Health Policy Update – May 10, 2018

McKesson Chairman Testifies at House Energy and Commerce Subcommittee

Hearing

On Tuesday, the House Energy and Commerce Subcommittee on Oversight and Investigations held a hearing to investigate the role of wholesale drug distributors in the opioid crisis. Witnesses included McKesson Corporation's Chairman, President, and CEO, John Hammergren.

The hearing, titled "Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion" sought to examine whether any breakdowns occurred in the closed distribution system established under the Controlled Substances Act.

Witnesses included:

- George Barrett Executive Chairman of the Board, Cardinal Health, Inc.
- Steven Collis Chairman, President, and CEO of AmerisourceBergen Corporation
- John Hammergren Chairman, President, and CEO of McKesson Corporation
- Dr. Joseph Mastandrea Chairman of the Board, Miami-Luken, Inc.
- J. Christopher Smith Former President and CEO, H.D. Smith Wholesale Drug Company

To view the hearing, <u>CLICK HERE</u>.

President Trump to Deliver Speech on Drug Pricing This Friday

On Friday, President Donald Trump is expected to deliver a much-anticipated speech announcing his Administration's plan to reduce drug costs.

While formal details of the plan have yet to be announced, it will likely address how the government pays for drugs through Medicare Part B and D, Medicaid and the 340B drug discount program. The plan will also be accompanied by an official Request for Information from the Department of Health and Human Services, asking stakeholders for input on how to control drug costs.

In its February budget proposal, the Administration outlined several ideas for how to reduce drug prices. Among them were:

- Changes to the Medicare Part D program to increase cost-sharing reductions for low-income beneficiaries and a requirement that manufacturers apply more of their rebates to reducing point of sale prices for consumers.
- Modifications to the way Medicare pays for Part B drugs, including tying reimbursement to inflation, reducing Wholesale Acquisition Cost (WAC) based payment from WAC plus 6 percent to WAC plus 3 percent, and changing the way Average Sales Price (ASP) is determined.
- A new mandate that 340B hospitals devote a portion of their drug savings to charity care.
- New authority for the HHS Secretary to move certain Part B drugs into Part D where savings could be gained through negotiation with manufacturers.

- A proposal to allow up to five state Medicaid programs to jointly negotiate lower prices from manufacturers.
- New rules to speed development of generic drugs by cracking down on manufacturers' ability to "park" generic drug applications with the FDA during an exclusivity period.

In a speech last week, HHS Secretary Alex Azar indicated that the Administration's forthcoming plan would go beyond existing proposals from February's budget.

To view a fact sheet outlining the Administration's existing drug pricing proposals from the FY2019 budget proposal, <u>CLICK HERE</u>.

HHS Secretary Azar, CMS Administrator Verma Deliver Remarks Before the American Hospital Association

This week, Health and Human Services Secretary Alex Azar and Centers for Medicare & Medicaid Services Administrator Seema Verma delivered remarks before the American Hospital Association's annual membership meeting.

Secretary Azar urged hospitals to shift more services to other, non-hospital settings, arguing that it would produce better care and saves patients money. He also touted his agency's efforts to increase price transparency by requiring hospitals to post their standard charges online. He further previewed the Trump Administration's forthcoming plans to reduce drug prices for consumers.

Administrator Verma discussed her agency's efforts to move to a "value-based" health care payment system, reform the Center for Medicare and Medicaid Innovation (CMMI), and reduce regulatory burdens facing hospitals. She also criticized the way Medicare Part B drug payments are made, saying the current structure "creates a perverse incentive for manufacturers to set higher prices, and for providers to pick drugs that are more expensive." Additionally, Verma touched on Medicare payment differentials based solely on site-of-service, stating that "whether a patient receives a therapy in one setting or another should be based on which setting is safest and most clinically appropriate – and not based on arbitrary payment differences".

To view Secretary Azar's full remarks, <u>CLICK HERE</u>.

To view Administrator Verma's full remarks, CLICK HERE.

Alliance for Site Neutral Payment Reform Applauds Republican Study Committee Budget

On May 4, the Alliance for Site Neutral Payment Reform submitted a letter to Republican Study Committee Chairman Rep. Mark Walker (R-NC) commending the group for including in its fiscal year 2019 budget proposal a provision to apply site neutral payments to all off-campus outpatient care.

Under Medicare's current payment policy, hospital outpatient departments (HOPDs) are reimbursed at significantly higher rates than independent physician practices for providing identical services. This is because HOPDs are able to

bill Medicare under the Outpatient Prospective Payment System, which pays higher rates than the Physician Fee Schedule independent practices use. While Congress enacted site neutral reforms in 2015 when it passed the Bipartisan Budget Act, it exempted existing HOPDs from having to align their payments with independent practices and allowed them to continue billing Medicare at higher rates. The Republican Study Committee budget closes that gap.

To read the Alliance's letter, <u>CLICK HERE</u>.

HRSA Delays 340B Rule for a Second Time

The Health Resources and Services Administration (HRSA) announced that it would delay a rule to set new drug ceiling prices for the 340B program until at least July 2019. The rule, which was first developed by the Obama Administration, would allow HHS to fine drug manufacturers that intentionally charge a hospital more than the set ceiling price. The agency has delayed the rule several times amid stakeholder opposition and most recently did so in mid-April of this year.

In its proposal announcing the latest delay, HRSA alluded to forthcoming policies from the Department of Health and Human Services to address drug pricing in government programs including Medicare Part B and D and the 340B drug discount program.

To read HRSA's proposal announcing the 340B rule delay, CLICK HERE.

Federal Appeals Court Hears Oral Arguments in 340B Cuts Lawsuit

A federal appeals court in the District of Columbia heard oral arguments in a lawsuit brought by several hospital trade groups challenging the Centers for Medicare and Medicaid Services' cuts to the 340B drug discount program.

In January, CMS reduced Medicare reimbursement for 340B drugs by approximately 28 percent – or \$1.6 billion annually – as part of its new initiative to save beneficiaries money on drug costs. The rate cuts are being challenged in federal court by a coalition led by the American Hospital Association, America's Essential Hospitals, the Association of American Medical Colleges and three hospitals.

Before the cuts went into effect, the court had rejected the group's lawsuit, arguing that the hospitals were not able to prove that they have been harmed by the rule change. However, the groups appealed after the cuts took effect on January 1 of this year. A ruling on the case is expected to be announced sometime this summer.

Survey Reveals ACOs Have Significant Concerns About Risk, Would Prefer to Stay in Track 1

On May 2, the National Association of ACOs (NAACOS) released the results of a survey showing that 71 percent of Medicare Shared Savings Program Track 1 Accountable Care Organizations (ACOs) are likely to leave the program as a result of having to assume risk.

The survey, which was designed to assess risk assumption and future participation plans for MSSP Track 1 ACOs, also found that respondents generally agreed on their top challenges. Almost 40 percent or respondents said that they felt the amount of risk was too great, that they had concerns about unpredictable changes to the ACO model, and that they desired more reliable financial projections. Furthermore, 76 percent of respondents said they would be "completely likely" or "very likely" to remain in Track 1 if it were an option available to them. Currently, all participants are required to move to a two-sided ACO model in their third agreement period.

To conduct the survey, researchers polled 82 ACOs that began the MSSP in 2012 or 2013 and were preparing to enter their third agreement period in 2019. Responses were collected by a web portal that was distributed over email.

To view the National Association of ACO's press release on the survey, CLICK HERE.