



Tuesday, August 11, 2020

Federal Circuit Court Rules CMS Has Authority to Implement 340B Payment Cuts

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President Signs “Buy American” Executive Order for Essential Medicines

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COVID-19 Relief Package Stalls in Congress; Trump Takes Executive Action

After weeks of negotiations between the Democrat-led House, Republican-led Senate, and Administration officials, an agreement on the next stage of COVID-19 relief remains elusive. On August 8th, President Trump took targeted executive action to address some of the fallout. [Read below.](#)

The Network Responds to National Cancer Institute RFI on Cancer Care Telehealth

On July 30th, The Network responded to the National Cancer Institute's Request for Information (RFI) seeking stakeholder input on the scientific gaps and research needs related to the delivery of cancer care via telehealth. [Read below.](#)

Telehealth Update: President Signs Executive Order Expanding Telehealth Access, Legislation Gains Traction in Congress

On August 3rd, the President signed an executive order directing federal agencies to develop policies to expand patient access to telehealth services with a specific focus on rural and underserved communities. [Read below.](#)

FULL STORIES

Federal Circuit Court Rules CMS Has Authority to Implement 340B Payment Cuts

On July 31st, U.S. Court of Appeals for the District of Columbia Circuit ruled that the Centers for Medicare & Medicaid Services (CMS) has the statutory authority to reduce 340B hospitals' Medicare Part B drug reimbursement rates by 28.5 percent. The ruling reversed a federal district court decision that previously blocked implementation of the cuts, which CMS first proposed in 2017.

The 340B drug pricing program is intended to provide eligible covered entities with significant discounts on outpatient drugs yielding savings that can “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” Some

stakeholders argue the program lacks sufficient regulatory controls, increases patient out-of-pocket costs, and contributes to provider consolidation.

340B hospitals quickly denounced the decision, arguing that it will result in cutbacks in patient services during the global pandemic and beyond. Meanwhile, CMS Administrator Seema Verma praised the ruling, claiming that the 340B payment cuts resulted in \$320 million in beneficiary out-of-pocket savings in 2018 alone.

On August 4th, CMS released the 2021 hospital outpatient prospective payment system (OPPS) proposed rule which would continue the reduced payments to 340B hospitals. The rule proposes to pay for drugs acquired under the 340B program at Average Sales Price (ASP) minus 34.7 percent, plus a 6 percent add-on payment. This figure is based on average hospital savings relative to ASP using recent survey data. Comments on the OPPS proposed rule are due October 5, 2020.

To read the Appellate Court's decision in *American Hospital Association v. Azar*, [CLICK HERE](#).

To read The Network's comments on the 340B payment cuts when first proposed, [CLICK HERE](#).

To read the CMS fact sheet on the OPPS proposed rule, [CLICK HERE](#).

To read the OPPS proposed rule in its entirety, [CLICK HERE](#).

President Signs “Buy American” Executive Order for Essential Medicines

On August 6, the President signed a new executive order (EO) to accelerate the development of cost-effective, domestically-produced essential medicines and medical countermeasures. The move is part of the Administration's efforts to secure the supply chain and reduce prescription drug costs.

In addition to promoting the manufacture of essential medicines and medical countermeasures in the U.S., the EO directs government agencies to prioritize the procurement of American-made products. Agencies can circumvent this order if unable to procure sufficient quantities, if products are of an unsatisfactory quality, or if procurement costs increase by more than 25 percent. The FDA is tasked with developing the list of essential medicines and medical countermeasures within 90 days.

This EO comes on the heels of four others signed by President Trump on July 24 to reduce prescription drug costs. The most significant of these proposals is a dramatic shift in how Medicare would pay for physician-administered drugs under the Part B program. While the text of this EO has not been released and is not scheduled to take effect until August 24th (barring an alternative agreement with drug manufacturers), it would establish a “most favored nation” (MFN) system where Medicare would base Part B drug reimbursement on prices in other countries. In addition to the MFN proposal, the President signed three additional EOs concerning insulin/epinephrine prices, drug importation, and manufacturer rebates provided to pharmacy benefit managers (PBMs).

All of these EOs require further rulemaking to implement, a process which could take several months.

To view the EO on essential medicines and medical countermeasures, [CLICK HERE](#).

To read the White House fact sheet on the drug pricing EOs, [CLICK HERE](#).

To read the EO on insulin/epinephrine prices, [CLICK HERE](#).

To read the EO on drug importation, [CLICK HERE](#).

To read the EO on the manufacturer rebates to PBMs, [CLICK HERE](#).

COVID-19 Relief Package Stalls in Congress; Trump Takes Executive Action

After weeks of negotiations between the Democrat-led House, Republican-led Senate, and Administration officials, an agreement on the next stage of COVID-19 relief remains elusive. On August 8th, President Trump took targeted executive action to address some of the fallout.

Though the eviction moratorium expired July 24th and enhanced unemployment benefits expired on August 1st, lawmakers remain divided over the size and scope of another COVID-19 relief package. Many originally expressed early hope that the next COVID-19 relief measure would pass by the end of July, but it now looks unlikely a deal will be reached and passed before September. While both House Democrats and Senate Republicans have proposed legislation, each chamber has competing priorities putting the two sides trillions of dollars apart.

Amid the ongoing negotiations, President Trump signed four executive orders (EOs) over the weekend aimed at providing economic relief from COVID-19. These EOs would provide temporary payroll tax relief, reduce and extend unemployment benefits, direct the Administration to prevent residential evictions and foreclosures, and extend deferment on federal student loans. Democrats and some Republicans were quick to challenge the effectiveness and legality of the EOs, which require additional regulatory action to implement.

To view the President's COVID-19 relief EOs, [CLICK HERE](#).

The Network Responds to National Cancer Institute RFI on Cancer Care Telehealth

On July 30th, The Network responded to the National Cancer Institute's Request for Information (RFI) seeking stakeholder input on the scientific gaps and research needs related to the delivery of cancer care via telehealth.

In its response, The Network highlighted its experience with telehealth since the onset of the COVID-19 pandemic and identified several issues for policymakers to consider in the future delivery of cancer care via telehealth. Drawing from internal data as well as the results of a Network-wide practice survey, the response reported that the number of appointments conducted via telehealth increased dramatically in April 2020 and remain historically high, with the vast majority of visits conducted by medical oncologists with established patient relationships.

The Network also identified several obstacles providers faced in the transition to telehealth. For example, many patients — particularly those in rural and underserved areas — lack access to the necessary technology and bandwidth to use telehealth platforms. In discussing future opportunities for telehealth cancer research, The Network stressed the need for medical societies to develop protocols to maximize the clinical benefits of telehealth and also urged that federal, state, and payer policies be harmonized to protect patient access to these services.

To view the National Cancer Institute's RFI, [CLICK HERE](#).

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

Telehealth Update: President Signs Executive Orders Expanding Telehealth Access, Legislation Gains Traction in Congress

On August 3rd, the President signed an executive order directing federal agencies to develop policies to expand patient access to telehealth services with a specific focus on rural and underserved communities. Specifically, the order directed the federal government to:

- Review and extend temporary telehealth measures put in place during the public health emergency as well as additional provider flexibilities granted to Medicare providers.
- Launch a new payment model that gives rural providers additional flexibilities from existing Medicare rules, establishes predictable financial payments, and encourages the adoption of high-quality, value-based care.
- Develop and implement a strategy to improve rural health by improving the physical and communication healthcare infrastructure available to rural Americans.
- Submit a report to the White House with recommendations to further eliminate regulatory burdens that limit the availability of clinical professionals, develop rural-specific efforts to drive improved health outcomes, reduce maternal mortality and morbidity, and improve mental health in rural communities.

The same day, the Centers for Medicare & Medicaid Services moved to permanently expand some regulatory flexibilities related to telehealth that were enacted during the public health emergency as a part of the 2021 Medicare Physician Fee Schedule proposed rule. The proposal would permanently add a handful of services to the Medicare telehealth list while extending coverage for even more through the end of the calendar year in which the public health emergency ends.

In addition, a number of proposals to expand telehealth access have been introduced on Capitol Hill. The bipartisan Protecting Access to Post-COVID-19 Telehealth Act (H.R. 7663) – introduced by Reps. Mike Thompson (D-CA), Peter Welch (D-VT), David Schweikert (R-AZ), Bill Johnson (R-OH) and Doris Matsui (D-CA) – would extend existing telehealth waivers for 90 days after the end of the public health emergency while expanding the definition of distant sites to include Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHCs). The bill would also allow any urban or rural patient to receive telehealth services in their home.

Senate Republicans have included a provision in their COVID-19 relief proposal (known as the HEALS Act), to temporarily extend telehealth waivers through the end of 2021, while extending the health expansion for FQHCs and RHCs for five years beyond the end of the public health emergency. Another bill introduced by Senator Ron Wyden (D-OR) would allow Medicare beneficiaries to receive virtual medical and mental health services if they have met with their providers in person at least once in the prior 18 months.

To view the EO on telehealth and rural access, [CLICK HERE](#).

To view a fact sheet on the 2021 Medicare Physician Fee Schedule proposed rule, [CLICK HERE](#).

To view the 2021 Medicare Physician Fee Schedule proposed rule, [CLICK HERE](#).

To view the Protecting Access to Post-COVID-19 Telehealth Act, [CLICK HERE](#).

To view Senate Republicans' telehealth provisions in the HEALS Act, [CLICK HERE](#).

To view Senator Wyden's bill S. 4230, [CLICK HERE](#).