



## Health Policy Briefing

February 27, 2023

### DEA Releases Proposed Rule to Scale Back COVID-Era Telehealth Policies

The Drug Enforcement Administration (DEA) has released a proposed [rule](#) to reinstate requirements that a patient see a doctor in-person before being prescribed certain controlled substances like Adderall and Oxycontin. These requirements had been waived for the duration of the COVID-19 pandemic. Providers would be permitted to prescribe an initial 30-day supply of buprenorphine for opioid use disorder, testosterone for gender affirming care, and ketamine for depression, but patients would then need to visit the provider in-person to continue their medications. Patients who began a covered medication during the pandemic would be given a 180-day grace period to comply with the in-person visit requirements. If finalized, the new regulation would go into effect when the COVID-19 public health emergency ends on May 11. The proposed rule will be open for public comment for 30 days.

### GOP Health Leaders Request Transparency on Medicare Drug Negotiation Implementation

Republican health committee leaders have sent a [letter](#) to the U.S. Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services regarding the \$3 billion fund created by the Inflation Reduction Act for the implementation of new drug pricing measures. “We write to request information and regular updates on how the Biden administration plans to allocate, apply, and monitor this staggering sum moving forward,” the letter states. “By sidestepping regular order and bypassing the standard appropriations process, proponents of the IRA set aside billions in taxpayer dollars with no reporting requirements or tools to prevent waste, fraud, and abuse.” The lawmakers request updates on projected spending over the next decade so that Congress can appropriately adjust the IRA’s statutory spending level. The letter was signed by Senate Finance Committee Ranking Member Mike Crapo (R-Idaho), House Energy and Commerce Committee Chair Cathy McMorris Rodgers (R-Wash.), and House Ways and Means Committee Chair Jason Smith (R-Mo.). They request a response from the administration by March 24.

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## Bilirakis, Tonko Launch Longevity Science Caucus

Reps. Gus Bilirakis (R-Fla.) and Paul Tonko (D-N.Y.) announced their formation of the Longevity Science Caucus last week. The group will work to promote aging technology and research in response to the decline in the nation's life expectancy and to "support science and research that will enable people to live fuller and healthier lives." Caucus membership includes Reps. Michael Burgess (R-Texas), Dan Crenshaw (R-Texas), and Anna Eshoo (D-Calif.), all members of the House Energy and Commerce Committee.

## McClellan Sworn-In to House of Representatives; Lee and Cicilline Announce Future Plans

Rep. Jennifer McClellan (D-Va.) was sworn in as a member of the House of Representatives last week. She was elected to fill the only vacant seat in Congress. She succeeds the late Donald McEachin (D), who passed away in late November 2022. McClellan is an attorney and a 17-year state legislator. Her campaign for the House seat focused on expanding access to health care and protecting voting rights, the environment, and abortion services. She is the first Black woman to be elected to Congress from the state of Virginia.

Rep. Barbara Lee (D-Calif.) announced that she is joining the race to fill the Senate seat being vacated by Sen. Dianne Feinstein in 2024. Lee, a member of the House Appropriations and Budget committees, joins Reps. Katie Porter (D-Calif.) and Adam Schiff (D-Calif.) in running for Feinstein's seat. Rep. David Cicilline (D-R.I.) announced that he will retire from the House of Representatives on June 1. Cicilline plans to become head of the Rhode Island Foundation. He currently serves as a member of the Judiciary Committee and Foreign Affairs Committee.

## Warren Leads Letter on Keytruda Patents

Sen. Elizabeth Warren (D-Mass.) has sent a [letter](#) to the U.S. Patent and Trademark Office (USPTO) asking the agency to investigate Merck & Co.'s requests for new patents on its cancer treatment Keytruda. Merck is looking to patent a new self-injectable form of the drug. Warren expresses concerns that the company may be trying to use the patent system to prevent competition and urges USPTO Director Kathi Vidal to reject any requests that do not clearly meet the agency's standards of novelty, utility, and non-obviousness. "Should the USPTO approve new patent applications for the drug, biosimilar competitors could be shut out of the market until 2036, giving Merck a total period of nearly 35 years of patent protection for Keytruda," Warren argues. The letter was cosigned by Sen. Bernie Sanders (I-Vt.) and Reps. Katie Porter (D-Calif.) and Pramila Jayapal (D-Wash.).

## Democrats Urge Administration to Address "Junk" Health Plans

A group of Senate Democrats have sent a [letter](#) to HHS Secretary Xavier Becerra asking the administration to take immediate action to address the availability of short-term, limited duration health insurance plans that violate the Affordable Care Act. The letter expresses concerns about individuals who will lose Medicaid coverage gained during the COVID-19 pandemic as state programs begin their redetermination processes. Without additional protections, "many Americans could find themselves enrolled in junk plans that do not provide comprehensive coverage or protection for individuals with pre-existing conditions," the letter states. "It is past time for your department to step up and address the expansion and proliferation of junk plans."

## Wyden, Warren Request Info on McKinsey Hospital Guidance

Sens. Ron Wyden (D-Ore.) and Elizabeth Warren (D-Mass.) have sent a [letter](#) to McKinsey & Co. criticizing the consulting firm's guidance to nonprofit hospitals, which they argue would take financial advantage of low-income patients. A recent report from the New York Times found that McKinsey was paid \$45 million by non-profit hospital Providence Health to create a plan to use predatory tactics to pressure patients into paying for their care, no matter their income or ability to pay. "We write to seek a greater understanding of the full scope of McKinsey's partnerships with nonprofit hospitals and the extent to which vulnerable patients may be exploited by them," the lawmakers state.

## Upcoming Congressional Hearings and Markups

House Veterans' Affairs Committee hearing "Building an Accountable VA: Applying Lessons Learned to Drive Future Success;" 2:00 p.m.; February 28

House Energy and Commerce Subcommittee on Innovation, Data, and Commerce hearing "Promoting U.S. Innovation and Individual Liberty through a National Standard for Data Privacy;" 8:30 a.m.; March 1

Senate Health, Education, Labor, and Pensions Committee hearing "Community Health Centers: Saving Lives, Saving Money;" 10:00 a.m.; March 2

House Veterans Affairs Committee hearing "Veterans Health Information Systems and Technology Architecture (VistA);" 3:00 p.m.; March 7

Senate Health, Education, Labor, and Pensions Committee hearing "Taxpayers Paid Billions for It: So Why Would Moderna Consider Quadrupling the Price of the COVID Vaccine?" 10:00 a.m.; March 22

House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies public witness hearing; March 23

## Recently Introduced Health Legislation

H.R.1092 — To strengthen the use of patient-experience data within the benefit-risk framework for approval of new drugs; Sponsor: Matsui, Doris O. [Rep.-D-CA-7]; Committees: House - Energy and Commerce

H.R.1090 — To amend the Federal Food, Drug, and Cosmetic Act to enhance medical device communications and ensure device cleanliness; Sponsor: Lieu, Ted [Rep.-D-CA-36]; Committees: House - Energy and Commerce

H.R.1089 — To require directors of medical centers of the Department of Veterans Affairs to submit annual fact sheets to the Secretary of Veterans Affairs on the status of such facilities, and for other purposes; Sponsor: Lesko, Debbie [Rep.-R-AZ-8]; Committees: House - Veterans' Affairs

H.R.1080 — To provide for the reinstatement or compensation of Federal employees forced to resign their careers between September 9, 2021, and January 24, 2022, because of the Federal COVID-19 vaccination mandate, and for other purposes; Sponsor: Gaetz, Matt [Rep.-R-FL-1]; Committees: House - Oversight and Accountability; Ways and Means

H.R.1079 — To amend title XIX of the Social Security Act to implement a minimum work requirement for able-bodied adults enrolled in State Medicaid programs; Sponsor: Gaetz, Matt [Rep.-R-FL-1]; Committees: House - Energy and Commerce

H.R.1074 — To amend title XIX of the Social Security Act to allow for greater State flexibility with respect to excluding providers who are involved in abortions; Sponsor: Cloud, Michael [Rep.-R-TX-27]; Committees: House - Energy and Commerce

H.R.1072 — To amend the Public Health Service Act to authorize supplemental awards to health centers to establish community transformation hubs; Sponsor: Clarke, Yvette D. [Rep.-D-NY-9]; Committees: House - Energy and Commerce

H.R.1066 — To require the Secretary of Health and Human Services to issue and disseminate guidance to States to clarify strategies to address social determinants of health under the Medicaid program and the Children's Health Insurance Program, and for other purposes; Sponsor: Blunt Rochester, Lisa [Rep.-D-DE-At Large]; Committees: House - Energy and Commerce

H.R.1110 — To direct the Secretary of Health and Human Services, the Medicare Payment Advisory Commission, and the Medicaid and CHIP Payment and Access Commission to conduct studies and report to Congress on actions taken to expand access to telehealth services under the Medicare, Medicaid, and Children's Health Insurance programs during the COVID-19 emergency; Sponsor: Balderson, Troy [Rep.-R-OH-12]; Committees: House - Energy and Commerce; Ways and Means

H.R.1113 — To streamline enrollment in health insurance affordability programs and minimum essential coverage, and for other purposes; Sponsor: Bera, Ami [Rep.-D-CA-6]; Committees: House - Energy and Commerce; Ways and Means

H.R.1114 — To provide for optimized care, a coordinated Federal Government response, public education, and insurance reimbursement guidance for Long COVID, and for other purposes; Sponsor: Blunt Rochester, Lisa [Rep.-D-DE-At Large]; Committees: House - Energy and Commerce

H.R.1117 — To implement certain recommendations to promote the inclusion of pregnant and lactating women in clinical research, and for other purposes; Sponsor: Castor, Kathy [Rep.-D-FL-14]; Committees: House - Energy and Commerce

H.R.1126 — To make improvements in prenatal and maternal care, and for other purposes; Sponsor: Fischbach, Michelle [Rep.-R-MN-7]; Committees: House - Energy and Commerce

H.R.1128 — To amend title XVIII of the Social Security Act to permit States to designate without any mileage limitations facilities that are located in rural areas as critical access hospitals; Sponsor: Green, Mark E. [Rep.-R-TN-7]; Committees: House - Ways and Means

H.R.1129 — To direct the Secretary of Health and Human Services to revise regulations to remove the requirement under the Medicare program that an off-campus facility or organization shall be located within a 35-mile radius of a hospital or critical access hospital; Sponsor: Green, Mark E. [Rep.-R-TN-7]; Committees: House - Energy and Commerce; Ways and Means

H.R.1144 — To direct the Secretary of Veterans Affairs to develop a strategy for telehealth furnished by the Veterans Health Administration and submit a report on end-user devices distributed by the Secretary to veterans to facilitate such telehealth; Sponsor: Rosendale Sr., Matthew M. [Rep.-R-MT-2]; Committees: House - Veterans' Affairs