Friday, August 3, 2018

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Last week, the House Energy & Commerce Committee held a hearing to examine the Merit-Based Incentive Payment System (MIPS). **Read below.**

HELP Committee Passes Bill to Ban PBM 'Gag Clauses'

On July 25, the Senate HELP Committee approved a bill that would ban pharmacy benefit managers (PBMs) from implementing "gag clauses" that prevent pharmacists from telling customers when they can save money on prescriptions by paying with cash instead of insurance. **Read below.**

House E&C Committee Requests FTC Review of PBM Mergers

On July 27, House Energy & Commerce Committee Chair Greg Walden (R-OR), oversight subcommittee Chair Gregg Harper (R-MS) and health subcommittee Chair Michael Burgess (R-TX) wrote to the Federal Trade Commission (FTC) Chairman Joseph Simons requesting the commission examine how mergers affect downstream prices for consumers and whether mergers have helped PBMs save plan sponsors money. **Read below.**

FDA Proposes Changes to Clinical Trial Review

This week, FDA Commissioner Scott Gottlieb announced the agency is considering moving forward with a plan to streamline the drug approvals process by adjusting how clinical trials are reviewed. **Read below.**

Site Neutral Payments, Further Cuts to 340B Included in OPPS Proposed Rule

On July 25, the Centers for Medicare & Medicaid Services (CMS) released the 2019 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System proposed rule.

The rule, if finalized, would reduce the payment differences between sites of service for outpatient clinic visits by applying Physician Fee Schedule equivalent payment rates to all off-campus providers under OPPS. In addition to ensuring that different sites of service operate on a more level playing field, the proposed rule would extend 340B payment cuts to previously exempt off-campus providers and remove a number of reporting requirements for OPPS and ASCs.

The Alliance for Site Neutral Payment Reform, of which The Network is a founding member, issued a press release applauding the expansion of site neutral payments. "Because healthcare costs have emerged as Americans' primary financial concern, and the cost of care has been steadily rising — especially for Medicare patients with cancer — it is absolutely essential that CMS close the regulatory loopholes that drive up the costs of care," said Randy Broun, MD, president of Oncology Hematology Care. CMS estimates its plan for site neutral payments would save Medicare $610 million per year, while patients would save $150 million in copays in 2019.

To read the complete text of the proposed rule, CLICK HERE.

To read a statement from the Alliance for Site Neutral Payment Reform commending the proposed rule, CLICK HERE.

To read an op-ed by Dr. Marcus Neubauer on site neutral payment reform, CLICK HERE.

HHS Calls for Input on a Competitive Acquisition Program for Medicare Drug Procurement

On July 25, the Department of Health and Human Services released additional details about a potential future proposal to create a Competitive Acquisition (CAP) program for acquiring drugs under Medicare Part B. The request for information, which was included in the 2019 Hospital Outpatient Prospective Payment System Proposed Rule, is asking stakeholders to comment on the proposed program’s scope, beneficiary protections, types of providers to include, and the role of private sector vendors.

Under a CAP program, physicians could order Part B drugs from third-party vendors who would negotiate prices from drug manufacturers. The Medicare Payments Advisory Committee (MedPAC) recommended last year that CMS implement a CAP program known as the Drug Value Program (DVP) and use value-based purchasing agreements to acquire drugs.

The US Oncology Network, along with 180 healthcare stakeholder groups, expressed concern with the DVP's proposed reductions in Part B payment rates, use of formulary and potential impact to patient access to necessary therapies.

To view the Request for Information, CLICK HERE.

House Committees Hold Hearings on MACRA, Stark Law Reform

Last week, the House Energy & Commerce Committee held a hearing to examine the Merit-Based Incentive Payment System (MIPS). The hearing included witnesses from several medical associations who were in broad agreement that there were opportunities to reduce reporting burdens and make it easier for physicians to participate. Nearly all witnesses agreed that the program should continue and stated that they would disagree with a proposal to eliminate it. In January, the Medicare Payments Advisory Commission (MedPAC) voted to eliminate MIPS, which is now in its second year of implementation.

Separately, the House Ways and Means Committee held a hearing to solicit input on how to modernize the so called "Stark Law" that prohibits physicians from referring patients to providers in which they have a financial interest. Lawmakers from both parties agreed that the law should be reformed in order to encourage integrated, value-based care and that changes can be made that don't violate the spirit of the law.

To view the Energy & Commerce Committee hearing on MACRA, CLICK HERE.

To view the Ways & Means Committee Hearing on Stark Law Reform, CLICK HERE.

HELP Committee Passes Bill to Ban PBM 'Gag Clauses'

On July 25, the Senate HELP Committee approved a bill that would ban pharmacy benefit managers (PBMs) from implementing "gag clauses" that prevent pharmacists from telling customers when they can save money on prescriptions by paying with cash instead of insurance. The vote to advance the bill takes place as more states move to ban gag clauses and as the bipartisan movement to lower the cost of prescription drugs gains momentum.

The Patient Right to Know Drug Prices Act (S.2554), introduced by Sen. Susan Collins (R-ME) and cosponsored by a bipartisan group of Senators, would outlaw PBMs from restricting pharmacists from telling customers if they could save money by purchasing a drug directly as opposed to using insurance. While the Pharmaceutical Care Management Association, the industry group for PBMs, argues that gag clauses are rare, in a survey conducted by the National Community Pharmacists Association (NCPA) in 2016, 39 percent of pharmacists said gag clauses prevented them from telling customers about cheaper alternatives more than 10 times in the past month.

The companion bill to S.2554 in the House, H.R.6143, was referred to the House Committee on Energy & Commerce in June.

To learn more about the Patient Right to Know Drug Prices Act (S.2554), CLICK HERE.

To view the NCPA survey, CLICK HERE.

House E&C Committee Requests FTC Review of PBM Mergers

On July 27, House Energy & Commerce Committee Chair Greg Walden (R-OR), oversight subcommittee Chair Gregg Harper (R-MS) and health subcommittee Chair Michael Burgess (R-TX) wrote to the Federal Trade Commission (FTC) Chairman Joseph Simons requesting the commission examine: “(1) how these mergers affected downstream prices for consumers and (2) whether these mergers have helped PBMs save plan sponsors money."

The lawmakers note the three largest PBMs in the United States accounted for approximately 70 percent of market revenues in 2016, raising questions about higher prices and limited competition. All three – CVS Health Corporation/CVS Caremark, Express Scripts Holding Company, and UnitedHealthcare/Optum Rx – have gained market share by engaging in mergers within the last decade.

Simmons, and fellow FTC Commissioner Christine Wilson, both expressed interest in conducting retrospective merger reviews of PBMs during their Senate confirmation hearing back in February. The FTC has until August 10 to respond to the Committee’s request.

To read the complete text of the letter, CLICK HERE.

FDA Proposes Changes to Clinical Trial Review

This week, FDA Commissioner Scott Gottlieb announced the agency is considering moving forward with a plan to streamline the drug approvals process by adjusting how clinical trials are reviewed. In a series of public and social media comments, Gottlieb discussed the potential for the agency to move beyond the current three-phase format for clinical trial design and explore other options, such as compressing the three-phase process into one continuous trial and holding basket and umbrella trials that allow for testing of multiple drugs against multiple diseases.

The FDA is expected to release a guidance document later this year with further details about the plan.

To read some of Commissioner Gottlieb’s social media comments, CLICK HERE.