

Health Policy Update – June 7, 2018

Community Oncology Alliance Sues HHS For Applying Sequestration to Part B Drugs

On May 31, the Community Oncology Alliance (COA) filed a lawsuit against the Department of Health and Human Services for continuing to apply sequestration cuts to Medicare reimbursement for Part B physician-administered drugs. As a part of the Budget Control Act of 2011, Congress implemented a 2% cut to Part B drug reimbursement, which reduces the payments doctors receive below the Average Sales Price (ASP) plus 6% formula currently used to determine rates.

In conjunction with the lawsuit, COA also sent a letter to HHS Secretary Alex Azar explaining the legal action and raising concerns about the proposed changes to Medicare Part B in the President's blueprint on drug prices. COA argues these proposals could raise out-of-pocket costs for patients while restricting access to certain medications.

To read COA's press release, [CLICK HERE](#).

HRSA Officially Delays 340B Penalties Rule

On June 1, the Health Resources and Services Administration (HRSA) officially announced that it would delay a rule to set new drug ceiling prices for the 340B drug discount program until July 1, 2019. The agency had previously signaled it would be delaying the rule when it asked for comments on a proposed delay last month.

First developed by the Obama Administration, the rule would allow HHS to fine drug manufacturers that intentionally charge a hospital more than the set ceiling price. The rule has been delayed several times in the past. The most recent announcement marks the fifth time the agency has done so. In announcing the delay, HRSA said that it wanted to ensure its rulemaking was in line with the Department of Health and Human Services' broader efforts to address high prescription drug prices.

To read HRSA's proposal announcing the 340B rule delay, [CLICK HERE](#).

Senate HELP Committee to Hold Hearing on 340B Drug Discount Program

On June 19, the Senate Health, Education, Labor and Pensions Committee is scheduled to hold a hearing on the Health Resources and Services Administration's (HRSA) oversight of the 340B drug discount program. Captain Krista Pedley, Director of the agency's Office of Pharmacy Affairs, is the sole witness slated to testify. Dr. Pedley has previously testified to Congress when she appeared before the House Committee on Energy and Commerce last summer.

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

Bipartisan Bill to Lower Part D Drug Prices Introduced in the House

On May 24, Congressmen Doug Collins (R-GA) and Vicente Gonzalez (D-TX) introduced bipartisan legislation that would require that all price concessions – including discounts and rebates – between pharmacies, pharmacy benefit managers (PBMs), and Medicare Part D plan sponsors be included at the point of sale. The Phair Pricing Act of 2018 (H.R. 5958) would also prevent companies from circumventing federal regulations by compelling PBMs to disclose these concessions to CMS and by requiring the Secretary of Health and Human Services to establish quality measures for pharmacy operations.

To view the full text of the bill, [CLICK HERE](#).

To read the lawmaker's press release, [CLICK HERE](#).

CBO Report Finds President's FY 2019 Budget Would Reduce Federal Health Care Spending by \$1.3 Trillion

A new report from the Congressional Budget Office (CBO) concludes that the president's fiscal year 2019 budget would reduce federal spending on health care programs by \$1.3 trillion, or 8%, through 2028. Some of the budget proposals that would reduce federal health care spending include:

- \$954 billion reduction between 2019 and 2028 from replacing the Affordable Care Act's premium subsidies with block grants to states;
- \$143 billion reduction from proposed changes in employment-based insurance coverage, repeal of the advance premium tax credit, and the elimination of the employer mandate;
- \$63 billion reduction from placing caps on damages awarded to successful plaintiffs;
- \$59 billion reduction from requiring Medicare Part D beneficiaries to pay higher out-of-pocket expenses for certain prescription drugs; and
- \$14 billion reduction by paying all hospital-owned physician offices located off-campus at the physician office rate.

To read the full CBO analysis, [CLICK HERE](#).

Senator Bill Cassidy Presents Health Care Reform Ideas in White Paper

On May 29, Senator Bill Cassidy, MD (R-LA) released a policy white paper outlining his ideas for reforming the U.S. health care system.

The white paper, called Ideas to Make Health Care Affordable Again, outlines six key pillars for reform:

1. Empowering Patients to Reduce Their Health Costs
2. Lowering Health Insurance Premiums
3. Ending Health Care Monopolies by Increasing Competition
4. Decreasing Drugs Costs for Patients
5. Eliminating Administrative Burdens and Costs
6. Reducing Costs through Primary Care, Prevention, and Chronic Disease Management

Under the umbrella of these six pillars, Senator Cassidy made many proposals including, implementing price transparency and real time benefit analysis; allowing greater use of freestanding care centers, especially in rural areas; creating a system of tiered exclusivity for new drugs based on how innovative they are; and studying the impact of current regulations and researching how to reduce their economic cost by at least 10 percent.

To view Senator Cassidy's white paper, [CLICK HERE](#).

Report Finds Drug Spending Doubled in the Past Five Years, Expected to Double Again in the Next Five Years

On May 24, the IQVIA Institute for Human Data Science Study released its annual report on global oncology trends. The study shows spending on drugs related to cancer care has doubled from \$75,000 in 2012 to more than \$150,000 in 2017. The researchers anticipate spending to double again from current levels by 2022. Due to employer cost sharing and prescription drug rebates at the pharmacy, the average patient with commercial insurance paid less than \$500 per year for outpatient, non-retail medicines in 2017.

The report also notes that all of the 14 new cancer drugs that hit the market last year were targeted therapies, with 11 classified as breakthrough status by the FDA. After accounting for rebates, IQVIA found that the costs of brand-name and specialty drugs rose by 1.9 percent in 2017, compared to the growth in spending for all drugs, which was just 0.6 percent.

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

Senate Judiciary Committee Approves Five Bipartisan Opioid Bills

On May 24, the Senate Judiciary Committee approved five bipartisan bills aimed to address the opioid and drug overdose epidemics. They are:

- **Using Data to Prevent Opioid Diversion Act (S. 2838)**, would ensure that drug manufacturers and distributors have electronic access to the DEA's data on the total number of registered controlled substance distributors and the total amount of opioids distributed on a quarterly basis. The legislation is intended to help manufacturers and distributors identify, report and stop suspicious orders of opioids and reduce diversion.
- **Opioid Quota Reform Act (S.2535)**, would, if the DEA approves a product quota for fentanyl, oxycodone, hydrocodone, oxymorphone or hydromorphone that's higher than the previous year's quota, require the attorney general to explain why the public health benefits of increasing the quota outweigh the potential consequences of such an increase.
- **Substance Abuse Prevention Act (S.2789)**, which would establish a number of new drug prevention and treatment programs and reauthorize several others. The legislation would also direct group health plan and health plan insurance issuers to ensure appropriate access to abuse-deterrent formulations of opioids as a prescription drug health benefit under the plan.
- **Synthetic Abuse and Labelling of Toxic Substances Act of 2017 (S.207)**, would enable the Justice Department to consider additional information when determining whether a controlled substance analogue is intended for human consumption.

- **Access to Increased Drug Disposal Act (S.2645)**, would authorize a new grant program to increase participation in prescription drug take back programs, which can help reduce excess opioids that may otherwise be diverted.