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Health Policy Update – July 14, 2021

President Biden Signs Executive Order Promoting Competition in the American Economy

On July 9, President Biden signed an executive order aimed at promoting competition in labor markets, healthcare, transportation, agriculture, internet service, technology, banking, and consumer finance. The order directs or encourages federal agencies to act and may result in further rulemaking for certain policies.

The order states that Americans are paying too much for prescription drugs and healthcare services and that hospital consolidation has left many areas with inadequate or more expensive healthcare options. Among the health care provisions, the executive order calls on:

- Directs the Secretary of Health and Human Services (HHS) to submit a report with 45 days to the Assistant to the President for Domestic Policy and Director of the Domestic Policy Council and to the Chair of the White House Competition Council, with a plan to combat excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such drugs, and to address the recurrent problem of price gouging;
- Directs HHS to lower the prices of and improve access to prescription drugs and biologics, including promoting generic drug and biosimilar competition;
- Directs the Centers for Medicare and Medicaid Services to prepare for Medicare and Medicaid coverage of interchangeable biological products and for payment models to support increased utilization of generic drugs and biosimilars;
- Directs HHS to support existing price transparency initiatives for hospitals, other providers, and insurers along with any new price transparency initiatives or changes made necessary by the No Surprises Act;
- Encourages the Federal Trade Commission (FDC) to issue regulations addressing anticompetitive conduct in the prescription drug industry, such as agreements to delay the market entry of generic drugs or biosimilars; and
- Directs the Food and Drug Administration (FDA) to work with states and tribes to safely import prescription drugs from Canada.

To address consolidation in the health care market, the executive order also encourages the FTC to review the horizontal and vertical merger guidelines and consider whether to revise them. It also encourages the FTC to exercise its statutory rulemaking authority under the Federal Trade Commission Act to curtail the unfair use of non-compete clauses.

To read the text of the Executive Order, CLICK HERE.

To read the factsheet, CLICK HERE.

To read President Biden's remarks, CLICK HERE.

Biden Administration Announces New CMS, Cancer Moonshot Leadership

On July 6, the Centers for Medicare & Medicaid Services (CMS) named Dr. Meena Seshamani, M.D., Ph.D. to lead the Center for Medicare as its Deputy Administrator and Director.

Seshamani most recently served as the Vice President of Clinical Care Transformation at MedStar Health, and previously served as the HHS Office of Health Reform Director and as Assistant Professor of Otolaryngology-Head and Neck Surgery at the Georgetown University School of Medicine. She brings decades of experience in health policy including coverage policy, delivery system reform, and public health policy.

"Providing quality health care to the people who rely on Medicare and advancing health equity as we do it is a priority for CMS," said CMS Administrator Chiquita Brook-LaSure in a press release. "I am delighted to say Dr. Seshamani will bring her unique perspective on how health policy impacts the real lives of patients to her leadership role as Deputy Administrator and Director of the Center for Medicare."

The Biden administration also announced that neuroscientist Danielle Carnival, a veteran of the Cancer Moonshot during the Obama administration, will oversee a new version of the initiative. Carnival is the CEO of the non-profit I Am ALS and previously served as Chief of Staff and Senior Policy Director for Cancer Moonshot and as Vice President of the non-profit Biden Cancer Initiative. According to a statement from the White House, Carnival will work on patient engagement and outreach.

To read the CMS press release, CLICK HERE.

To read more about the new Cancer Moonshot initiative, CLICK HERE.

Supreme Court Declines to Hear Challenge to Site Neutral Policy, Will Take Up 340B Payments & Mail Order Prescription Discrimination Case

On June 28, the U.S. Supreme Court declined to hear an appeal challenging the HHS site neural payment policy, upholding a ruling from the U.S. Court of Appeals for the District of Columbia Circuit that allowed the policy to move forward. The appeal was filed by a coalition of hospital trade groups led by the American Hospital Association and the American Association of Medical Colleges which had challenged the initial rule arguing that HHS had overstepped its authority in implementing the policy.

Advocates for site neutral payment reform applauded the decision as a victory for payment parity across sites of service. Originally included in the 2019 Hospital Outpatient Prospective Payment

System (OPPS) final rule, the policy change equalizes payments for routine Evaluation and Management (E/M) services across sites of service. Previously, hospital outpatient departments were able to bill Medicare at a higher rate for these services than physician offices despite the fact that both sites were providing the exact same services. The new policy change was estimated to save the Medicare program an estimated $300 million and lower patient co-payments by $80 million annually.

In related news, the Supreme Court announced that it will take up two cases concerning prescription drug policy. The first concerns CMS' 2018 decision to reduce reimbursement rates for certain outpatient drugs to hospitals participating in the 340B drug discount program. Hospital groups led by the AHA filed suit, alleging that CMS didn't have the authority to implement the cuts. Lower courts have twice ruled in favor of CMS.

The Supreme Court will also hear a class action suit against CVS Caremark where the plaintiffs – a group of patients with HIV/AIDS – argued that the pharmacy benefit manager's (PBM) decision to require prescriptions to be filled by mail order or drop shipment to a CVS pharmacy for pickup threatened their health and privacy. In CVS Pharmacy v. John Doe, plaintiffs would have otherwise been required to pay out-of-network insurance rates to get their drugs at a pharmacy of their choosing. The case is expected to have major implications for the Affordable Care Act's anti-discrimination protections and could open the door to more litigation against PBMs over how they design prescription drug plans.

To view the Supreme Court's announcement that it will review the 340B and CVS cases, CLICK HERE.

Congress Preparing Hearings on FDA Approval of Biogen's Alzheimer's Drug, FDA Chief Asks for OIG Investigation

On June 25, two Congressional committees announced plans to investigate the FDA's controversial decision to grant accelerated approval to Aduhelm (aducanumab), Biogen's drug to treat Alzheimer's disease.

In a joint statement issued by House Committee on Oversight & Reform Chair Carolyn Maloney (D-NY) and Energy & Commerce Committee Chair Frank Pallone (D-NJ), said: "We have serious concerns about the steep price of Biogen's new Alzheimer's drug Aduhelm and the process that led to its approval despite questions about the drug's clinical benefit."
The FDA's approval of the first drug to treat Alzheimer's in nearly 20 years stirred up debate over whether the new drug – which carries an initial price tag of $56,000 – would or should be easily accessible to patients.

Critics have argued that there is insufficient evidence to demonstrate Aduhelm's effectiveness in slowing disease progression and that the current price tag is too high given the uncertainties of the drug's benefits. A preliminary analysis from the Kaiser Family Foundation found that, at the current price tag, spending on Aduhelm could be as high as $56 billion annually if the number of patients the drug is prescribed to is applied to the lower end of Biogen's estimate.

Separately, Senators Elizabeth Warren (D-MA) and Bill Cassidy (R-LA) sent a letter to the Senate Finance Committee chair and ranking member calling for a hearing to “examine the vexing new questions and challenges arising from” the FDA’s approval of Aduhelm.

On July 8, the FDA announced that it will update the prescribing information for Aduhelm in order to target a narrower group of patients that match the characteristics of those who participated in the drug’s initial trials.

On July 9, following press reports that Biogen waged a secret effort to secure FDA approval for Adulhelm after poor performance in clinical trials, FDA acting commissioner Janet Woodcock requested the HIS OIG conduct an investigation “into the interactions between Biogen and the FDA during the process leading to the decision to approve the drug to determine whether any of those interactions were inconsistent with FDA policies and procedures.”

On July 12, CMS announced that it is opening a National Coverage Determination (NCD) analysis, with a 30-day public comment period. This NCD analysis will be applicable to national coverage considerations for aducanumab, as well as any future monoclonal antibodies that target amyloid for the treatment of Alzheimer's disease. A proposed decision is expected to be posted within 6 months (with a second 30-day comment period to follow) and a final decision within 9 months.

To view the joint statement from Reps. Maloney and Pallone, CLICK HERE.

To view the letter from Sens. Warren and Cassidy, CLICK HERE.

To read the letter requesting the OIG investigation, CLICK HERE.

To view the Kaiser Family Foundation analysis, CLICK HERE.

New Report: Majority of U.S. Physicians Now Employed by Hospitals or Corporations

In late June, the Physicians Advocacy Institute released the results of a new analysis which highlight the impact of the COVID-19 pandemic on healthcare consolidation. By the end of 2020, approximately 70% of physicians in the United States were employed by hospitals or corporations, suggesting that vertical consolidation has accelerated during the public health emergency. Less than one-third of American physicians practiced medicine independently at the beginning of 2021.

According to the report, the sharpest increase (32%) in medical practice acquisitions during 2019 and 2020 was in corporate entities such as private equity firms and health insurers. Meanwhile, nearly 50,000 physicians decided to leave private practice and enter a hospital or health system practice in 2019 and 2020. The new report underscores concerns that increasing healthcare consolidation could lead to higher costs and undercut physician independence.

To read the Physicians Advocacy Institute analysis, CLICK HERE.