

Health Policy Update – May 21, 2019

FDA Issues Final Rule on Biosimilars

On May 10, the U.S. Food and Drug Administration (FDA) issued final guidance detailing specifically what kind of studies biosimilar drug manufacturers must conduct in order to have their products considered as “interchangeable” with a biologic drug. The final rule was hailed by biosimilar groups for streamlining data and study design requirements.

As described in the January 2017 draft policy, drug makers will be required to conduct a clinical trial that switches patients between the biologic and the biosimilar to show there are no adverse effects on the patient. The final policy will also permit biosimilar manufacturers to use non-U.S. versions of biologics in the switching studies. The agency also scrapped previous recommendations that drug makers conduct costly studies on whether there are more errors when consumers and caregivers use the biosimilar versus a biologic.

To read the final rule, [CLICK HERE](#).

CMS Finalizes Rule Requiring Drug Prices in Direct-to-Consumer Ads

On May 8, the Centers for Medicare & Medicaid Services (CMS) finalized a rule requiring pharmaceutical companies to include the list prices of their drugs in direct-to-consumer advertisements if that price is equal to or greater than \$35 for a month's supply or the usual course of therapy.

The announcement is notable because it is one of the first policies included in the Administration's American Patients First drug pricing blueprint to be finalized. However, the rule has come under significant criticism from drug manufacturers who argue the list price does not accurately reflect the true cost of the drugs and that most patients pay far less than that amount.

To read the final rule, [CLICK HERE](#).

To read the CMS fact sheet on the rule, [CLICK HERE](#).

New Court Ruling Orders CMS to Quickly Rectify 340B Pay Cuts

On May 6, a federal judge in the District of Columbia announced it is giving the Centers for Medicare & Medicaid Services (CMS) an opportunity to quickly rectify cuts it made to the 340B drug discount program in 2018 and 2019. The court said CMS exceeded its authority in both 2018 and 2019 when it reduced reimbursement for drugs acquired under the 340B program from ASP+6 percent to ASP-22.5 percent.

Because the reduction in 340B payments in 2018 and 2019 increased payments for other Medicare Part B products and services, and HHS has already processed claims under the lower rates, the judge chose not to vacate the rule, and instead directed CMS to determine an appropriate remedy. The ruling provides additional details on the issue of remedies; and both sides must submit a status report by August 5 on the agency's progress.

Meanwhile, the hospital groups filing suit argued for the cuts to be fully restored, with interest, and also asked the court to set a firm June deadline for proposed remedies.

To read the district court's decision, [CLICK HERE](#).

To read the hospital groups' request for a June deadline for remedies, [CLICK HERE](#).

House Lawmakers Launch Effort to Block Site Neutral Payments

On May 9, Representatives Derek Kilmer (D-WA) and Elise Stefanik (R-NY) introduced a bill to override the Centers for Medicare & Medicaid Services (CMS) site neutral payment policy implemented in the 2019 Hospital Outpatient Prospective Payment Final Rule. The bill, Protecting Local Access to Care for Everyone (PLACE) Act of 2019 (H.R. 2552), would undo the part of the rule that reimburses all off-campus hospital outpatient facilities at a rate equivalent to the physician fee schedule for clinic visits.

CMS implemented the site neutral policy in an effort to increase the sustainability of the Medicare program and ensure procedures cost the same regardless of the site of service. The policy is expected to save the Medicare program an estimated \$300 million and lower patient co-payments by \$80 million in 2019 alone.

When announcing the introduction of the bill, Representatives Kilmer and Stefanik said their intent was to help regional hospitals and patients living in rural areas.

To read the text of the PLACE Act, [CLICK HERE](#).

To read Congressman Kilmer's statement on the bill, [CLICK HERE](#).

Forty-Four States Sue Generic Drug Makers, Allege Price-Fixing

On May 10, a group of 44 states' attorneys general filed a lawsuit against 20 generic drug manufacturers as well as more than a dozen individual executives, alleging an industry-wide conspiracy to fix price. The lawsuit, led by Connecticut Attorney General William Tong, focuses on generic drug products used to treat a variety of chronic conditions, some of which have seen price increases of over 1,000 percent since 2013.

The states allege that several companies not only colluded with each other to keep prices high, but also coordinated price increases and destroyed evidence of communication between those responsible for making these decisions.

The suit was filed in Federal District Court in Connecticut and builds on litigation filed against some of the named companies in 2016 that is still ongoing.

To view the full complaint, [CLICK HERE](#).

To view a fact sheet on the suit, [CLICK HERE](#).

Senate Judiciary Committee Examines Drug Patents

On May 7, the Senate Judiciary Committee held a hearing to discuss how best to reform the drug patent system to lower prices for patients while ensuring the development of innovative products is protected. The hearing, titled “Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition,” featured witnesses from academia, the drug industry, and patient advocate groups.

Several bipartisan bills under the committee’s jurisdiction, including the [CREATES Act](#), the [Prescription Pricing for the People Act](#), the [Stop STALLING Act](#), and the [Preserve Access to Affordable Generics and Biosimilars Act](#) aim to encourage new drug development and prevent branded drug manufactures from using the patent system to keep generic competitors off the market.

To view the hearing, [CLICK HERE](#).

Energy & Commerce Subcommittee on Health Holds Hearing on Drug Supply Chain

On May 9, the House Energy and Commerce Subcommittee on Health held a hearing titled “Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain” in which lawmakers examined the role various stakeholders play in the distribution of prescription medications.

The hearing featured a variety of witnesses from the pharmaceutical sector including representatives from the manufacturer, pharmacy benefit manager, patient, and insurer communities.

To view the hearing, [CLICK HERE](#).

Senator Elizabeth Warren, Representative Elijah Cummings Introduce Comprehensive Opioid Legislation

On May 8, Senator Elizabeth Warren (D-MA), Representative Elijah Cummings (D-MD), and 95 of their colleagues in both houses of Congress unveiled the Comprehensive Addiction Resources Emergency (CARE) Act, which would invest \$100 billion over the next decade to address the opioid overdose epidemic. The bill provides billions of dollars in direct grants to states, local governments, and community organizations to improve treatment capacity.

The CARE Act also includes funding to train more addiction treatment professionals in the screening, supports prevention and treatment of addiction and directs the Department of Health & Human Services to develop model standards for the regulation of substance abuse disorder treatment services.

The lawmakers highlight this legislation is directly modeled on the Ryan White Comprehensive AIDS Resources Emergency Act, which was enacted in 1990 to coordinate the federal response to the HIV/AIDS epidemic. The bill has earned the endorsement from a variety of addiction treatment and advocacy organizations, including the American Medical Association, American Society of Addiction Medicine, and the 146-member Coalition to Stop Opioid Overdose.

To read the bill, [CLICK HERE](#).

To read a fact sheet from Senator Warren’s office, [CLICK HERE](#).