U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

March 25, 2019

TO: Republican Members

FROM: Republican Committee Staff

RE: Subcommittee on Health Markup

I. INTRODUCTION

The Subcommittee on Health will meet in open markup session on Wednesday, March 27, 2019, in 2123 of the Rayburn House Office Building, and subsequent days as necessary, to consider the following legislation:

1. **H.R. 1781,** Payment Commission Data Act of 2019;
2. **H.R. 938**, BLOCKING Act of 2019;
3. **H.R. 1520**, Purple Book Continuity Act of 2019;
4. **H.R. 1503,** Orange Book Transparency Act of 2019;
5. **H.R. 1499**, Protecting Consumer Access to Generic Drugs Act of 2019;
6. **H.R. 965,** CREATES Act of 2019;
7. **H.R. 1385**, SAVE Act;
8. **H.R. 1386**, ENROLL Act of 2019;
9. **H.R. 1425**, State Health Care Premium Reduction Act;
10. **H.R. 987**, "MORE Health Education Act;
11. **H.R. 986**, Protecting Americans with Preexisting Conditions Act of 2019; *and*
12. **H.R. 1010**, A bill to provide that the rules entitled "Short-Term, Limited Duration Insurance.

II. BACKGROUND

1. H.R. 1781, Payment Commission Data Act of 2019

H.R. 1781, introduced by Rep. Carter and O'Halleran amend titles XVIII and XIX of the Social Security Act to provide the Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission with access to certain drug rebate information. H.R. 1781 would make a technical update to the statute regarding information CMS may provide to the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment Advisory Commission (MACPAC). The commissions already receive a wide swath of data from CMS regarding the Medicare, Medicaid, and CHIP programs, including proprietary information, such as that relating to plan bids under Medicare Advantage. In letters to the Committee, the commissions have been advised by CMS that due to current statute, the commissions cannot access drug rebate data. Since the commissions can still provide recommendations on these issues to Congress, the bill would provide the commissions access to this data, so that any such recommendations for Medicare and Medicaid beneficiaries are informed by factual data. The

rules regarding the sharing of such information from CMS with the commissions would be held to the same confidentiality standards under which similar data is treated.

2. H.R. 938, Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2019, or the BLOCKING Act

The first generic to file a substantially complete application under a paragraph (iv) certification can be granted 180 days of exclusivity to sell their product without other generic competition. This 180-day period was established to incentivize generics to challenge the patent of the brand and thus have generics come to market quicker. Some "first filers" receive "tentative" approval of their application, but delay receiving "final" approval and thus delay the start of the 180-day exclusivity clock and subsequent generic approvals.

H.R. 938, the BLOCKING Act, makes the tentative approval of a subsequent generic drug applicant that is blocked solely by a first applicant's 180-day exclusivity, where the first applicant has not yet received final approval, a trigger of the first applicant's 180-day exclusivity.

3. H.R. 1520, Purple Book Continuity Act of 2019

H.R. 1520, the Purple Book Continuity Act, codifies the requirement to list: name of biologic; date of licensing; studies necessary for biosimilar applications; updates every 30 days; patents disclosed during "patent dance"; and withdrawal or suspension of licensure. The bill also requires FDA to report recommendations of what patents should be listed in the Purple Book going forward.

4. H.R. 1503, Orange Book Transparency Act of 2019

H.R. 1503, the Orange Book Transparency Act, codifies the current requirement to list drug substance patents, drug product patents, and method-of-use patents; allows the listing of other patents at agency discretion; and prohibits the listing of drug-delivery device patents. It further requires manufacturers to notify FDA of any court decision finding a patent invalid and requires that FDA remove those patents from the Orange Book.

5. H.R. 1499, Protecting Consumer Access to Generic Drugs Act of 2019

Under Hatch-Waxman, when submitting a generic drug application, the prospective generic can make one of four certifications related to the patents on the products. A paragraph (iv) certification states that a patent is invalid or would not be infringed by the generic product. Paragraph (iv) certifications often start patent litigation. In some instances, the litigation results in a settlement where the brand manufacturer pays some amount to the generic manufacturer and agrees that the generic manufacturer can enter the market at a date prior to the expiration of the challenged patent, but later than they would have if the patent were found invalid ("pay-for-delay"). H.R. 1499, the Preserve Access to Affordable Generics and Biosimilars Act, would amend the Federal Trade Commission Act to create a presumption that these agreements are anticompetitive.

In the 2013 case, *FTC v. Actavis*, the Supreme Court held that a branded drug manufacturer's reverse payment to a generic competitor to settle patent litigation can, depending on the facts of an individual case, violate the antitrust laws. Since that time there has been a steady decrease in these settlements. The Federal Trade Commission reported in November 2017 that only 5 of the 170 final settlements in FY2015 included compensation to the generic and a restriction on generic entry.

During the legislative hearing, witnesses indicated that this legislation could delay patient access to generics and biosimilars. Furthermore, witnesses raised concerns that this legislation as drafted would apply retroactively to agreements that were legal when entered into but would be subject to a presumption of illegality if this bill were enacted.[1]

6. H.R. 965, Creating and Restoring Equal Access to Equivalent Samples Act of 2019, or CREATES Act

Under H.R. 965, the CREATES Act, an eligible product developer can file suit against a license holder of a FDA-approved drug or biological product alleging the license holder has declined to provide a sufficient quantity of the covered product on "commercially reasonable, market-based terms." If the developer prevails, it receives samples of the product and may be awarded damages up to all revenue earned by the brand manufacturer on the relevant product for the period of time starting at the request for samples until settlement.

During the legislative hearing, witnesses with expertise in generic drug policy noted a lack of awareness of any federal statute that allows for recapture of a company's revenue, rather than profit, derived from anticompetitive behavior.[2]

7. H.R. 1385, State Allowance for a Variety of Exchanges Act, or SAVE Act

This bill provides $200 million for states to establish State-based Marketplaces (SBMs). The bill is not paid for.

PPACA provided states with the option of building their own SBM or utilizing the FFM.[3] An unlimited authorization and appropriation was made available to states in the form of grants for the planning and establishment of SBMs. No funding was awarded after December 31, 2014, in accordance with the law. In 2018, 11 states and the District of Columbia operated SBMs.[4]

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[1] *Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 116th Cong. 1 (2019) (question of Rep. Fred Upton).
[2] *Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 116th Cong. 1 (2019) (question of Rep. Greg Gianforte).
[3] P.L. 111-148, as amended by P.L. 111-152.
[4] Henry J. Kaiser Family Foundation. "State Health Insurance Marketplace Types, 2018." Retrieved on March 3, 2019, from: https://www.kff.org/health-reform/state-indicator/state-health-insurance-marketplace-types/?activeTab=map&currentTimeframe=0&selectedDistributions=marketplace-type&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

This same year, five states operated on a State-based Marketplace-Federal Platform (SBM-FP) while six states operated on a State-Partnership Marketplace (SPM).[5] According to the Congressional Research Service (CRS), 17 states were awarded roughly $4.5 billion in grants to plan and establish grants.[6]

The Committee on Energy and Commerce issued a Majority Staff report entitled, "Implementing Obamacare: A Review of CMS' Management of the State-Based Exchanges," on September 13, 2016.[7] Among the report's key findings in 2016:

- CMS is not confident that the remaining SBEs will be sustainable in the long term.
- As of September 2016, every SBE still relies upon federal establishment grant funds – 20 months after SBEs were to be self-sustaining by law.
- CMS eased the transition for failed SBEs to join HealthCare.gov by allowing them to keep user fees collected by insurance carriers intended to pay for the use of HealthCare.gov.

8. H.R. 1386, Expanding Navigators' Resources for Outreach, Learning, and Longevity Act of 2019

This legislation redirects $100 million annually from the exchange user fee program to the Navigator program. CMS recently proposed reducing the Federally-facilitated marketplace (FFM) exchange user fee from 3.5 to 3.0 percent, prior to the introduction of H.R. 1386.[8]

PPACA established the Navigator program and enrollment education to provide guidance to enrollees, inform consumers of Open Enrollment Periods, and notify potential enrollees about ways to sign up for coverage.[9] For plan year 2017, Navigators received a total of $62.5 million in grants and enrolled 81,426 individuals,[10] which accounted for fewer than one percent of total enrollees. Meanwhile, according to CMS, "By contrast, agents and brokers assisted with 42 percent of [Federally Facilitated Exchange (FFE)] enrollment for plan year 2018, which cost the

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[5] Henry J. Kaiser Family Foundation. "State Health Insurance Marketplace Types, 2018." Retrieved on March 3, 2019, from: https://www.kff.org/health-reform/state-indicator/state-health-insurance-marketplace-types/?activeTab=map&currentTimeframe=0&selectedDistributions=marketplace-type&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[6] Congressional Research Service. "Overview of Health Insurance Exchanges." June 20, 2018. https://www.crs.gov/Reports/R44065#_Toc524344378.

[7] Committee on Energy and Commerce. "Implementing Obamacare: A Review of CMS' Management of the State-Based Exchanges." September 13, 2016. https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/analysis/20160916Review_of_CMS_Management_of_the_State_Based_Exchanges_0.pdf

[8] Centers for Medicare and Medicaid Services. "Proposed rule. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020. January 17, 2019. https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-00077.pdf.

[9] P.L. 111-148, as amended by P.L. 111-152.

[10] Centers for Medicare and Medicaid Services. "CMS Announcement on ACA Navigator Program and Promotion for Upcoming Open Enrollment." August 31, 2017. https://www.cms.gov/newsroom/press-releases/cms-announcement-aca-navigator-program-and-promotion-upcoming-open-enrollment.

FFE only $2.40 per enrollee to provide training and technical assistance."[11] For this reason, Navigator grantees received funding for plan year 2018 based on their ability to reach enrollment goals for the previous year.

9. H.R. 1425, State Health Care Premium Reduction Act

This bill provides $100 billion over 10 years for states to establish reinsurance programs, strictly for individuals enrolled in PPACA's QHPs. The bill is not paid for, nor does it contain a state match or state allocation formula, delegating the latter to the HHS Secretary like the transitional reinsurance program did. Finally, the bill does not include language affirming the long-standing consensus that federal dollars should not pay for abortion services.

Congress has taken recent steps to provide states with reinsurance opportunities. In the 115th Congress, the House-passed H.R. 1628, the American Health Care Act of 2017, included the Patient and State Stability Fund.[12] This provision would have provided states with the flexibility and resources to cut out-of-pocket costs like premiums and deductibles, promote access to health care services, and repair insurance markets. For states that chose not to access the available funding, the federal government would have established and implemented a reinsurance program. In addition to reinsurance, the Patient and State Stability Fund's uses of funds included: helping high-risk individuals enroll in health insurance coverage; promoting participation in the individual market and small group market; and providing assistance to reduce out-of-pocket costs, such as copyaments, coinsurance, premiums, and deductibles. The fund included a modestly phased-in state match as well as a state allocation formula based on each state's previously incurred claims. The Patient and State Stability Fund was fully paid for and included language affirming the long-standing consensus that federal dollars should not pay for abortion services.

10. H.R. 987, Marketing and Outreach Restoration to Empower Health Education Act of 2019

This bill would provide $100 million annually for outreach and education. The money is strictly available for outreach and education about PPACA's qualified health plans (QHPs) and is restricted for promoting association health plans (AHPs) and short-term, limited-duration insurance (STLDI) plans. The proposal is not paid for.

The Centers for Medicare and Medicaid Services (CMS) allocated $10 million to outreach and education for plan year 2018, consistent with promotional spending levels on Medicare Advantage and Medicare Part D. While CMS devoted more than $100 million to

[11] Centers for Medicare and Medicaid Services. "CMS Announces New Funding Opportunity Announcement for the Federally-Facilitated Exchange Navigator Program." July 10, 2018. https://www.cms.gov/newsroom/press-releases/cms-announces-new-funding-opportunity-announcement-federally-facilitated-exchange-navigator-program.
[12] H.R. 1628, 115th Congress. 2017.

outreach and education for plan year 2017, or roughly twice as much as for plan year 2015, first-time enrollment numbers declined by 42 percent.[13]

According to CMS, for plan year 2019, the Trump Administration "…sent over 700 million reminder emails and text messages to consumers, as well as 3.2 million outreach emails to help Navigators, agents, and brokers assist consumers."[14]

11. <u>H.R. 986, Protecting Americans with Preexisting Conditions Act of 2019</u>

This legislation would invalidate the Trump Administration's guidance for 1332 Waivers for State Innovation.

Section 1332 of the Patient Protection and Affordable Care Act (PPACA) established Waivers for State Innovation beginning January 1, 2017.[15] These waivers give the Secretary of HHS and the Secretary of the Treasury the discretion to grant states new flexibility within their health care markets as long as the model provides coverage that is as comprehensive, affordable, covers a comparable number of residents, and is budget neutral to the federal government. If approved, the state may receive funding equal to the amount of forgone federal financial assistance that would have been provided to its residents pursuant to specified PPACA programs, known as pass-through funding. An approved waiver can remain in place for five years and can be renewed.

The updated guidance focused on loosening restrictions limiting state flexibility and consumer choice and providing flexibility for states to meet the legislative authority standard. More specifically, the modernized guidance centers on the availability of comprehensive and affordable coverage, expands the definition of coverage to include short-term plans, and clarifies that existing state legislation providing statutory authority to enforce PPACA may satisfy the requirement that each state enact a law to apply for and receive a 1332 waiver.

To date, eight states have active waivers, all of which were approved under the Obama Administration guidance.[16] Among these states, for 2018 alone: Alaska experienced a 26 percent premium reduction, Minnesota saw their rate increase reduced to 11.3 percent, significantly less than their 2017 57 percent increase; and, Oregon rate changes ranged from -1.6 to 14.8 percent, dropping to a range of -9.6 to 10.1 percent for 2019.[17]

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[13] Centers for Medicare and Medicaid Services. "CMS Announcement on ACA Navigator Program and Promotion for Upcoming Open Enrollment." August 31, 2017. https://www.cms.gov/newsroom/press-releases/cms-announcement-aca-navigator-program-and-promotion-upcoming-open-enrollment.
[14] Centers for Medicare and Medicaid Services. "CMS Releases Final Snapshot for the 2019 Federal Exchange Open Enrollment Period." January 3, 2019. https://www.cms.gov/newsroom/press-releases/cms-releases-final-snapshot-2019-federal-exchange-open-enrollment-period.
[15] [15] P.L. 111-148, as amended by P.L. 111-152
[16] Center for Consumer Information and Insurance Oversight. "Section 1332: State Innovation Waivers." https://www.cms.gov/cciio/programs-and-initiatives/state-innovation-waivers/section_1332_state_innovation_waivers-.html#Section%201332%20State%20Application%20Waiver%20Applications.
[17] Jack O'Brien. Health Leaders. "ACA Reinsurance Waivers Provide Relief from Premium Hikes." November 27, 2018. https://www.healthleadersmedia.com/finance/aca-reinsurance-waivers-provide-relief-premium-hikes.

12. H.R. 1010, To provide that the rule entitled "Short-Term, Limited Duration Insurance" shall have no force or effect

This legislation would invalidate the Trump Administration's STLDI plan rule.

In coordination with the Department of Labor and the Department of the Treasury, HHS revised the Obama Administration regulations limiting STLDI plans from 12-months to three months by allowing the plans to be available to consumers for up to 364 days and renewable up to 36 months.[18]

The Trump Administration regulation aims to provide relief from rising premiums and expand access affordable health care plans. According to CMS, "[i]n the fourth quarter of 2016, a short-term, limited-duration policy cost approximately $124 a month compared to $393 for an unsubsidized ACA-compliant plan."[19] The Administration projected roughly 100,000 to 200,000 individuals would move from PPACA-compliant plans to STLDI. These more affordable plans may be attractive options for individuals who are between jobs, cannot afford PPACA coverage, or cannot continue to see their doctor because they are out of network.

III. REPUBLICAN STAFF CONTACTS

If you have any questions regarding this hearing, please contact Danielle Steele, J.P. Paluskiewicz, or Adam Buckalew of the Republican Committee staff at (202) 225-3461.

[18] 26 CFR Part 54, 29 CFR Part 2590, 45 CFR Parts 144, 146, and 148
[19] Centers for Medicare and Medicaid Services. "Fact Sheet: Short-Term, Limited-Duration Insurance Proposed Rule." February 20, 2018. https://www.cms.gov/newsroom/fact-sheets/fact-sheet-short-term-limited-duration-insurance-proposed-rule.