



MEMORANDUM

March 25, 2019

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Subcommittee Markup

On **Wednesday, March 27, 2019, at 10:00 a.m. in the John D. Dingell Room, 2123 of the Rayburn House Office Building**, the Subcommittee on Health will hold a markup of the following 12 bills: **H.R. 1781**, the “Payment Commission Data Act of 2019”; **H.R. 938**, the “Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act of 2019”; **H.R. 1520**, the “Purple Book Continuity Act of 2019”; **H.R. 1503**, the “Orange Book Transparency Act of 2019”; **H.R. 1499**, the “Protecting Consumer Access to Generic Drugs Act of 2019”; **H.R. 965**, the “Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019”; **H.R. 1385**, the “State Allowance for a Variety of Exchanges (SAVE) Act”; **H.R. 1386**, the “Expand Navigators’ Resources for Outreach, Learning, and Longevity (ENROLL) Act of 2019”; **H.R. 1425**, the “State Health Care Premium Reduction Act”; **H.R. 987**, the “Marketing and Outreach Restoration to Empower (MORE) Health Education Act of 2019”; **H.R. 986**, the “Protecting Americans with Preexisting Conditions Act of 2019”; and **H.R. 1010**, A bill to provide that the rule entitled “Short-Term, Limited Duration Insurance” shall have no force or effect.

I. H.R. 1781, PAYMENT COMMISSION DATA ACT OF 2019

H.R. 1781, the “Payment Commission Data Act of 2019”, introduced by Reps. Carter (R-GA), O’Halloran (D-AZ), Rice (R-SC), Panetta (D-CA), Gianforte (R-MT), and Welch (D-VT), would provide the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) with access to drug pricing and rebate data under Medicare Parts B and D, as well as under Medicaid. MedPAC and MACPAC are independent, nonpartisan commissions that advise Congress on issues affecting the Medicare and Medicaid programs. Currently, MedPAC and MACPAC lack access to this drug pricing data and are limited in their ability to analyze and provide information on related topics to Congress, such as issues related to prescription drug costs. H.R. 1781 would ensure the Commissions have access to this data in order to analyze and report to Congress on these issues.

II. H.R. 938, the “BLOCKING ACT OF 2019”

H.R. 938, the “Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act of 2019”, introduced by Reps. Schrader (D-OR) and Carter (R-GA), would discourage parking of 180-day exclusivity by a first generic applicant. It allows the Food and Drug Administration (FDA) to approve a subsequent generic application prior to the first applicant’s first date of commercial marketing when the following four conditions have all been met: (1) the subsequent application is ready for full approval; (2) a minimum of 30 months has passed since at least one first applicant submitted their application for the drug; (3) any related patent litigation has been fully resolved; and (4) no first applicant has received final approval.

III. H.R. 1520, the “PURPLE BOOK CONTINUITY ACT OF 2019”

H.R. 1520, the “Purple Book Continuity Act of 2019”, introduced by Subcommittee Chair Eshoo (D-CA), would amend the Public Health Service Act to codify publication of approved biological products in the Purple Book in a similar format and with similar requirements to the Orange Book, specify that the Purple Book should be published electronically on FDA’s website and updated routinely, and direct FDA to consider the types of patents that should be listed in the Purple Book.

IV. H.R. 1503, the “ORANGE BOOK TRANSPARENCY ACT OF 2019”

H.R. 1503, the “Orange Book Transparency Act of 2019”, introduced by Rep. Kelly (D-IL), would help to ensure that the Orange Book is accurate and up-to-date, by requiring manufacturers to share complete and timely information with FDA, as well as ensuring that patents listed in the Orange Book are relevant to the approved drug product. Patents found to be invalid through a court decision or a decision by the Patent Trial and Appeal Board would be required to be removed promptly. FDA is also directed to reconsider the types of patents that should be listed in the Orange Book within one year of enactment.

V. H.R. 1499, the “PROTECTING CONSUMER ACCESS TO GENERIC DRUGS ACT OF 2019”

H.R. 1499, the “Protecting Consumer Access to Generic Drugs Act of 2019”, introduced by Rep. Rush (D-IL), would make it illegal for brand-name and generic drug manufacturers to enter into agreements in which the brand-name drug manufacturer pays the generic manufacturer to keep a generic equivalent off the market.

VI. H.R. 965, the “CREATES ACT OF 2019”

H.R. 965, the “Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019”, introduced by Reps. Cicilline (D-RI), Sensenbrenner (R-WI), Nadler (D-NY), Collins (R-GA), Welch (D-VT), and McKinley (R-WV), would establish a process by which generic manufacturers could request that FDA authorize them to obtain sufficient quantities of samples for testing. The bill would allow a generic manufacturer facing delay tactics to bring an

action in federal court to obtain the samples it needs. Courts would be authorized to award monetary damages sufficient to deter future gaming. It would also clarify FDA's discretion to allow generic manufacturers to operationalize equivalent safety protocols in a separate system instead of entering a shared safety protocol with brand manufacturers, provided that such separate protocol meets the same safety standard as the original system.

VII. H.R. 1385, the "SAVE ACT"

H.R. 1385, the "State Allowance for a Variety of Exchanges (SAVE) Act", introduced by Reps. Kim (D-NJ) and Fitzpatrick (R-PA), would provide states with \$200 million in federal funds to establish state-based marketplaces.

VIII. H.R. 1386, the "ENROLL ACT OF 2019"

H.R. 1386, the "Expand Navigators' Resources for Outreach, Learning, and Longevity (ENROLL) Act of 2019", introduced by Rep. Castor (D-FL), would fund the Navigator program for the federally-facilitated Marketplace (FFM) at \$100 million per year. The bill would require the Department of Health and Human Services (HHS) to ensure that Navigator grants are awarded to organizations with a demonstrated capacity to carry out the duties specified in the ACA and would reinstate the requirement that there be at least two Navigator entities in each state. The legislation would further give Navigators new duties pertaining to enrolling individuals in Medicaid and the Children's Health Insurance Program, and it would allow Navigators to provide their services year-round. Lastly, the bill would prohibit HHS from taking an entity's capacity to provide information regarding association health plans or short-term, limited duration insurance (STLDI) into account in awarding grants.

IX. H.R. 1425, the "STATE HEALTH CARE PREMIUM REDUCTION ACT"

H.R. 1425, the "State Health Care Premium Reduction Act", introduced by Reps. Craig (D-MN) and Peters (D-CA), would provide \$10 billion annually to states, with the option for states to establish a state reinsurance program or to provide financial assistance for individuals enrolled in qualified health plans by reducing their out-of-pocket costs. The bill further requires the Centers for Medicare and Medicaid Services (CMS) to establish and implement a reinsurance program in states that do not apply for federal funding. The bill sets a state's allocation amount based on the state's share of claims of high-cost enrollees.

X. H.R. 987, the "MORE HEALTH EDUCATION ACT OF 2019"

H.R. 987, the "Marketing and Outreach Restoration to Empower (MORE) Health Education Act of 2019", introduced by Rep. Blunt Rochester (D-DE), would require HHS to conduct consumer outreach and enrollment educational activities for the ACA marketplaces. The legislation would fund these activities at \$100 million per year. The bill further prohibits HHS from expending the funds on promoting plans that do not provide comprehensive consumer protections, including STLDI plans and association health plans.

XI. H.R. 986, THE “PROTECTING AMERICANS WITH PREEXISTING CONDITIONS ACT OF 2019”

H.R. 986, the “Protecting Americans with Preexisting Conditions Act of 2019”, introduced by Reps. Kuster (D-NH), Beyer (D-VA), and Courtney (D-CT), would revoke the Section 1332 guidance issued by the Trump Administration on October 2018. The bill would also prevent the Secretaries of HHS and Treasury from promulgating any substantially similar guidance or rule.

XII. HR 1010, A BILL TO PROVIDE THAT THE RULE ENTITLED “SHORT-TERM, LIMITED DURATION INSURANCE” SHALL HAVE NO FORCE OR EFFECT

H.R. 1010, introduced by Reps. Castor (D-FL) , Barragán (D-CA), Horsford (D-NV), Moore (D-WI), Underwood (D-IL), and DeSaulnier (D-CA), would overturn the STLDI final rule, giving it no force or effect. These plans are not required to comply with any of the ACA’s consumer protections, such as guaranteed issue, community rating, and essential health benefits, and expanding them raises premiums and undermines the individual market.