



Thursday, January 10, 2019

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MedPAC Releases Comments on Proposed IPI Model

In late December, the Medicare Payments Advisory Commission (MedPAC) submitted comments on CMS' proposed International Pricing Index (IPI) Model for Medicare Part B drugs. [Read below.](#)

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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. [Read below.](#)

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 about the agency's plans to reform the Center for Medicare and Medicaid Innovation (CMMI) and incorporate more input from public stakeholders throughout the process. [Read below.](#)

Senators Urge CMS to Establish Guardrails for Step Therapy Policy

On January 3, Senators Sherrod Brown (D-OH) and Rand Paul (R-KY) sent a letter to the Centers for Medicare & 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. [Read below.](#)

Government Shutdown Impacts & Updates

On December 22, appropriations for approximately one quarter of the federal government lapsed, leading to a partial government shutdown. [Read below.](#)

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On December 30, the federal judge in Texas who ruled the Affordable Care Act unconstitutional said the law can stand while his judgment is under appeal. [Read below.](#)

Senate Confirms New Science Advisor and Drug Czar

On January 2, the lame-duck Senate voted to confirm Kelvin Droegemeier as director of the White House Office of Science and Technology Policy, and James Carroll to lead the Office of National Drug Control Policy. [Read below.](#)

FULL STORIES

The Network Submits Comments on Proposed IPI Drug Pricing Model

On December 31, The US Oncology Network submitted formal comments on the Centers for Medicare & Medicaid Services (CMS) advanced notice of proposed rulemaking regarding a potential International Pricing Index Model (IPI) for Medicare Part B drugs. The IPI model would establish an expansive mandatory demonstration project to allow private-sector vendors to negotiate Medicare Part B drug prices to purportedly align payments with the prices paid in other countries.

“We have strong concerns regarding the IPI Model under consideration, which would fundamentally disrupt patient access to timely, personalized cancer treatment options close to home,” The Network letter states. “The proposed model could further escalate consolidation in oncology care and impede ongoing investments and efforts to transition toward value-based care delivery. **Given these concerns, The US Oncology Network urges CMS to not move forward with the IPI model.**”

The Network’s comments focused on several concerning elements of the IPI Model:

- The IPI’s mandatory participation will jeopardize the success and savings achieved from voluntary value-based payment models, like the Oncology Care Model (OCM), and make it unrealistic for CMS to extract usable data.
- Inserting a third-party vendor in the procurement and distribution of Medicare Part B drugs will disrupt Medicare patients’ access to personalized cancer treatment and introduce an unparalleled level of complexity and administrative burden for community-based providers.
- The IPI Model flat-fee does not adequately account for provider risk and operational challenges, nor does it fully account for the inherent system costs that would remain.
- The IPI Model could limit patient access to novel, innovative therapies not available in other countries.

- The disruptive elements of the IPI Model pose excessive risk and unpredictability to community-based practices and could result in providers closing their doors, further pushing patients out of the community-setting and into less convenient, more costly settings of care.
- The Network supports proven strategies such as the development of voluntary, targeted, collaborative payment models, including the OCM, and use of evidence-based treatment guidelines such as Value Pathways.

The Network will continue to work with policymakers, coalition partners and other stakeholders to oppose the IPI Model.

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

To view a one-page summary of The Network's comments, [CLICK HERE](#).

MedPAC Releases Comments on Proposed IPI Model

In late December, the Medicare Payments Advisory Commission (MedPAC) submitted comments on the Center for Medicare & Medicaid Services' (CMS) proposed International Pricing Index (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](#).

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.

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.

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

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"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, The Network joined a coalition of 240 patient and provider groups in sending [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 has have 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.