



Alexander Hecht, AHecht@mlstrategies.com
Andrew Shin, AJShin@mlstrategies.com
Abby Matousek, AMatousek@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

May 11, 2015

Health Care Update

340B Drug Discount Program Guidance Nearing Finish Line: On May 6th, the Health Resources and Services Administration (HRSA) formally submitted highly-anticipated guidance on the 340B drug program to the White House Office of Management and Budget (OMB) for final review. The guidance entitled, “340B Program Omnibus Guidelines,” also commonly referred to as the “mega-rule” [follows a series of legal battles last year](#) that called into question HRSA’s authority over certain aspects of the 340B program.

Stakeholders are anxiously awaiting HRSA guidance on a variety of 340B issues ranging from contract pharmacy compliance requirements to the definition of a qualifying “patient” to the possible extension of discounts to off-site facilities of covered entities. Depending on the length of OMB review, most experts believe that the guidelines could be published as early as this summer. The Obama Administration has indicated that there would be a normal public comment period.

Although the guidelines will attempt to update and clarify significant areas of concern in the 340B program, the overarching issue of whether HRSA has the regulatory authority to oversee various aspects of the program is still likely to be front and center. Lawmakers in Congress have been working behind the scenes to on issues related to HRSA authority and the 340B program.

ONC Releases Privacy and Security Guidance Geared to Small Providers: The Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) released a revised version 2.0 of their [Guide to Privacy and Security of Electronic Health Information](#). The ONC reorganized and rewrote the guidance to more user-friendly for small providers addressing federal privacy and security requirements for their practices. Though the Guide is targeted to small providers, it is meant for use by providers of all sizes, and their business associates. The Guide provides a general overview of the HIPAA Privacy and Security Rules and the EHR Incentive Programs, and gives pragmatic advice in areas including:

- How to identify whether a contractor is a Business Associate under HIPAA;
- When patient authorizations are required to disclose protected health information (“PHI”);
- Questions to ask EHR health IT developers about security; and
- How to implement a security management process to address the security requirements of the EHR Incentive Programs.

More information on the ONC guide can be found in a Mintz Levin Health Law & Policy Matters blog [post](#).

Implementation of the Affordable Care Act

Pioneer ACO Model Yields Savings: A [evaluation](#) by the Office of the Actuary in the Centers for Medicare & Medicaid Services (CMS) found that the Pioneer ACO Model created by the ACA generated savings of \$348 million over two years. CMS has certified that this patient care model is the first to meet the stringent criteria for expansion to a larger population of Medicare beneficiaries.

ACA Funding for Community Health Centers: The Department of Health and Human Services (HHS) [announced](#) \$101 million in ACA funding to 164 new health center sites for the delivery of comprehensive primary health care services in underserved communities.

CMS Clarifies Out-of-Pocket Cap: CMS released [guidance](#) clarifying that, even if an individual is enrolled in a family plan with higher out-of-pocket cost caps, insurers must limit a person's out-of-pocket costs to the ACA's individual limit.

Treasury Report on IRS ACA Compliance: The Treasury Inspector General for Tax Administration released a [report](#) finding that, due to delays in the implementation of the employer and insurer health information reporting, the Internal Revenue Service (IRS) has not yet developed processes and procedures to verify minimal essential coverage compliance.

Federal Regulatory Initiatives

HHS to Allow HIV-Positive Organ Donations: HHS released a final [rule](#) implementing the HIV Organ Policy Equity (HOPE) Act, which allows HIV-infected persons to donate organs for use in transplants in those who are also already HIV-positive.

Report on Medicare Telehealth Payments: According to CMS [data](#) released by the Center for Telehealth and eHealth Law, Medicare reimbursement for telehealth in 2014 totaled \$13.9 million in 2014—an 18 percent increase over 2013.

HHS Celebrates Children's Mental Health Awareness Day: HHS and Substance Abuse and Mental Health Services Administration (SAMHSA) [celebrated](#) the 10th anniversary of National Children's Mental Health Awareness Day. In remarks, HHS Secretary Burwell said that: "When families and children seek help for behavioral health conditions, our health care system must be prepared to deliver the medical care and community supports they need."

AHRQ Brief on EHRs for Pediatrics: The Agency for Healthcare Research and Quality (AHRQ) released a [brief](#) suggesting improvements that can be made to EHRs to better serve pediatricians. Some suggestions include adding information on vaccinations, child development, physiologic medication dosing, pediatric disease management, pediatric norms, and the parent-child relationship.

CMS Releases 2016 Quality Reporting Measures: CMS [released](#) its 2016 update for the electronic clinical quality measures (eCQMs) which are used by eligible hospitals and eligible professional for quality reporting programs, including the Physician Quality Reporting System, Inpatient Quality Reporting Program, and the EHR Incentive Programs.

GAO Appoints Health IT Committee Members: The Government Accountability Office (GAO) [announced](#) the appointment of new members to two health care entities — the Methodology Committee of the Patient-Centered Outcomes Research Institute (PCORI) and the Health Information Technology (HIT) Policy Committee. New members include: Kathleen Blake, vice president for performance improvement at the American Medical; Donna Cryer, founder and President of the Global Liver Institute; and Brent Snyder, Chief Information Officer at Adventist Health System.

HHS OIG on FDA Oversight of Generics: The HHS Office of Inspector General [released](#) a report finding that the FDA has improved its oversight of generic drugs but is still unable to conduct all of the preapproval inspections requested by the agency's generic drug application reviewers. FDA increased its preapproval inspections of manufacturers of generic drugs by 60 percent between 2011 and 2013.

HRSA Telemedicine Research Grant: The Health Resources and Services Administration (HRSA) [announced](#) the availability of a \$750,000 research grant to "provide infrastructure to support telehealth services researchers as they explore the complexities of telehealth issues."

CDC Report on Hep C Rates: A new report from the Centers for Disease Control (CDC) [found](#) that between 2006 and 2012, Hepatitis C rates grew in certain parts of America—in part due to the use of injected drugs.

CDC Report on Cancer Morbidity Rates: According to the most recent CDC Morbidity and Mortality Weekly [Report](#) screening for colorectal, breast, and cervical cancers did not improve, or worsened, in 2013.

Congressional Initiatives

Senate HELP Continues Innovation Hearings: The Senate Health, Education, Labor, and Pensions Committee met to hear [testimony](#) from representatives from the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) on precision medicine and the NIH's Precision Medicine Initiative, which seeks to create a synthetic cohort of one million genomes, whose properties doctors can base their treatments off of for any patients who have similar properties.

Senate Appropriations Rural Health Hearing: The Senate Appropriations Subcommittee on Labor, Health And Human Services, and Related Agencies [met](#) to consider rural health funding. Speaking at the hearing, CMS Deputy Administrator and Director Sean Cavanaugh touched on rural health coordinators at regional offices, the Rural Health Open Door Forum, Medicare's telehealth benefit for rural health clinics and critical access hospitals, and new delivery models for rural health.

ICD-10 Delay Bill Reintroduced: Representative Ted Poe (R-TX) reintroduced the Cutting Costly Codes Act ([H.R. 2126](#)) with six cosponsors, which would stop the implementation of the ICD-10 coding system indefinitely. Currently, health care providers must begin using the system on October 1st.

Narcotics Control Caucus Hearing on Drug Shortages: The Senate Drug Caucus on International Narcotics Control held a [hearing](#) on the findings and recommendations of a recent GAO report which highlights challenges with the Drug Enforcement Administration (DEA) and the FDA's management the Controlled Substances quota process, which has resulted in shortages of drugs such as anesthesia, narcotic pain relievers, and drugs to treat anxiety and attention deficit disorders.

Lawmakers Press HHS on Contraception Access: Thirty-nine Senate Democrats [wrote](#) to HHS Secretary Burwell with concerns that insurers are failing to cover forms of contraception approved by the FDA, as required by the ACA, and failing to provide women with accurate information about the range of essential health care services that are now available without cost-sharing.

Other Health Care News

ATA Updates State Telemedicine Grades: The American Telemedicine Association (ATA) released updated versions of their two reports which grade states on aspects of telemedicine implementation. The reports cover progress on [coverage and reimbursement](#) and [practice standards and licensure](#).

Report on Consumer Health Costs: The U.S. News & World Report [Health Care Index](#) found that between 2000 and 2013, consumers spent 1.7 times more of their own money on health care. Over the period studied, the average cost of deductibles doubled, employees paid 4 percent more of their premiums, and prescription drug costs borne by consumers went up 55 percent.

Upcoming Congressional Hearings

Senate

On Thursday, May 14th, the Senate Finance Committee will hold a [hearing](#) titled "A Pathway to Improving Care for Medicare Patients with Chronic Conditions."

House

On Friday, May 15th, the House Veterans' Affairs Subcommittee on Health will hold a [markup](#) to consider pending legislation.

* * *

Boston · Washington www.mlstrategies.com

