Health Policy Update – May 18, 2021

House Committees Hold Hearings on H.R. 3 as Moderate Democrats Urge Bipartisan Cooperation on Drug Pricing

On May 4 and 5, hearings were held by the House Energy & Commerce and Education & Labor Committees, respectively, on lowering prescription drug costs. Committee members heard testimony in favor of and against the Lower Drug Costs Now Act (H.R. 3) which would allow Medicare to directly negotiate drug prices. The committee also discussed H.R. 19, a Republican-sponsored bill to address prescription drug prices that does not include Medicare negotiation.

The committee hearings occurred less than a week after President Biden came out in support of Medicare drug price negotiation during a joint address to Congress, though he was criticized for failing to include the proposal in his American Families Plan. House Speaker Nancy Pelosi (D-CA) and Senate Majority Leader Chuck Schumer (D-NY) are both in favor of the bill, which passed the House in 2019 largely along party lines. But this year, with the Democrats' majority in the House much smaller than the previous Congress and a 50-50 split in the Senate, it is unclear if the bill has enough support to pass either chamber.

Just prior to the congressional hearings, a group of 10 moderate House Democrats sent a letter to Speaker Pelosi adding a new wrinkle to consideration of H.R. 3. Led by Representatives Scott Peters (D-CA) and Jake Auchincloss (D-MA), the letter stressed the need for "balance between innovation and affordability" and urged the Speaker to work collaboratively on drug pricing legislation.

"It is imperative that we pass legislation that can reach the President's desk to deliver on our promise of bringing down health care costs for the American people. To achieve this, we must garner bipartisan, bicameral support, with buy-in from a majority of Americans and stakeholders in the public and private sectors," the Democratic lawmakers wrote.

To view the Energy & Commerce hearing, CLICK HERE.

To view the Education & Labor hearing, CLICK HERE.

To read more about H.R. 3 and H.R. 19, CLICK HERE.

To view the moderate Democrats' letter, CLICK HERE.

HHS Secretary Becerra Testifies Before E&C Committee, Lawmaker Announce Plans to Include ARPA-H in Cures 2.0 Bill

HHS Secretary Xavier Becerra fielded a wide range of questions from lawmakers during a House Energy & Commerce (E&C) Health Subcommittee hearing on the Biden Administration's FY 2022 Health and Human Services budget request. The Secretary was pressed by lawmakers on subjects including surprise billing, short-term insurance plans, Medicare drug price negotiation, abortion, gun violence research, and how HHS is addressing the sharp increase in unaccompanied migrant children apprehended at the US-Mexico border.

Secretary Becerra was also asked whether HHS will extend the June 30, 2021 deadline for healthcare providers to use remaining Provider Relief Fund (PRF) dollars for unreimbursed expenses and lost revenue attributable to the COVID-19 pandemic. He indicated the department is considering extending the deadline, but he did not provide a timeline for when such a decision would be made. Secretary Becerra also noted that requests for aid outpace the availability of funds and promised that HHS will pay close attention to accountability and transparency when it distributes what's left of the $178 billion PRF. It is unclear how much money is left in the fund, as details of the most recent disbursements have yet to be made public.

Representative Fred Upton (R-MI) also made news in the hearing by announcing his intention to include the Biden Administration's ARPA-H proposal in the next version of the 21st Century Cures Act, known as Cures 2.0. Rep. Upton was the lead Republican of the first Cures Act, which was enacted in 2016 with overwhelming bipartisan support.

The Biden Administration's FY 2022 budget request includes $6.5 billion to establish the new agency, to be known as the Advanced Research Projects Agency for Health (ARPA-H), within the National Institutes of Health (NIH). The agency would be tasked with driving "transformational innovation" in the areas of cancer care as well as other chronic diseases including Alzheimer's and diabetes. President Biden touted the project as a "DARPA for health" and part of a bipartisan effort to "end cancer as we know it" during his joint address to Congress. More details are expected on the APRA-H proposal in the president's full budget request due for release May 27.

The first draft of the Cures 2.0 bill, which is being written by Rep. Upton alongside Rep. Diana DeGette (D-CO) is planned for later this year. While the 2016 bill was focused on the NIH and the FDA, this legislation is expected to focus on care delivery, innovative payment models, and improving the use of information technology in health care.

To view the E&C Committee hearing, CLICK HERE.

Biden Administration Supports Using TRIPS Waiver to Lift COVID-19 Vaccine Patents

U.S. Trade Representative Katherine Tai announced on May 5 that the Biden Administration will support a proposal before the World Trade Organization (WTO) that would waive intellectual property protections for COVID-19 vaccines and therapies and allow for generic production.

The proposal to waive certain intellectual property protections under the international Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for COVID-19 related drugs and products was proposed last year to the WTO by the governments of India and South Africa with the support of more than 100 countries as well as hundreds of public health advocacy groups and NGOs. The waiver is opposed by several countries including the European Union, the United Kingdom, Japan, Switzerland and Canada.

Following the United States' announcement, the Director General of the WTO urged member states to move forward to text-based discussions on the waiver in an effort to reach a compromise among member states, a process that is likely to take months. Unanimous support among all WTO members will be necessary for any final agreement.

The Biden Administration's endorsement of the TRIPS waiver was met with a harsh response from the pharmaceutical industry. "In the midst of a deadly pandemic, the Biden Administration has taken an unprecedented step that will undermine our global response to the pandemic and compromise safety. This decision will sow confusion between public and private partners, further weaken already strained supply chains and foster the proliferation of counterfeit vaccines," said Stephen Ubl, president of Pharmaceutical Researchers and Manufacturers of America (PhRMA) in a statement.

Critics have also argued that the TRIPS waiver would do little to increase the immediate production of COVID-19 vaccines and therapies as current supply issues are mostly the result of a lack of manufacturing capacity and a shortage of raw materials. They also argue that weakening IP protections would threaten innovation and make it more difficult to respond to future pandemics.

Some groups have expressed optimism that the Biden Administration's stance on TRIPS bodes well for the prospects of withdrawing a Trump-era rule that limits the government's ability to exercise domestic patent march-in rights under the Bayh-Dole Act. Some advocates have urged the Administration to use march-in rights as a way to bring down drug prices by licensing the generic production of certain high-priced drugs that have little competition.

To view the U.S. Trade Representative's announcement, CLICK HERE.

To view PhRMA's statement in response, CLICK HERE.

Study: Physician Practice Consolidation Associated with Higher Medicare Costs

On May 5, *Health Affairs* released a new report on the impact of physician group consolidation. The study reveals new evidence about how vertical integration and payment disparities across sites of service lead to higher Medicare expenditures. In analyzing all Medicare fee-for-service claims data between 2013 and 2016, the researchers discovered that the monthly number of diagnostic imaging tests performed in a hospital setting grew, as did the number of hospital-based laboratory tests. At the same time, the number of monthly tests performed outside the hospital setting decreased significantly. Because the average Medicare reimbursement rose by $6.38 for imaging tests and $0.57 for laboratory tests, Medicare spent an additional $40.2 million and $32.9 million during the entire study period.

On May 6, the American Medical Association (AMA) released the results of a new survey, which found that less than half of all physicians in the United States worked in a private practice in 2020. The previous survey, conducted in 2018, found that 54% of respondents said they worked primarily in a private, physician-owned practice. The results show the largest 2-year decline since the AMA started administering the survey in 2012. The new survey also found a significant increase in the number of physicians working in practices with 50 or more physicians (17.2% in 2020, up from 14,7% in 2018), indicating an increase in vertical consolidation in healthcare.

To read the *Health Affairs* study, CLICK HERE.

To read the AMA Physician Practice Benchmark Survey, CLICK HERE.

CMS Sends Warning to Hospitals Not Complying with Price Transparency Rules

On May 7, a spokesperson for the Centers for Medicare & Medicaid Services (CMS) confirmed that the agency has begun sending warning letters to hospitals breaking new federal rules requiring them to make public the prices they negotiate with insurers. Though hospitals are supposed to comply with the new price transparency regulations that went into effect on January 1, roughly two-thirds of the largest hospitals in the U.S. have yet to post a consumer-friendly and machine-readable list of services they provide online, according to a recent *Health Affairs* study.

Though CMS recently issued guidance that it will enforce the rules against hospitals who fail to make machine-readable files available, many health systems are still out of compliance, prompting CMS to start issuing warning letters in April. Hospitals will have 90 days to correct the issues outlined in the warning letters or face fines up to $300 per day.

While the executive branch looks to enforce existing financial transparency regulations, nonprofit hospitals have separately turned to Congress to request federal funds through the Community Project Funding program. Under a new agreement that again authorizes the use of congressional earmarks, each Member of Congress is permitted to request up to ten projects for non-profit entities in their

district in upcoming appropriations bills. The House Appropriations Committee will then decide what projects will receive a portion of the $14 billion in discretionary funds. According to an analysis by *Fierce Healthcare*, lawmakers have requested millions of dollars for non-profit hospitals. If appropriated, the funds would be used to invest in community health centers and rural clinics, purchase new equipment and innovative technology, and improve mobile units, according to explanations accompanying the requests.

To read the *Health Affairs* study, CLICK HERE.

To view the list of projects Members of Congress requested for Community Project Funding, CLICK HERE.

To read the *Fierce Healthcare* analysis of non-profit hospital appropriations requests, CLICK HERE.

Analysis Shows Emerging Crisis of Undiagnosed Cancers as the Pandemic Enters its Second Year

On May 4, the nonprofit newsroom *ProPublica* published an exposé about the impact of the COVID-19 pandemic on cancer care. Noting that the number of preventative cancer screenings fell by as much as 94% in the first four months of 2020, the article details how many Americans have developed undiagnosed or untreated cancers during the pandemic. As hospitals and oncologists were forced to suspend biopsies, screenings, chemotherapy, and radiation treatments, Americans risked developing later stage cancers and other complications resulting from delayed treatment.

In June 2020, the National Cancer Institute estimated that there would be approximately 10,000 excess deaths over the next 10 years from just breast and colorectal cancer. Now the severity of the delay in care is being felt—particularly by Black and Latino Americans who are already disproportionately impacted by cancer deaths.

To read the *ProPublica* article, CLICK HERE.

To read the National Cancer Institute report on excess cancer deaths, CLICK HERE.

Stakeholders Share Feedback on ONC Interoperability, Info-Blocking Rules

Thursday, May 6 was the last day for stakeholders to submit comments to the HHS about a proposed rule to reform the Health Insurance Portability and Accountability Act (HIPAA). More than 1,400 providers, information technology firms, and patient advocate groups submitted comments, largely

agreeing on the benefits of making it easier to share patients' health information yet differing on the scope of the proposed rule and patient safeguards.

Healthcare providers broadly supported the changes outlined in the proposed rule because it would help them improve interoperability, care coordination, and patient management, but expressed concern that patient data could be made vulnerable since app developers are not covered by HIPAA. Conversely, app developers urged HHS to broaden the proposed privacy rule, saying that it runs counter to the 21st Century Cures Act and the Office of the National Coordinator for Health Information Technology's information blocking rules.

On May 3, Micky Tripathi, head of HHS' Office of the National Coordinator, which regulates the nation's health information technology framework, discussed the importance of moving forward with interoperability in an interview with Healthcare Dive. In discussing the importance of advancing interoperability in the nation's healthcare infrastructure, Director Tripathi suggested the federal government has no plans to again delay the compliance deadlines, as was done twice during the Trump Administration. Currently, that deadline is 18 months away. Tripathi also said he expects a final rule on information blocking to be published by the end of 2021.

To read the proposed modifications to the HIPAA Privacy Rule, CLICK HERE.

To read the comments submitted by stakeholders, CLICK HERE.

To read ONC Director Micky Tripathi's interview in *Healthcare Dive*, CLICK HERE.