Joseph P. Hammang, PhD, JPHammang@mlstrategies.com
Alexander Hecht, AHecht@mlstrategies.com
Andrew Shin, AJShin@mlstrategies.com
Abby Matousek, AMatousek@mlstrategies.com

FOLLOW US ON TWITTER: @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

- **FDA Releases Menu Labeling Rule:** Before the Thanksgiving holiday, the Food and Drug Administration (FDA) released its final rule to implement nutrition labeling provisions of the ACA. The rule, which covers restaurants and "similar retail food establishments that are part of a chain with 20 or more locations," mandates that these establishments provide calorie and nutritional information for food on display and for self-service food. Unlike the proposed rule, the final version also covers alcohol vendors and movie theaters, provides additional flexibility on pizza labeling, and narrows what prepared foods are covered—such as sliced deli meat at grocery stores. Covered entities will have one year to comply with these regulations.

  The scope of the final rule has been met with resistance from the food retail industry. In particular, the broadened definition of venues where labeling is required has been criticized by grocery store groups and food retailers who are concerned that the rule does not recognize the nuances between the grocery industry and restaurants. Addressing these concerns, Jessica Leighton, FDA's Office of Foods and Veterinary Medicine's senior nutrition science and policy advisor, clarified that it is not the agency's intent to capture all foods offered at grocery stores.

  Still, proponents of the rule, such as public health advocates, applauded the final rule for prioritizing consumer health. Senate Health, Education, Labor, and Pensions (HELP) Committee Chairman Tom Harkin (D-IA) praised the FDA, saying: "This rule closes the restaurant loophole and empowers consumers to make wise decisions about their health whether they dine in a restaurant, a grocery store, or an entertainment venue."

  In a separate rule, the FDA implemented the vending machine food labeling provisions of the ACA, which requires vending machine operators with more than 20 machines to post calorie information on or near the machine. Vending companies will have two years to come into compliance.

Implementation of the Affordable Care Act

HHS Releases Enrollment Numbers: On November 26th, the Department of Health and Human Services (HHS) released updated enrollment numbers for the Federal Marketplace. The report details that 462,125 people selected plans through the federal Marketplace between November 15th and November 21st. Of these enrollees, 48 percent were new consumers while the remaining were consumers renewing their health care coverage.

Proposed Rule on Health Exchange Transparency: The Centers for Medicare & Medicaid Services (CMS) and HHS released a proposed rule that would "set forth payment parameters and provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost sharing parameters and cost sharing reductions; and user fees for Federally-facilitated Exchanges."

Other Federal Regulatory Initiatives

CMS Releases Proposed MA, Part D Star Ratings Changes: CMS released a request for comments on enhancements to 2016 Star Ratings for Medicare Advantage (MA) and Prescription Drug Plans (PDPs). The agency is looking for industry comments on how to measure care coordination using MA data, new measurements for Medication Therapy Management, potential expansion of medication reconciliation, and including additional prescriptions in the Medicare Plan Finder pricing measure.

GAO Report on Group Purchasing Organizations: The Government Accountability Office (GAO) released a report on group purchasing organizations (GPO) contracting practices and the impact of the GPO funding structure. The agency found that the HHS Inspector General does not always assess whether fees from GPOs to hospitals are included in Medicare cost reports and recommended HHS "determine whether hospitals are appropriately reporting administrative fee revenues on their Medicare cost reports."

FDA Updates Home Use Guidance: The FDA released updated final guidance on design considerations for home use devices. The guidance provides recommendations for minimizing the risks associated with home use devices and "provides clarification about the use of standards applicable to supply mains and electromagnetic compatibility."

FDA Considers Opening Blood Donations: At an advisory committee meeting on December 2nd, the FDA will consider revising the agency's ban on gay men donating blood. The proposal under consideration would allow gay men to donate if they have not had sex with a man for one year.

Progress on NIAID/GSK Vaccine: The results of tests of an experimental Ebola vaccine co-developed by the NIH's National Institute of Allergy and Infectious Diseases (NIAID) and GlaxoSmithKline (GSK) found that it was "well-tolerated and produced immune system responses in all 20 healthy adults who received it in a phase 1 clinical trial."

Adult Smoking Rate at Low: The Centers for Disease Control and Prevention (CDC) found in the Morbidity and Mortality Weekly Report that the U.S. adult smoking rate is at an all-time low, dropping from 20.9 percent in 2005 to 17.8 percent in 2013.

Upcoming Congressional Hearings

House

On Wednesday, December 3rd, the House Energy and Commerce Subcommittee on Health will hold a hearing titled "The Future of the Children's Health Insurance Program."

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