
Health Policy Update – September 14, 2018

240 Stakeholder Groups Call on Congress to Ask CMS to Reverse Step Therapy Proposal

This week, a coalition of patient and provider groups, led by the Part B Access for Seniors and Physicians Coalition sent a letter to Senate and House leadership calling on lawmakers to encourage CMS to reverse its proposal to allow Medicare Advantage plans to implement step therapy measures. The groups instead want CMS to consider alternative utilization management solutions that incorporate evidence-based guidelines designed with the input of medical practitioners, patients and advocates.

The groups worry that the current proposal lacks basic patient safeguards, including adequate standards and transparency that ensure step therapy policies are clinically appropriate and rooted in evidence. It also expresses concern that the proposed policy does not provide an adequate process for patients to seek exceptions to step therapy, as well as the “aggressive implementation timeline” which aims for the new policy to go into effect January 1, 2019.

To view the complete text of the group letter, [CLICK HERE](#).

CMS to Allow Indication-Based Formulary Design for Part D Plans

Last week, the Centers for Medicare & Medicaid Services (CMS) issued a guidance allowing Medicare Part D prescription drug plans to tailor their formularies to exclude certain disease indications for covered drugs - as long as the plans cover an alternative therapy for the excluded indication. Previously, plans were required to cover each on-formulary drug for all indications approved by the FDA.

This action is the next step in the Administration’s “American Patients First” drug pricing blueprint to reduce prescription drug prices through better negotiation. The Administration claims that this action will increase the number of drugs available on formularies and promote diversity of formularies. McKesson Specialty Health will continue to examine the impact of this announcement and work with CMS to ensure patients maintain access to appropriate treatment.

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

Hospital Groups Refile Lawsuit to Challenge 340B Cuts, Force Implementation of Ceiling Pricing Rule

On September 5, the American Hospital Association, the Association of American Medical Colleges, America’s Essential Hospitals and three other hospital systems refiled their lawsuit against the Trump Administration. The groups are challenging the Administration’s decision to pay separately payable, nonpass-through drugs and biologicals (other than vaccines) purchased through the 340B program at the average sales price (ASP) minus 22.5 percent rather than ASP plus 6 percent.

In July, the District of Columbia Circuit Court of Appeals threw out the case, stating that the groups did not have standing to sue at the time because the cuts had not yet taken effect when the original suit was filed. Now that the cuts have taken effect, the hospital groups petitioned the court for expedited relief.

Separately, another coalition of hospital groups filed a lawsuit aimed at challenging the Administration's delays of a January 2017 rule that would set ceiling prices for 340B drugs and fine drug manufacturers if they intentionally overcharge eligible hospitals. The Administration has repeatedly delayed this rule and has hinted that it might be doing so in order to avoid conflicting with future forthcoming 340B-related regulations.

PhRMA Report Finds Hospitals Mark-up Prescription Drugs by up to 500 Percent

A new report from the Pharmaceutical Research and Manufacturers of America (PhRMA) found that hospitals typically markup prescription drugs by about 500 percent on average. At least one in six hospitals charged prices seven times above what they originally paid for them.

The report analyzed federal cost reports from 3,800 U.S. hospitals and compared their purchase price for certain drugs with the maximum amount they can charge. However, the report also notes that insurers often pay much less than the hospital's listed sticker price, so the real mark-up for these may actually be less than 500 percent.

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

E&C Leaders Seek More Information on Role of PBMs in Impacting Drug Prices

On August 30, the House Energy & Commerce Committee sent letters to seven pharmacy benefit managers (PBMs) asking for additional information about their role in the drug supply chain. The request for stakeholders' perspectives came one month after the Committee requested the Federal Trade Commission conduct a retrospective review of PBM mergers and their effects on consumer prices.

Since PBMs serve more than 266 million Americans, the Committee is closely examining how their practices, including proposed mergers between CVS and Aetna, as well as Cigna and Express Scripts, are influencing the cost of prescription drugs.

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

House E&C Committee Advances PBM Gag Clause Ban

This week, the House Energy & Commerce Committee advanced a bill to ban pharmacy benefit managers (PBMs) from inserting so-called "gag clauses" into contracts with pharmacies (H.R. 6733). Gag clauses prevent pharmacists from informing patients about the true cost of their medications, such as when the out-of-pocket cost may be lower than their copay.

In the Senate, a bipartisan bill banning gag clauses from Medicare Advantage and Part D plans, the Know the Lowest Price Act (S. 2553), passed the chamber on September 5. A related bill, which would ban gag clauses in employer-sponsored plans, is currently awaiting amendments before it can be put to a vote.

To view H.R. 6733, [CLICK HERE](#).

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

E&C Committee Leaders Ask MedPAC to Study Hospital Consolidation

Last week, the House Energy & Commerce Committee Chair Greg Walden (R-OR) – with Congressmen Michael Burgess, MD (R-TX) and Gregg Harper (R-MS) – sent a letter requesting the Medicare Payment Advisory Commission (MedPAC) conduct research on the financial impact of hospital consolidation on patients and the Medicare system.

The letter notes the trend of hospital consolidation has been increasing in recent years, especially as large health systems purchase physician practices and convert them into hospital outpatient departments (HOPDs) and specifically calls out site neutral payment policies - which mandate that Medicare reimburse HOPDs at the same rates as other physician offices for performing the same services.

The lawmakers also want MedPAC to determine whether consolidation leads to higher patient costs.

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