



Thursday, August 30, 2018

The Network Responds to Health Care Innovation Caucus RFI on Value-Based Provider Payment Reform

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House Energy & Commerce and Senate HELP Committee Leaders Urge Effective Administration of 340B Drug Pricing Program

On August 27, the bicameral, bipartisan leadership of the House Energy & Commerce Committee and Senate HELP Committee sent a letter to Health Resources and Services Administration (HRSA) Director Krista Pedley asking the agency to implement regulations to better administer the 340B Drug Pricing Program. **Read below.**

HHS Issues Report on Administration's Drug Pricing Actions to Date

On August 20, the Department of Health and Human Services published a report to update stakeholders on the progress made in the 100 days since President Trump released its *American Patients First* blueprint to lower drug prices. **Read below.**

Senate Passes HHS Spending Bill

On August 23, the Senate approved an \$854 billion "minibus" appropriations bill to fund several federal agencies including the Department of Health and Human Services. **Read below.**

HHS OIG issues Request for Information on Changes to Anti-Kickback Statute Safe Harbors

On August 27, the Department of Health and Human Services released its much-awaited *Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalties*. **Read below.**

Senate Plans to Act on Opioid Legislation Post-Labor Day

Senate Majority Leader Mitch McConnell (R-KY) recently indicated that the Senate will act to address the opioid epidemic soon after Labor Day. **Read below.**

The Network Responds to Health Care Innovation Caucus RFI on Value-Based Provider Payment Reform

The US Oncology Network recently responded to a Request for Information (RFI) from the U.S. House of Representative's Health Care Innovation Caucus, which sought guidance from stakeholders to inform its future efforts. The Health Care Innovation Caucus is a new, bipartisan caucus formed this year, co-chaired by Congressmen Mike Kelly (R-PA), Ron Kind (D-WI), Markwayne Mullin (R-OK) and Ami Bera, MD (D-CA), that seeks to examine innovative policy ideas that improve healthcare quality and lower costs.

In its response, The Network highlighted its members' participation in CMS' Oncology Care Model and offered recommendations for how the agency can improve its payment and delivery models to encourage greater provider participation.

The Network also urged the Caucus to consider site neutral payment policies as a way to promote innovation in the Medicare program. Medicare's current payment policy puts independent physician practices at a disadvantage in favor of large health systems, which are able to turn the freestanding physician offices they acquire into hospital outpatient departments and bill Medicare at higher rates for performing the same procedures. These practices hamper market competition, which is necessary for innovation to thrive.

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

To view The Network's Response, [CLICK HERE](#).

Congressman Erik Paulsen Visits Minnesota Oncology



On August 17, Congressman Erik Paulsen (R-MN) visited Minnesota Oncology in Edina, MN. Congressman Paulsen represents the third district of Minnesota and serves on the Ways and Means Committee. Dr. Dean Gesme led a tour of the clinic and spoke with Congressman Paulsen about issues impacting community oncology such as the 340B drug discount program and prior authorization challenges, as well as the importance of advancing site neutral payment reform.

(L-R) Dr. Dean Gesme, Congressman Erik Paulsen, and Jill Lee in Edina, MN.

House Energy & Commerce and Senate HELP Committee Leaders Urge Effective Administration of 340B Drug Pricing Program

On August 27, the bicameral, bipartisan leadership of the House Energy & Commerce Committee and Senate HELP Committee sent a letter to Health Resources and Services Administration (HRSA) Director Krista Pedley asking the agency to implement regulations to better administer the 340B Drug Pricing Program. The lawmakers note although recent judicial rulings have curtailed HRSA's rulemaking authority in some areas, it still has the power to:

- Establish a binding Administrative Dispute Resolution process to mediate certain disputes related to compliance with the 340B program requirements;
- Impose civil monetary penalties against manufacturers that knowingly and intentionally overcharge a covered entity for a drug; and
- Issue precisely defined standards for calculating 340B ceiling prices.

The lawmakers also point out that HRSA has been reluctant to use its existing rulemaking authority and expressed their disappointment that action has not come sooner.

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

HHS Issues Report on Administration's Drug Pricing Actions to Date

On August 20, the Department of Health and Human Services published a report to update stakeholders on the progress made in the 100 days since President Trump released its *American Patients First* blueprint to lower drug prices. The report highlights positive developments the Administration has made in making prescription drugs more affordable for patients.

Specifically, the report commends several drug companies for voluntarily acting to lower prices by either canceling planned increases or committing to implement price freezes through the end of the year. According to the report, there were 60 percent fewer price increases for brand drugs between May 11 through August 15, 2018, compared to the same period in 2017. There were also 54 percent more generic and brand drug price decreases than the same period in 2017.

Underscoring the Administration's commitment to boosting competition for prescription drugs, the report notes that the FDA approved a record-breaking 126 generic medications in July, more than in any single month in its history.

The report also highlights other steps the Administration has taken in effort to lower drug prices including implementing step therapy for Part B drugs in Medicare Advantage plans, updating CMS' Drug Pricing Dashboard, banning pharmacy "gag clauses," and lowering payments for drugs under the 340B discount program.

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

To read a fact sheet on the first 100 days of results, [CLICK HERE](#).

Senate Passes HHS Spending Bill

On August 23, the Senate approved an \$854 billion “minibus” appropriations bill to fund several federal agencies including the Department of Health and Human Services.

Among the most noteworthy provisions of the FY 2019 appropriations bill:

- A \$2 billion increase in funding for the National Institutes of Health (NIH)
- \$1.5 billion in grants for community health centers to expand treatment for substance use disorder (SUD)
- \$1 million in funding to implement requirements on pharmaceutical companies to disclose pricing information in direct to consumer advertisements, a key provision of President Trump’s *American Patients First* Blueprint

The Senate and the House will need to reconcile their separate appropriations bills before the end of the fiscal year on September 30.

To read the text of the bill, [CLICK HERE](#).

HHS OIG issues Request for Information on Changes to Anti-Kickback Statute Safe Harbors

On August 27, the Department of Health and Human Services released its much-awaited *Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalties*. The RFI seeks public input on potential new safe harbors to the Anti-Kickback Statute, which prohibits offering, paying, soliciting or receiving anything of value in exchange for or inducing a person to make referrals to services that are covered by federal health care programs.

This RFI comes on the heels of a similar request by CMS in June seeking public input on potential changes to the Stark Law in order to lay the groundwork for policies that promote more coordinated care and value-based payment.

The White House Office of Management and Budget (OMB) is separately reviewing a proposed rule by the HHS Inspector General on anti-kickback safe harbors for drug rebates. There could be overlap between the two as the anti-kickback law includes safe harbors relevant to beneficiary inducements. Those safe harbors allow hospitals and other providers to waive beneficiary coinsurance and deductibles, and they allow health plans to increase coverage, reduce cost sharing or reduce premiums.

Stakeholder responses to the RFI are due by October 26, 2018.

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

Senate Plans to Act on Opioid Legislation Post-Labor Day

Senate Majority Leader Mitch McConnell recently indicated that the Senate will act to address the opioid epidemic soon after Labor Day. While the House passed the SUPPORT for Patients and Communities Act (H.R. 6) in June, the Senate has yet to take up the bill or hold a vote on its own package.

Instead of taking up the House bill for consideration, the Senate is planning to combine bills approved by four Senate committees to expand access to substance use disorder treatment and prevention programs, curb the flow of illegal opioids and encourage the development of non-opioid-based pain medications

Additionally, the Senate minibus provides \$3.7 billion in funding for programs aimed at curbing the opioid epidemic, including \$500 million for NIH research to develop non-addictive pain medications, and \$1.5 billion for State Opioid Response Grants. These grants will fund prevention programs, training for health care practitioners, and medication-assisted treatment programs.

The motivation to pass opioid legislation has increased in recent weeks, as President Trump recently called on the Senate to stop the flow of illicit fentanyl – a potent synthetic opioid – into the country through the U.S. postal system.