Health Policy Update – June 30, 2020

The Network Urges Support for Bipartisan Bill to Improve CMMI

On June 12, The Network joined over 300 groups in signing a letter to Representatives Terri Sewell (D-AL) and Adrian Smith (R-NE) expressing their strong support for H.R. 5741, the "Strengthening Innovation in Medicare and Medicaid Act." The groups praised the bipartisan legislation for addressing patient and provider concerns about the impact of the Center for Medicare and Medicaid Innovation (CMMI) demonstrations on Americans' access to quality healthcare.

Specifically, the groups commended the bill for taking steps to protect patients from potentially harmful models by liming the scope of models to only the number of participants necessary to achieve a statistically valid sample, limiting testing of new delivery and payment models to no more than five years, requiring continuous real-time monitoring of the effects of a model on beneficiaries, and establishing the opportunity for judicial review at key CMMI decision points.

In addition, H.R. 5741 would enhance transparency, improve accountability, and formalize the process of collecting and incorporating feedback from beneficiaries, providers, and other key stakeholders when developing new CMMI models. Finally, the bill would improve Congressional oversight over the expansion of CMMI models by establishing an expedited process for Congressional disapproval of demonstrations.

Taken together, these provisions would go a long way toward protecting Medicare and Medicaid patients' access to high-quality care when implementing value-based arrangements. The groups urged Congress to pass H.R. 5741 quickly.

To read the stakeholder letter of support, <u>CLICK HERE</u>.

To read the text of the Strengthening Innovation in Medicare and Medicaid Act, CLICK HERE.

Senate HELP Committee Holds Hearing on Telehealth

On June 17, the Senate Health, Education, Labor and Pensions (HELP) Committee held a hearing to examine the use of telehealth services during the COVID-19 pandemic as well as future policies related to the practice of healthcare during the pandemic. Titled, "Telehealth: Lessons from the COVID-19 Pandemic", the hearing included witnesses from both academia and industry.

Ahead of the hearing, HELP Committee Chairman Lamar Alexander (R-TN) highlighted a list of temporary policy changes that have been made since the pandemic began and expressed support for making permanent two telehealth changes. These changes include permanently repealing the so-called "originating site" rule — currently suspended since the start of the pandemic — that

restricts patients from accessing telehealth services from their homes, as well as permanently extending the policy changes that expanded the number of telehealth services covered by Medicare, such as emergency room visits. During the hearing witnesses also discussed the impact of extending the temporary Health Insurance Portability and Accountability Act (HIPAA) waivers, allowing services to be conducted by telephone, permitting telehealth across state lines, and the need for more broadband in rural areas.

Separately, a group of stakeholders comprised primarily of health plans, providers, and consumer advocates announced the formation of a taskforce to advance the use of telehealth during and after the COVID-19 pandemic. The task force was convened by the National Committee for Quality Assurance (NCQA), the Alliance for Connected Care, and the American Telemedicine Association and includes a non-voting federal liaison from HHS as well as Director of the Center for Clinical Standards & Quality at CMS. It plans to issue its first set of recommendations in September.

To view the Senate HELP Committee hearing, CLICK HERE.

To read more about the NCQA telehealth task force, CLICK HERE.

CMS Proposal Encourages 'Value- Based' Drug Payments in Medicaid

An Advanced Notice of Proposed Rulemaking issued by the Centers for Medicare and Medicaid Services on June 17 would give state Medicaid programs more flexibility to engage in value-based purchasing (VBP) arrangements with drug manufacturers and encourage private payors to adopt these arrangements as well.

The proposal makes several modifications to Medicaid's "best price" rule, which requires drug makers to give Medicaid the lowest net price for drugs offered in the U.S. after factoring in all rebates and discounts. Stakeholders have argued Medicaid's best price rule discourages manufacturers from negotiating VBP arrangements with private insurers because they would then have to extend the lowest price under these arrangements to Medicaid, which is some cases could be \$0.

For example, under current rules, if a private insurer negotiates a VBP arrangement with a drug manufacturer where it will pay \$1,000 if the drug is found to be effective for a particular patient (based on a set of pre-determined endpoints) but only \$200 if ineffective, then the manufacturer must still offer Medicaid the drug for \$200 as the "best price."

CMS's proposed changes would add flexibility to this requirement by enabling drug makers to report multiple "best prices" to Medicaid — freeing them to engage in VBP arrangements with private insurers and report "bundled sales" prices that would still ensure Medicaid gets the best price. Advocates hope that this will encourage more VBP arrangements among private payors which could then be extended to Medicaid should they be found to be effective.

"CMS's rules for ensuring that Medicaid receives the lowest price available for prescription drugs have not been updated in thirty years and are blocking the opportunity for markets to create innovative payment models," said CMS Administrator Seema Verma in a press statement. "By

modernizing our rules, we are creating opportunities for drug manufacturers to have skin in the game through payment arrangement that challenge them to put their money where their mouth is."

To view the proposal, <u>CLICK HERE</u>.

To view a CMS fact sheet on the proposal, <u>CLICK HERE.</u>

To read CMS Administrator Verma's Health Affairs blog on the proposal, CLICK HERE.

Congress Update: House Passes ACA Expansion Bill, Revives Drug Pricing Proposal

On June 29, the House passed the Patient Protection and Affordable Care Enhancement Act (H.R. 1425), a bill that would expand the Affordable Care Act's insurance premium subsidies and encourage more states to expand their Medicaid programs. The bill passed along party lines by a vote of 234 to 179. The bill is intended to give Democrats an opportunity to highlight their healthcare priorities heading into the November election, but it is not expected to be considered by the Senate.

The bill would make ACA premium subsidies available to more households by expanding eligibility beyond the current limit of 400% of the federal poverty level. The bill's Medicaid provisions would include enhanced federal funding for states that expand their programs to cover the newly eligible adult population under the ACA and reduce administrative funds for those that do not. States would be given the option to expand their Medicaid programs by raising the maximum income threshold to qualify. The bill also permanently extends federal funding for the Children's Health Insurance Program (CHIP) and allows states to cover children whose family incomes exceed current eligibility thresholds.

To offset the cost of these new programs, Democratic leaders plan to revive the Elijah E. Cummings Lower Drug Costs Now Act (HR 3) which was projected to reduce federal spending by \$500 million over 10 years. That bill, which passed the House in December, would enable Medicare to directly negotiate drug prices using international reference prices as a baseline and extend those prices to all public and private payors.

To view the full text of the Patient Protection and Affordable Care Enhancement Act, CLICK HERE.

To view a one-page summary of the bill, <u>CLICK HERE</u>.

To view a section-by-section summary of the bill, CLICK HERE.

Federal Court Rejects Challenge to Hospital Price Transparency Rule

On June 23, the U.S. District Court for the District of Columbia rejected a challenge brought by several hospital industry groups to the Department of Health and Human Services' proposed rule requiring hospitals to publicly post their negotiated rates with insurers for 300 common medical

services along with the discounted cash price they're willing to accept for those services. U.S. District Judge Carl Nichols said the rule was reasonably related to the government's interest in lowering healthcare costs and giving consumers more pricing data to help them decide on treatment.

A group of hospital trade associations led by the American Hospital Association filed a lawsuit against HHS in last year alleging the rule was arbitrary and capricious, exceeded the Department's rulemaking authority and violated the First Amendment by mandating speech that fails to directly advance a substantial government interest. Hospital groups have also criticized the rule on the grounds that it would disrupt negotiations between hospitals and insurers and could even lead to higher prices.

The rule is scheduled to take effect on Jan. 1, 2021; however, the American Hospital Association said in a statement that it plans to appeal the ruling.

To view the District Court ruling, Am. Hospitals Assoc. v. Azar, CLICK HERE.

Appeals Court Strikes Down Rule Requiring Drug List Prices in Ads

On June 16th, the United States Court of Appeals for the District of Columbia Circuit upheld a lower court's decision to reject a proposed rule by CMS to require drug manufacturers to disclose drug list prices in their television ads. The court ruled in *Merck v. HHS* that exceeded its authority in implementing the rule and that the agency cannot write rules that are based on the so-called "hoped-for trickle-down effect" to Medicare and Medicaid. For example, according to presiding judge Patricia Millett, CMS would not have the authority to ban vending machines or smoking breaks at companies that employ Medicare and Medicaid beneficiaries just because those bans would lead to lower program costs.

The ruling marks another setback for the Administration's efforts to address prescription drug prices.

To view the full ruling, **CLICK HERE**.

NCI Director Sharpless Warns Recent Decline in Cancer Screenings Could Lead to Excess Cancer Death

On June 19, *Science* published an article by Ned Sharpless, director of the U.S. National Cancer Institute that warned of thousands of "excess" cancer deaths due to delayed screenings, diagnoses, and treatment during the COVID-19 national public health emergency.

Examining only breast and colorectal cancers—diseases that account for about one-sixth of all cancer deaths in the United States—the analysis estimates that there will be 10,000 more breast and colorectal cancer deaths over the next decade than would have been expected had the COVID-19 pandemic not struck the country, causing delays in routine care. Specifically, since the coronavirus crisis began in March, there has been a roughly 75-90 percent drop in the number of colonoscopies

and mammograms performed across the country, while at the same time, there has been a dramatic drop in the number of cancer diagnoses made. Predicting that the cancers will be discovered at later stages, which make them deadlier and more difficult to treat, there will likely be a one percent increase in the number of cancer deaths over the next decade.

Since the analysis only focused on two cancers, the estimate for the excess number of cancer deaths is conservative, according to Sharpless, meaning that the true number is probably much higher.

Sharpless' study comes a week after *Cancer Epidemiology, Biomarkers & Prevention* published a study that found the cost of cancer care will rise dramatically over the next decade. By examining the Surveillance, Epidemiology, and End Results Medicare database and used claims from 2007 to 2013 to estimate costs by cancer site, phases of care and stage of diagnosis, the researchers estimate that the cost of cancer-related care will rise to \$246 billion by 2030—a 34 percent rise over current costs.

To read Sharpless' full article in Science, CLICK HERE.

To read the full article on the cost of cancer-related care in *Cancer Epidemiology, Biomarkers & Prevention*, CLICK HERE.

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