staff members in IT techniques so they can have more responsibilities and doctors and nurses can focus on patient care.

AHA Letter on Public Health Readiness: The AHA sent a [letter](#) to Office of Information and Regulatory Affairs (OIRA) head Howard Shelanski asking him to urge the CMS to expedite the creation of a website, announced in 2012, to gather information on public health agencies' ability and readiness to receive data from hospitals.

Upcoming Hearings and Markups

Senate

On June 17th, the Consumer Protection, Product Safety and Insurance Subcommittee of the Senate Commerce, Science and Transportation Committee will hold a [hearing](#) titled "Protecting Consumers from False and Deceptive Advertising of Weight-Loss Products."

On June 18th, the Senate Commerce, Science and Transportation Committee will hold a [hearing](#) titled "Aggressive E-Cigarette Marketing and Potential Consequences for Youth."

House

On June 18th, the Health Subcommittee of the House Ways and Means Committee will hold a [hearing](#) on the Medicare Payment Advisory Commission June report to Congress.

On June 18th, the House Veterans' Affairs Committee will hold a [hearing](#) titled "Non-Department of Veteran Affairs Care: An Integrated Solution for Veteran Access."

On June 18th, the House Oversight and Government Reform Subcommittee on Economic Growth, Job Creation

and Regulatory Affairs will hold a [hearing](#) titled, "Poised to Profit: How ObamaCare Helps Insurance Companies Even If It Fails Patients."

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