

Health Policy Update – May 24, 2018

Administration Releases Drug Pricing Proposal

On May 11, President Donald Trump and Health and Human Services (HHS) Secretary Alex Azar announced the Administration's plan to lower drug costs. The drug pricing blueprint titled "American Patients First" lays out actions that HHS may take along with a Request for Information (RFI) on several policy proposals. The President's blueprint includes four key strategies for reform: improved competition, better negotiation, incentives for lower list prices and lowering out-of-pocket costs for patients.

The President's proposal directs HHS to evaluate a number of concepts including:

- Leveraging authority of the Part B Competitive Acquisition Program
- Examining which Medicare Part B drugs could be negotiated for a lower price by Part D plans
- Experimenting with value-based pricing in Medicare and Medicaid
- Allowing more substitution in Medicare Part D to address single-source generics
- Prohibiting Part D plan contracts from preventing pharmacists' telling patients when they can pay less out-of-pocket by not using insurance

The RFI requests feedback on the following proposals:

Medicare Part B:

- Changes to the Part B Competitive Acquisition Program
- Moving certain Part B drugs to Part D
- Requiring site neutrality for physician-administered drugs and between inpatient and outpatient settings

Medicare Part D:

- Requiring beneficiaries be told what their out-of-pocket cost will be prior to receiving a Part B drug or a Part D drug prescription, and whether lower-cost alternatives exist
- Restricting the use of rebates, including revisiting the safe harbor under the Anti-Kickback statute for drug rebates
- Imposing fiduciary duty for Pharmacy Benefit Managers (PBMs)
- Evaluating use of manufacturer-sponsored drug copay discount cards

340 Drug Discount Program:

- Requiring "safety net" hospitals paid under Medicare Part B to use their 340B drug discounts to provide care to more low-income and vulnerable patients
- Changing the definition of "patient", changing the requirements around contracted pharmacies or registering of child sites
- Preventing duplicate discounts

The US Oncology Network is assessing the impact of these proposals on community-based cancer care and will submit responses to HHS.

To view the American Patients First blueprint, [CLICK HERE](#).

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

CMS Releases Updated Drug Spending Dashboard

On May 15, the Centers for Medicare & Medicaid Services (CMS) rolled out a new set of updates to its Drug Spending Dashboard that, in addition to making it more user-friendly, provides new insights about Medicare's drug spending.

According to the new data, Medicare spent \$174 billion on prescription medications in 2016, about 23 percent of its total budget, which is up from the \$109 billion or 17 percent of its total budget spent in 2012. The data also shows that several drugs more than doubled in price between 2015 and 2016, although the drugs that accounted for most of the program's spending had price increases of less than 20 percent over that period.

The updated dashboard, which was originally introduced in 2014, now shows information about CMS' average spending on drugs per dosage in 2015 and 2016, as well as the annual growth rate in average spending per dosage between 2012 and 2016. For Part B drugs, the drug's average sales price is listed.

The dashboard does not include information about manufacturer rebates which are used to lower costs in Medicare Part D.

To view a fact sheet explaining the update, [CLICK HERE](#).

CMS Urges Medicare Part D Plans to Stop Using Pharmacy Gag Orders

On May 17, the Centers for Medicare & Medicaid Services (CMS) sent a letter warning Medicare Part D plans that "gag clauses" – provisions in contracts that prevent pharmacies from telling customers about lower cost options for prescription drugs – are "unacceptable and contrary to [the agency's] efforts to promote drug price transparency and lower drug prices."

The letter also reminded plan sponsors that current law requires them to ensure their network pharmacies disclose price differences between the price of a Part D drug and the price of the lowest cost generic version of that drug.

The Administration's drug pricing plan released on May 11 specifically highlights gag clauses as a contributor to high drug prices and announces that the Department of Health and Human Services (HHS) will soon act to prohibit them in future Part D plan contracts.

To view the letter from CMS, [CLICK HERE](#).

COA Survey Highlights Physician Concerns with Part B Reform Proposals

On May 16, the Community Oncology Alliance (COA) released a survey showing that a majority of physicians are concerned that recent proposals to reform the Medicare Part B drug program – particularly plans to establish a competitive acquisition program for certain drugs and shift payment for Part B drugs into Part D – will negatively impact patient care.

The survey, taken by 100 oncologists and 50 rheumatologists, found that 88 percent of providers believe that a competitive acquisition program would take care decisions away from the person in the best position to make that decision. Eighty-five percent of providers believe moving Part B drugs to Part D will create affordability issues for patients. Large majorities of respondents were also concerned that such proposals would delay patient access to treatment while increasing administrative burdens on physicians and practices.

To view the full results of the survey, [CLICK HERE](#).

House Passes Right to Try Bill, Sending it to President Trump's Desk

On May 22, the House of Representatives passed a bill that would allow terminally ill patients to access experimental treatments that have yet to be approved by the Federal Drug Administration (FDA). The bill, S.204, passed with a vote of 250-169 and now heads to the President's desk. It had already passed the Senate unanimously late last year.

President Trump has been a supporter of right-to-try, having recently urged Congress to enact the legislation in his speech unveiling the Administration's drug price plan. He is expected to sign the bill this week.

To read the right-to-try bill, [CLICK HERE](#).

House Energy & Commerce, Ways & Means Committees Advance Additional Bills to Combat Opioid Abuse

On May 17, the House Committee on Energy and Commerce passed over a dozen bills to combat the opioid crisis, among them:

- The Overdose Prevention and Patient Safety Act (H.R. 5795), which will allow providers, payers and others to more easily access patients' medical records for information about substance abuse treatment, even if the patients have not consented to disclose that information.
- A bill to partially repeal the Institutions for Mental Diseases (IMD) exclusion which prohibits federal funding for mental health and substance use disorder residential treatment facilities larger than 16 beds. States would now be allowed to remove the IMD exclusion for stays of up to 30 days for patients receiving treatment for opioid use disorder.

- Legislation to expand Medicare coverage of telehealth services for addiction treatment, require state Medicaid programs to monitor the concurrent prescribing of opioids and other drugs, and require CMS to identify and notify “outlier prescribers” who prescribe abnormal amounts of opioids.

Separately last week, the House Ways and Means Committee approved six bipartisan bills to reduce opioid abuse within the Medicare system. These include:

- The Medicare and Opioid Safe Treatment Act (H.R. 5776), which would require HHS to evaluate medication-assisted treatment options for Medicare Advantage plans, review whether Part B payments can be used to support non-opioid alternatives to pain management and educate current beneficiaries on the availability of psychological services.
- The Securing the International Mail Against Opioids Act (H.R. 5788), which require the U.S. Postal Service to share advance electronic data about its shipments with the Customs and Border Protection agency, so it can better track high-risk international mail shipments.
- Legislation that would mandate that Part D plans “lock-in” at risk beneficiaries to a single prescriber or pharmacy and allow them to suspend payments to pharmacies facing credible allegations of fraud.

The Committee also enacted legislation that directs CMS to develop a set of best practices for hospitals to reduce opioid prescribing, directs the Medicare Payment Advisory Commission (MedPAC) to issue a report on pain management in Medicare, and requires plans to educate beneficiaries about the proper disposal of unused opioids.

These bills now join the dozens of other bills passed by House Committees in recent weeks in heading to the floor for a full vote. Lawmakers expect to vote on a full package of legislation by mid-June.

To view the Energy and Commerce Committee mark-up hearing, [CLICK HERE](#).

To view the Ways & Means Committee mark-up hearing, [CLICK HERE](#).

Senate HELP Committee Hearing Examines Oversight of the 340B Drug Discount Program

On May 15, the Senate Health, Education, Labor, and Pensions (HELP) Committee held a hearing to examine recent oversight reports from the Government Accountability Office (GAO) and the Office of the Inspector General (OIG). Witnesses included representatives from OIG and GAO respectively who offered recommendations to improve accountability, transparency and oversight of the 340B drug discount program. Both witnesses applauded Congress for taking action to clarify the intent and structure of the program.

The GAO representative also revealed that the agency is preparing additional reports on the 340B program to be released this summer. Their focus will likely be on how participating hospitals work with contract pharmacies and third-party administrators and how often 340B hospitals share their discounts with patients.

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