

Health Policy Update – January 10, 2019

Healthcare Stakeholders Submit Comments on IPI Model

Thousands of healthcare stakeholders submitted comments to the Centers for Medicare & Medicaid Services (CMS) regarding a potential International Pricing Index Model (IPI) for Medicare Part B drugs ahead of the agency's deadline late last year. Many groups, especially those representing specialty doctors, were critical of the proposal arguing that it could compromise patient access to care if not implemented carefully.

Groups, including The US Oncology Network, the American Society of Clinical Oncology (ASCO), and the Community Oncology Alliance (COA) argued against making the demonstration project mandatory and instead offered their own solutions to bringing down prescription drug prices. In December, these groups joined a coalition of 339 patient, provider and caregiver groups, in sending [a letter to Congressional leaders](#) urging them to pressure CMS to withdraw the model.

To read The Network's comments, [CLICK HERE](#).

To read ASCO's comments, [CLICK HERE](#).

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

MedPAC Releases Comments on Proposed IPI Model

The Medicare Payment Advisory Commission (MedPAC) also submitted comments on the IPI Model for Medicare Part B drugs. The Commission commended CMS for taking concrete steps to reduce Medicare's spending on specialty drugs but expressed concerns with several elements of the agency's proposal.

Specifically, the Commission argued the third-party vendors who would be licensed by Medicare to obtain Part B drugs on the behalf of physician practices could run into difficulty obtaining drugs at a price below Medicare's set payment rate, which is necessary to keep the model financially viable. In addition, the Commission noted several transparency concerns with the methodology for calculating the International Pricing Index, which may lead it to become an unreliable method for determining international reference prices.

MedPAC also urged CMS to consider elements of its own drug pricing proposal released in 2017, the Part B drug value program, which it argues could address some of the logistical challenges presented with the IPI Model.

To read MedPAC's full comment letter, [CLICK HERE](#).

Pelosi Sworn in as Speaker of the House

On January 3, Representative Nancy Pelosi (D-CA) was elected Speaker of the House of Representatives by a margin of 220-192, defeating Republican Kevin McCarthy (CA) to retake the gavel.

In outlining House Democrats' priorities, Pelosi listed lowering health care costs, investing in green infrastructure and restoring "integrity to government." Speaker Pelosi also announced the House Rules and Budget Committees will hold hearings on Medicare for All legislation within the next few weeks.

Taking the gavel in an era of divided government, Speaker Pelosi pledged to "reach across the aisle in this chamber and across the divisions across our nation." In order to win support of reluctant members from her own party, Speaker Pelosi also promised to serve no more than four years in leadership before stepping aside.

Federal Court Strikes Down CMS 340B Drug Cuts

In late December, the U.S. District Court for the District of Columbia ruled the Centers for Medicare and Medicaid Services (CMS) had overstepped its authority when making cuts to the 340B drug discount program last year. Effective January 1, 2018, reimbursement for non-pass-through drugs and biologics purchased through the 340B drug discount program was reduced from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent.

The court was responding to a lawsuit brought against the proposal by a coalition of hospital groups led by the American Hospital Association, the American Association of Medical Colleges, and America's Essential Hospitals. The groups argued that HHS had overstepped its statutory authority and that the policy was disproportionately harming hospitals serving low income patients. Given the budget neutrality implications, both sides were ordered to submit briefs within 30 days of the ruling, after which the court will make an additional ruling on the issue of remedies.

House Ways & Means Committee Leadership Urges Greater Transparency in CMMI Reform

This week, House Ways & Means Committee Chairman Richard Neal (D-MA) and Ranking Member Kevin Brady (R-TX) sent a letter to CMS Administrator Seema Verma asking for greater transparency in the agency's plans to reform the Center for Medicare and Medicaid Innovation (CMMI) and to incorporate more input from public stakeholders throughout the process.

"We have long been advocates for healthcare innovation. However, significant policy changes made unilaterally by the executive branch without sufficient transparency could yield unintended negative consequences for beneficiaries and the health care community," the letter reads. "We strongly urge the Agency to provide more sunshine in this process."

Administrator Verma announced last year that CMMI, which was established in 2010 to test payment models meant to improve care, lower costs, and support patient-centered practices, would pursue a "new direction" under the Trump Administration aimed at increasing healthcare competition and giving providers more flexibility to implement payment models.

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

Senators Urge CMS to Establish Guardrails for Step Therapy Policy

On January 3, Senators Sherrod Brown (D-OH) and Rand Paul, MD (R-KY) sent a letter to the Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma urging the agency to implement a clear set of guardrails protecting patient access before moving forward with a proposal to allow Medicare Advantage plans to implement step therapy protocols for Part B drugs. The Senators also urged CMS to work with the beneficiary and provider stakeholder communities to determine how best to reduce any potential barriers to care.

“While we support the goal of reducing costs for beneficiaries and taxpayers by addressing the high cost of drugs paid for by the Medicare program, changes with the significance and potential to cause disruption such as step therapy must be conducted through a diligent and transparent process that includes stakeholder input,” the letter reads. “Therefore, we urge the Administration to not move forward with the proposed step therapy policy this year without adopting corresponding measures to ensure it adequately protects beneficiary access to care and does not interfere with the practice of medicine.”

CMS first issued the new guidance allowing MA plans to apply step therapy to Medicare Part B drugs last August, which took effect on January 1, 2019. Late last year, a coalition of 240 patient and provider groups sent [a letter to Senate and House leadership](#) calling on lawmakers to encourage CMS to reverse this proposal and instead consider alternative utilization management solutions designed with the input of medical practitioners, patients and advocates.

To read the letter from Senators Brown and Paul, [CLICK HERE](#).

Government Shutdown Impacts & Updates

On December 22, appropriations for approximately one quarter of the federal government lapsed, leading to a partial government shutdown.

An estimated 800,000 federal employees have been placed on furlough and an additional 420,000 have been working without pay since the shutdown began. Affected departments include the departments of Agriculture, Commerce, Justice, Homeland Security, Housing and Urban Development, Interior, State, Transportation and Treasury. Of the 21 government shutdowns since 1976, the current situation is already the second longest shutdown on record.

The partial shutdown has forced nearly 60 percent of FDA employees to be furloughed and caused the agency to further slow its hiring process, threatening to upend the drug review process. The slowdown in hiring and onboarding adds further strain to the agency, which has more than 1,400 vacant positions.

Texas ACA Case Under Appeal

On December 30, the federal judge in Texas who ruled the Affordable Care Act (ACA) unconstitutional said the law can stand while his judgment is under appeal. In his order issuing a stay, U.S. District Court Judge Reed O'Connor reiterated his belief the entire ACA is invalidated without the individual mandate penalty in effect.

Judge O'Connor's order means the ACA will likely remain in effect for at least another year. Depending on how the appeal proceeds, it also creates the possibility of a Supreme Court ruling on the case in 2020.

On January 9, the Democrat-controlled House of Representatives voted to join the appeal against the ruling, which is being led by 17 state Attorneys General.

To read the complete Order Granting Stay and Partial Final Judgment, [CLICK HERE](#).

Senate Confirms New Science Advisor and Drug Czar

On January 2, the lame-duck Senate voted to confirm Kelvin Droegemeier, a former University of Oklahoma professor, as director of the White House's Office of Science and Technology Policy. The position has been vacant since President Trump's inauguration and the office has had its staffing significantly reduced over the years.

The Senate also confirmed James Carroll to lead the Office of National Drug Control Policy, giving the White House a top drug policy adviser amid a national epidemic in which 70,000 Americans die each year from drug overdoses. Carroll has filled the role in an acting position since February.

Both confirmations took place by voice vote.