

May 15, 2018

TO: Members, Committee on Energy and Commerce  
FROM: Committee Majority Staff  
RE: Full Committee Markup

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## **I. INTRODUCTION**

The Committee on Energy and Commerce will meet in open markup session on Thursday, May 17, 2018, at 10:00 a.m. in 2123 Rayburn House Office Building to consider the following:

### Public Health Service Act

1. H.R. 3692, Addiction Treatment Access Improvement Act of 2017;
2. H.R. 4684, Ensuring Access to Quality Sober Living Act of 2018;
3. H.R. 5329, Poison Center Network Enhancement Act of 2018;
4. H.R. 5580, STOP Fentanyl Deaths Act of 2018;
5. H.R. 5587, Peer Support Communities of Recovery Act;
6. H.R. 5795, Overdose Prevention and Patient Safety Act;
7. H.R. 5807, Substance Use Disorder Coordination, Access, Recovery Enhancement (SUD CARE) Act of 2018;
8. H.R. 5812, Creating Opportunities that Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies Act (CONNECTIONS) Act;

### Medicare Part B

9. H.R. 5590, Opioid Addiction Action Plan Act;
10. H.R. 5603, Access to Telehealth Services for Opioid Use Disorder;
11. H.R. 5605, Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act;
12. H.R. 5798, Opioid Screening and Chronic Pain Management Alternatives for Seniors Act;
13. H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act;
14. H.R. 5809, Postoperative Opioid Prevention Act of 2018;

### Medicare Part D

15. H.R. 5715, Strengthening Partnerships to Prevent Opioid Abuse Act;
16. H.R. 5716, Commit to Opioid Medical Prescriber Accountability and Safety for Seniors (COMPASS) Act;
17. H.R. 5796, Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment (REACH OUT) Act of 2018;

### Medicaid

18. H.R. 1925, At-Risk Youth Medicaid Protection Act of 2017;

19. H.R. 3192, CHIP Mental Health Parity Act;
20. H.R. 4005, Medicaid Reentry Act;
21. H.R. 4998, Health Insurance for Former Foster Youth Act;
22. H.R. 5477, Rural Development of Opioid Capacity Services Act;
23. H.R. 5583, Requiring Medicaid Programs to Report on All Core Behavioral Health Measures;
24. H.R. 5789, To amend title XIX of the Social Security Act to provide for Medicaid coverage protections for pregnant and postpartum women while receiving inpatient treatment for a substance use disorder;
25. H.R. 5797, IMD CARE Act;
26. H.R. 5799, Medicaid DRUG Improvement Act;
27. H.R. 5800, Medicaid IMD ADDITIONAL INFO Act;
28. H.R. 5801, Medicaid PARTNERSHIP Act;
29. H.R. 5808, Medicaid Pharmaceutical Home Act of 2018;
30. H.R. 5810, Medicaid Health HOME Act;

*Federal Food, Drug, and Cosmetic Act*

31. H.R. 5228, Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act;
32. H.R. 5752, Stop Illicit Drug Importation Act of 2018;
33. H.R. 5806, 21st Century Tools for Pain and Addiction Treatments; and
34. H.R. 5811, To amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes.

In keeping with Chairman Walden's announced policy, Members must submit any amendments they may have two hours before they are offered during this markup. Members may submit amendments by email to [peter.kielty@mail.house.gov](mailto:peter.kielty@mail.house.gov). Any information with respect to an amendment's parliamentary standing (e.g., its germaneness) should be submitted at this time as well.

## II. LEGISLATION

*Public Health Service Act*

1. **H.R. 3692, Addiction Treatment Access Improvement Act of 2017:** H.R. 3692, authored by Rep. Paul Tonko (D-NY) and Rep. Ben Ray Lujan (D-NM), will expand access to medication-assisted treatments (MAT) by allowing clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists to prescribe buprenorphine and permanently authorize all non-physician providers to prescribe buprenorphine. In addition, the bill would codify regulations that increased the cap on the number of patients a waived-practitioner can treat with buprenorphine to 275 patients.
2. **H.R. 4684, Ensuring Access to Quality Sober Living Act of 2018:** H.R. 4684, authored by Rep. Judy Chu (D-CA), Rep. Mimi Walters (R-CA), Rep. Gus Bilirakis (R-FL), and Rep. Raul Ruiz (D-CA), will authorize the Substance Abuse and Mental Health Services

Administration to develop, publish, and disseminate best practices for operating recovery housing that promotes a safe environment and sustained recovery from SUD.

3. **H.R. 5329, Poison Center Network Enhancement Act of 2018:** H.R. 5329, authored by Rep. Susan Brooks (R-IN) and Rep. Eliot Engel (D-NY), will reauthorize the national network of Poison Control Centers, which offer free, confidential, expert medical advice 24 hours a day, 7 days a week, oftentimes serving as the primary resource for poisoning information, and helping reduce ER visits through in-home treatment. Over two million poisonings are reported annually to poison control centers.<sup>1</sup> The National Poison Data System has reported year over year increases in all analgesic exposures, including opioids and sedatives, with 9,039 opioid exposures reported to poison control centers in one month alone.<sup>2</sup>
4. **H.R. 5580, STOP Fentanyl Deaths Act of 2018:** H.R. 5580, authored by Rep. Anne Kuster (D-NH), will authorize grants to Federal, state, and local agencies for the establishment or operation of public health laboratories to detect fentanyl, its analogues, and other synthetic opioids.
5. **H.R. 5587, Peer Support Communities of Recovery Act:** H.R. 5587, authored by Rep. Ben Ray Lujan (D-NM) and Rep. Bill Johnson (R-OH), will enhance the Comprehensive Addiction and Recovery Act's Building Communities of Recovery Program and authorize the Department of Health and Human Services to award grants to peer support specialist organizations for the development and expansion of recovery services. Peer support specialists/peer recovery coaches are health workers who are in recovery from SUD. New programs are emerging across the country to use peers in a range of settings, including hospitals, to provide immediate and ongoing support and treatment linkages to individuals who have overdosed from opioids, or support individuals newly in recovery.
6. **H.R. 5795, Overdose Prevention and Patient Safety Act:** H.R. 5795, authored by Rep. Earl Blumenauer (D-OR) and Rep. Markwayne Mullin (R-OK) will align the use of substance use disorder (SUD) treatment records with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of treatment, payment, and healthcare operations between covered entities. H.R. 5795 will also enhance the penalties in the event of a disclosure of SUD treatment records, add breach notification requirements, and provide strong discrimination prohibitions to protect people seeking and receiving SUD treatment.
7. **H.R. 5807, Substance Use Disorder Coordination, Access, Recovery Enhancement (SUD CARE) Act of 2018:** This legislation, authored by Rep. Markwayne Mullin (R-OK) and Rep. Earl Blumenauer (D-OR), will expand access to MAT by extending the authorization for nurse practitioners and physician assistants to prescribe buprenorphine by ten years, pushing the expiration back from October 1, 2021 to October 1, 2028. The legislation will

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<sup>1</sup> Gummin DD, Mowry JB, Spyker DA, Brooks DE, Fraser MO, Banner W, 2016 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 34th Annual Report. *Clinical Toxicology*. 55: 1072-1252 (2017). Available at <https://www.ncbi.nlm.nih.gov/pubmed/29185815>.

<sup>2</sup> American Association of Poison Control Centers. "Opioid Exposures." January 1, 2018. Available at <http://www.aapcc.org/alerts/opioids/>.

also permit a waived-practitioner to immediately start treating 100 patients at a time with buprenorphine (skipping the initial 30 patient cap) if the practitioner has board certification in addiction medicine or addiction psychiatry; or if practitioner provides MAT in a qualified practice setting. Finally, the legislation will align the use of SUD treatment records with HIPAA for the purposes of treatment, payment, and healthcare operations between covered entities. H.R. 5795 will enhance the penalties in the event of disclosure SUD treatment records, add breach notification requirements, and provide strong discrimination prohibitions to protect people seeking and receiving SUD treatment.

8. **H.R. 5812, Creating Opportunities that Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies Act (CONNECTIONS) Act:** This legislation, authored by Rep. Morgan Griffith (R-VA) and Rep. Frank Pallone (D-NJ), will improve current Federal support for state-run prescription drug monitoring programs (PDMPs). The bill authorizes the Centers for Disease Control and Prevention to carry out certain controlled substances overdose prevention and surveillance activities in order to improve data collection and integration into physician clinical workflow so that timely, complete, and accurate information will get into the hands of providers and dispensers so that they can make the best clinical decisions for their patients.

#### Medicare Part B

9. **H.R. 5590, Opioid Addiction Action Plan Act:** This bill, authored by Rep. Adam Kinzinger (R-IL), Rep. Yvette Clarke (D-NY), Rep. Darin LaHood (R-IL), and Rep. Danny Davis (D-IL), will establish an action plan, including studies, reports to Congress authored by HHS, as well as meetings with stakeholders, for the purpose of addressing the opioid crisis.
10. **H.R. 5603, Access to Telehealth Services for Opioid Use Disorder:** This bill, authored by Rep. Doris Matsui (D-CA), Rep. Tony Cardenas (D-CA), and Rep. Bill Johnson (R-OH), will instruct the Centers for Medicare and Medicaid Services (CMS) to evaluate the utilization of telehealth services in treating substance use disorder.
11. **H.R. 5605, Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act:** This bill, authored by Rep. Raul Ruiz (D-CA), will create a demonstration project for an Alternative Payment Model for treating substance use disorder. This model includes the development of measures to evaluate the quality and outcomes of treatment.
12. **H.R. 5798, Opioid Screening and Chronic Pain Management Alternatives for Seniors Act:** This bill, authored by Rep. Larry Bucshon (R-IN), Rep. Debbie Dingell (D-MI), and Rep. Erik Paulsen (R-MN), will add a review of current opioid prescriptions and, as appropriate, a screening for opioid use disorder as part of the Welcome to Medicare initial examination.
13. **H.R. 5804, Post-Surgical Injections as an Opioid Alternative:** This bill, authored by Rep. John Shimkus (R-IL), Rep. Raja Krishnamoorthi (D-IL), and Rep. Peter Roskam (R-IL), will seek to incentivize post-surgical injections as a pain treatment alternative to opioids by

reversing a reimbursement cut for these treatments in the Ambulatory Service Center setting, as well as collect data on a subset of codes related to these treatments.

**14. H.R. 5809, Postoperative Opioid Prevention Act of 2018:** This bill, authored by Rep. Scott Peters (D-CA) and Rep. Larry Bucshon (R-IN), will create a pass through payment to encourage the development of non-opioid drugs for post-surgical pain management in Medicare.

#### Medicare Part D

**15. H.R. 5715, Strengthening Partnerships to Prevent Opioid Abuse Act:** This bill, authored by Rep. James Renacci (R-OH), Rep. Terri Sewell (D-AL), Rep. Brett Guthrie (R-KY), and Rep. Scott Peters (D-CA), will help facilitate communication among Medicare Advantage (MA) organizations, Part D plan sponsors, and CMS relating to substantiated fraud, waste, and abuse investigations.

**16. H.R. 5716, Commit to Opioid Medical Prescriber Accountability and Safety for Seniors (COMPASS) Act:** This bill, authored by Rep. Peter Roskam (R-IL), Rep. John Larson (D-CT), Rep. Susan Brooks (R-IN), and Rep. Peter Welch (D-VT), will require CMS to establish a prescriber threshold based on specialty and geographic area, which could designate a prescriber as an outlier opioid prescriber. CMS would then be responsible for notifying prescribers identified as outliers of their status.

**17. H.R. 5796, Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment (REACH OUT) Act of 2018:** This bill, authored by Rep. Brian Fitzpatrick (R-PA), Rep. Carlos Curbelo (R-FL), and Rep. Mike Thompson (D-CA), will direct CMS to work with eligible entities, including Quality Improvement Organizations, to engage in outreach with prescribers identified as clinical outliers to share best practices to evaluate their prescribing behavior.

#### Medicaid

**18. H.R.1925, At-Risk Youth Medicaid Protection Act of 2017:** This bill, authored by Rep. Tony Cárdenas (D-CA) and Rep. Morgan Griffith (R-VA), requires state Medicaid programs not to terminate a juvenile's medical assistance eligibility because the juvenile is incarcerated. A state may suspend coverage while the juvenile is an inmate, but must restore coverage upon release without requiring a new application unless the individual no longer meets the eligibility requirements for medical assistance.

**19. H.R. 3192, CHIP Mental Health Parity Act:** The bill authored by Rep. Joseph P. Kennedy (D-MA), requires state Children's Health Insurance Programs (CHIP programs) to cover mental health benefits. All state CHIP programs currently cover such benefits.

**20. H.R. 4005, Medicaid Reentry Act:** The bill, authored by Rep. Paul Tonko (D-NY), allows Medicaid payment for medical services furnished to an incarcerated individual during the 30-day period preceding the individual's release. The Committee expects a bipartisan

amendment that requires the Secretary to convene a stakeholder group that will produce a report of best practices for states to consider in health care related transitions for inmates of public institutions.

- 21. H.R. 4998, Health Insurance for Former Foster Youth Act:** The Patient Protection and Affordable Care Act (PPACA) enabled former foster youth who are in care by their 18th birthday and previously enrolled in Medicaid to receive healthcare until the age of 26. However, PPACA did not extend Medicaid coverage to former foster youth if they move out of state. This bill, authored by Rep. Karen Bass (D-CA), would enable such youth to receive Medicaid coverage if they moved to a different state. The Committee expects a bipartisan amendment that would revise the underlying policy and also direct CMS to publish guidance on how states can remove barriers, track coverage status, and conduct outreach to this population.
- 22. H.R. 5477, Rural Development of Opioid Capacity Services Act:** The bill, authored by Rep. Tom O'Halleran (D-AZ), requires CMS to carry out a demonstration project to provide an enhanced Federal matching rate for state Medicaid expenditures related to the expansion of substance-use treatment and recovery services targeting provider capacity.
- 23. H.R. 5583, Requiring Medicaid Programs to Report on All Core Behavioral Health Measures:** The bill, authored by Rep. Yvette Clarke (D-NY), requires state Medicaid programs to report on the 11 behavioral health measures that are included in CMS's 2018 Core Set of Adult Health Care Quality Measures for Medicaid.
- 24. H.R. 5789, To amend title XIX of the Social Security Act to provide for Medicaid coverage protections for pregnant and postpartum women while receiving inpatient treatment for a substance use disorder:** This bill, authored by Reps. Bill Foster (D-IL) and Brett Guthrie (R-KY), improves access to inpatient treatment services for women with substance use disorder who are pregnant or who are suffering from postpartum depression.
- 25. H.R. 5797, IMD CARE Act:** The bill, authored by Rep. Mimi Walters (R-CA), allows state Medicaid programs from FY2019 through FY2023 to remove the Institutions for Mental Diseases (IMD) exclusion for Medicaid beneficiaries aged 21-64 with a opioid use disorder. This bill improves the continuum of care by removing a barrier to care under current law, so Medicaid would pay for up to 30 total days of care in an IMD during a 12-month period and eligible individuals can get the care they need.
- 26. H.R. 5799, Medicaid DRUG Improvement Act:** The bill, authored by Rep. Marsha Blackburn (R-TN), builds on current state Medicaid drug utilization review activities to help combat the opioid crisis. Under the bill, state Medicaid programs will be required to have safety edits in place for opioid refills, monitor concurrent prescribing of opioids and certain other drugs, and monitor antipsychotic prescribing for children.

- 27. H.R. 5800, Medicaid IMD ADDITIONAL INFO Act:** The bill, authored by Rep. Fred Upton (R-MI), directs the Medicaid and CHIP Payment and Access Commission (MACPAC) to conduct a study on institutions for mental disease that receive Medicaid reimbursement. The study shall report on the requirements and standards that state Medicaid programs have in place for IMDs. MACPAC, considering input from stakeholders, shall summarize the findings and make recommendations on best practices and data collection. The report is due no later than January 2020.
- 28. H.R. 5801, Medicaid PARTNERSHIP Act:** The bill authored, by Rep. Morgan Griffith (R-VA), requires the Medicaid program in each state to integrate prescription drug monitoring act (PDMP) usage into a Medicaid provider's clinical workflow and require such providers to check the PDMP before prescribing a Schedule II controlled substance. The bill also establishes standard criteria that a PDMP must meet to be counted as a qualified PDMP and requires state Medicaid programs to report to CMS on several PDMP issues.
- 29. H.R. 5808, Medicaid Pharmaceutical Home Act of 2018:** The bill, authored by Rep. Bilirakis (R-FL), requires all state Medicaid programs to have a beneficiary assignment program that identifies Medicaid beneficiaries at-risk for substance use disorder and assigns them to a pharmaceutical home program. The pharmaceutical home program must set reasonable limits on the number of prescribers and dispensers that beneficiaries may utilize.
- 30. H.R. 5810, Medicaid Health HOME Act:** This bill, authored by Rep. Leonard Lance (R-NJ) and Rep. Peter Welch (D-VT), will improve the state option for Medicaid health homes under current law that improve the coordination of, and access to care for Medicaid beneficiaries with substance use disorder. The bill extends the enhanced matching rate for qualified activities from eight quarters to 10 quarters.

*Federal Food, Drug, and Cosmetic Act*

- 31. H.R. 5228, Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act:** This bill, authored by Rep. Frank Pallone (D-NJ), will provide the Food and Drug Administration (FDA) with stronger recall and seizure authority to disrupt the entry of counterfeit and illicit drugs through International Mail Facilities (IMFs).
- 32. H.R. 5752, Stop Illicit Drug Importation Act of 2018:** This legislation, authored by Rep. Marsha Blackburn (R-TN), will streamline and enhance FDA's tools to intercept illegal products. Illicit or unapproved drugs enter the U.S. supply chain through IMFs and pose serious public health threats to individuals across the country.
- 33. H.R. 5806, 21st Century Tools for Pain and Addiction Treatments:** This bill, authored by Rep. Michael Burgess (R-TX), Rep. Larry Bucshon (R-IN), and Rep. Morgan Griffith (R-VA) will direct the FDA to issue or update existing guidance on ways these existing pathways can be used to bring novel non-addictive treatments for pain and addiction to patients. Several approaches have proven successful in speeding the availability of treatments for serious diseases through the FDA. The FDA's accelerated approval program

facilitates faster approval of medications using surrogate endpoints for serious conditions where there is an unmet medical need. The breakthrough therapy pathway is a process designed to expedite the development and review of drugs, which may demonstrate substantial improvement over available therapy.

**34. H.R. 5811, To amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes:** This bill, authored by Rep. Jerry McNerney (D-CA) and Rep. Morgan Griffith (R-VA), will enhance FDA's authorities and enforcement tools to ensure timely post-marketing studies for chronically administered opioids. Currently, there is limited data on the long-term efficacy of opioids, their increased addictive tendencies over time, and their overall place in the treatment of pain.

### **III. STAFF CONTACTS**

If you have questions regarding the health legislation, please contact Paul Edattel, Josh Trent, Kristen Shatynski, Caleb Graff, James Paluskiewicz, Jay Gulshen, Danielle Steele, or Adam Buckalew of the Committee staff. All Committee staff can be contacted at (202) 225-2927.