

April 23, 2018

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Subcommittee Markup

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## **I. INTRODUCTION**

The Subcommittee on Health will meet in open markup session on April 25, 2018, at 1:00 p.m. in 2123 Rayburn House Office Building to consider the following:

### Controlled Substance Act

1. H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act;
2. H.R. 5041, Safe Disposal of Unused Medication Act;
3. H.R. 5202, Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018;
4. H.R. 5483, Special Registration for Telemedicine Clarification Act of 2018;
5. H.R. \_\_\_\_, Improving Access to Remote Behavioral Health Treatment Act of 2018;

### Public Health Service Act

6. H.R. 449, Synthetic Drug Awareness Act of 2017;
7. H.R. 3545, Overdose Prevention and Patient Safety Act;
8. H.R. 3692, Addiction Treatment Access Improvement Act of 2017;
9. H.R. 4284, Indexing Narcotics, Fentanyl, and Opioids Act of 2017;
10. H.R. 4684, Ensuring Access to Quality Sober Living Act of 2017;
11. H.R. 5002, ACE Research Act;
12. H.R. 5009, Jessie's Law;
13. H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act of 2018;
14. H.R. 5176, Preventing Overdoses While in Emergency Rooms Act of 2018;
15. H.R. 5197, Alternatives to Opioids (ALTO) in the Emergency Department Act;
16. H.R. 5261, TEACH to Combat Addiction Act of 2018;
17. H.R. 5272, Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018;
18. H.R. 5327, Comprehensive Opioid Recovery Centers Act 2018;
19. H.R. 5329, Poison Center Network Enhancement Act of 2018;
20. H.R. 5353, Eliminating Opioid-Related Infectious Diseases Act of 2018;
21. H.R. \_\_\_\_, To enhance and improve state-run prescription drug monitoring programs;
22. H.R. \_\_\_\_, To improve fentanyl testing and surveillance;
23. H.R. \_\_\_\_, To support the peer support specialist workforce;

Medicare Part B

24. H.R. 3331, To amend title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology;
25. H.R. \_\_\_\_\_, CMS Action Plan;
26. H.R. \_\_\_\_\_, Welcome to Medicare;
27. H.R. \_\_\_\_\_, Adding Resources on Non-Opioid Alternatives to the Medicare Handbook;
28. H.R. \_\_\_\_\_, Post-Surgical Injections as an Opioid Alternative;
29. H.R. \_\_\_\_\_, Alternative Payment Model for Treating Substance Use Disorder;
30. H.R. \_\_\_\_\_, Use of Telehealth to Treat Opioid Use Disorder;
31. H.R. \_\_\_\_\_, Incentivizing Non-Opioid Drugs;

Medicare Part D

32. H.R. 3528, Every Prescription Conveyed Securely Act;
33. H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018;
34. H.R. \_\_\_\_\_, Mandatory Lock-In;
35. H.R. \_\_\_\_\_, Beneficiary Education;
36. H.R. 5582, Abuse Deterrent Access Act of 2018;
37. H.R. \_\_\_\_\_, Prescriber Notification;
38. H.R. \_\_\_\_\_, Prescriber Education;
39. H.R. \_\_\_\_\_, Medication Therapy Management (MTM) Expansion;
40. H.R. \_\_\_\_\_, CMS/Plan Sharing;

Medicaid

41. H.R. 1925, At-Risk Youth Medicaid Protection Act of 2017;
42. H.R. 3192, CHIP Mental Health Parity Act;
43. H.R. 4005, Medicaid Reentry Act;
44. H.R. 4998, Health Insurance for Former Foster Youth Act;
45. H.R. 5477, Rural Development of Opioid Capacity Services Act;
46. H.R. 5562, To require the Secretary of Health and Human Services to develop a strategy implementing certain recommendations relating to the Protecting Our Infants Act of 2015, and for other purposes;
47. H.R. \_\_\_\_\_, Limited repeal of the IMD Exclusion for adult Medicaid beneficiaries with substance use disorder;
48. H.R. \_\_\_\_\_, Medicaid Pharmaceutical Home Act;
49. H.R. \_\_\_\_\_, Medicaid DRUG Improvement Act;
50. H.R. \_\_\_\_\_, Medicaid PARTNERSHIP Act;
51. H.R. \_\_\_\_\_, Incentives to Create Medicaid Health Homes to Treat Substance Use Disorder;
52. H.R. \_\_\_\_\_, Medicaid IMD ADDITIONAL INFO Act;
53. H.R. \_\_\_\_\_, Medicaid Graduate Medical Education Transparency Act;
54. H.R. \_\_\_\_\_, HUMAN CAPITAL in Medicaid Act;
55. H.R. \_\_\_\_\_, Require Medicaid Programs to Report on All Core Behavioral Health Measures;

56. H.R. \_\_\_\_\_, 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;

Federal Food, Drug, and Cosmetic Act

57. H.R. 5228, Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act;  
58. H.R. 5554, To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs;  
59. H.R. \_\_\_\_\_, FDA and International Mail;  
60. H.R. \_\_\_\_\_, 21st Century Tools for Pain and Addiction Treatments;  
61. H.R. \_\_\_\_\_, FDA Opioid Sparing;  
62. H.R. \_\_\_\_\_, FDA Packaging and Disposal;  
63. H.R. \_\_\_\_\_, FDA Long-term Efficacy; and  
64. H.R. \_\_\_\_\_, FDA Misuse/Abuse.

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. EXPLANATION OF LEGISLATION

*Controlled Substances Act*

1. **H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act:** H.R. 4275, authored by Rep. Mark DeSaulnier (D-CA) and Rep. Buddy Carter (R-GA), will help pharmacists detect fraudulent prescriptions. H.R. 4275 will help develop and disseminate education materials, giving pharmacists greater understanding and ability to detect prescriptions that are fraudulent, forged, or appear to be for abuse or diversion.
2. **H.R. 5041, Safe Disposal of Unused Medication Act:** H.R. 5041, authored by Rep. Tim Walberg (R-MI) and Rep. Debbie Dingell (D-MI), will help reduce the number of unused controlled substances at risk of diversion or misuse by allowing hospice workers to dispose of these medications in patients' homes safely.
3. **H.R. 5202, Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018:** H.R. 5202, authored by Rep. Ryan Costello (R-PA) and Rep. Rick Nolan (D-MN), will update Federal law to improve dispensing of implantable and injectable therapies developed to make abuse, misuse, and diversion more difficult.
4. **H.R. 5483, Special Registration for Telemedicine Clarification Act of 2018:** This legislation, authored by Rep. Buddy Carter (R-GA) and Rep. Cheri Bustos (D-IL), will clarify telemedicine waivers. Federal law permits the Attorney General to issue a special registration to health care providers to prescribe controlled substances via telemedicine in legitimate emergency situations, such as a lack of access to an in-person specialist.

Unfortunately, the waiver process has never been implemented through regulation, and some patients do not have the emergency access they need to treatment. This bipartisan bill directs the Attorney General, with the Secretary of Health and Human Services, to promulgate interim final regulations within 90 days of passage of the law.

5. **H.R. \_\_\_\_\_, Improving Access to Remote Behavioral Health Treatment Act of 2018:** This discussion draft, authored by Rep. Gregg Harper (R-MS) and Rep. Doris Matsui (D-CA), will expand access for patients in rural and underserved communities who may live near community mental health centers, but not a hospital or state-licensed clinic. Without a Drug Enforcement Administration (DEA) registration, these health facilities do not qualify for the Ryan Haight Act's telemedicine exception, and they are unable to provide care to patients in need. This discussion draft would direct the Attorney General to report to Congress within 60 days of passage of the law a plan for these treatment facilities to register with the DEA to engage in the practice of telemedicine. The discussion draft outlines the registration process for these centers.

### *Public Health*

6. **H.R. 449, Synthetic Drug Awareness Act:** H.R. 449, authored by Rep. Hakeem Jeffries (D-NY), will require the United States Surgeon General to submit a comprehensive report to Congress on the public health effects of the rise in synthetic drug use among youth aged 12 to 18 in order to educate parents and the medical community on the health effects of synthetic drugs. Synthetic drugs, such as synthetic cannabinoids (Spice, K2), cathinones (Bath Salts), and psychedelic phenethylamines (N-Bomb) are produced in labs and can have chemical structures that can be either identical to or different from naturally occurring drugs.<sup>1</sup> Their effects are designed to mimic or enhance those of natural drugs. Synthetic drugs can be modified to circumvent the DEA's scheduling regime. Fentanyl, a substance that is 50 times more potent than heroin and 100 times more potent than morphine, has numerous analogs.<sup>2</sup> Before DEA's recently issued order to schedule *all* fentanyl-related compounds under Schedule I, when the agency would temporarily control one given fentanyl substance, illicit manufacturers abroad would produce new analogs through minor structural modifications to be smuggled and distributed as a purportedly "noncontrolled substances."
7. **H.R. 3545, Overdose Prevention and Patient Safety Act:** H.R. 3545, authored by Rep. Markwayne Mullin (R-OK) and Rep. Earl Blumenauer (D-OR), 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. An amendment in the nature of a substitute to H.R. 3545 will also 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.

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<sup>1</sup> Sacco LN and Finklea K, Synthetic Drugs: Overview and Issues for Congress. *Congressional Research Service R42066*. May 3, 2016. Available at <http://www.crs.gov/reports/pdf/R42066>.

<sup>2</sup> Centers for Disease Control & Prevention, Injury Prevention & Control. "Opioid Overdose, Synthetic Opioid Data." December 16, 2016. Available at <https://www.cdc.gov/drugoverdose/data/fentanyl.html>.

8. **H.R. 3692, Addiction Treatment Access Improvement Act:** H.R. 3692, authored by Rep. Paul Tonko (D-NY) and Rep. Ben Ray Lujan (D-NM), will expand access to medication-assisted treatment (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 waivered-practitioner can treat with buprenorphine to 275 patients. An amendment in the nature of a substitute would also permit waivered-practitioners to immediately start treating 100 patients at a time with buprenorphine (skipping the initial 30 patient cap) if they meet certain requirements.
9. **H.R. 4284, Indexing Narcotics, Fentanyl, and Opioids (INFO) Act:** H.R. 4284, authored by Rep. Bob Latta (R-OH), will direct the Department of Health and Human Services (HHS) to create a public and easily accessible electronic dashboard linking to all of the nationwide efforts to combat the opioid crisis. An amendment in the nature of a substitute to H.R. 4284 will also create an Interagency Substance Use Disorder Coordinating Committee to review and coordinate opioid use disorder (OUD) and other SUD research, services, and prevention activities across all relevant Federal agencies, evaluate the effectiveness of these activities, and make specific recommendations for actions that agencies can take to better coordinate the administration of services for patients with OUD and SUD.
10. **H.R. 4684, Ensuring Access to Quality Sober Living Act:** 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 SAMHSA to develop, publish, and disseminate best practices for operating recovery housing that promotes a safe environment and sustained recovery from SUD. Recovery housing can provide a safe, structured, and supportive environment for people in recovery from an SUD. These alcohol- and drug-free housing arrangements typically take the form of ordinary housing, located in residentially zoned areas and distinguished only by the residents shared commitment not to use alcohol or other drugs.<sup>3</sup> Unfortunately, an increasing number of reports have revealed the nefarious practice of patient brokering where individuals known as “patient brokers” treat men and women with SUD as a commodity by pushing them to seek treatment at certain outpatient facilities and to live at affiliated recovery residences while undergoing treatment. In exchange for steering patients towards said facilities and/or housing, patient brokers receive generous financial kickbacks. Usually, the recovery residence and the treatment center involved in the kickback scheme lack any oversight, transparency, and accountability.
11. **H.R. 5002, ACE Research Act:** H.R. 5002, authored by Rep. Debbie Dingell (D-MI) and Rep. Fred Upton (R-MI), will provide the National Institutes of Health (NIH) with new authorities to conduct research on innovative non-addictive pain medications.

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<sup>3</sup> Wittman, FD, Affordable Housing for People with Alcohol and Other Drug Problems. *Contemporary Drug Problems*. 541 (1993). Available at <http://heinonline.org/HOL/LandingPage?handle=hein.journals/condp20&div=35&id=&page=>.

12. **H.R. 5009, Jessie’s Law:** H.R. 5009, authored by Rep. Tim Walberg (R-MI), Rep. Debbie Dingell (D-MI), and Rep. Bob Latta (R-OH), will ensure medical professionals have access to a consenting patient’s complete health information when making treatment decisions by requiring HHS to develop and disseminate best practices regarding the prominent display of SUD history in records of patients who have previously provided this information to a health care provider.
13. **H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act:** H.R. 5102, authored by Rep. Katherine Clark (D-MA), Rep. Harold Rogers (R-KY), Rep. John Sarbanes (D-MD), and Rep. Brett Guthrie (R-KY), will create a loan repayment program for SUD treatment providers. The bill will offer student loan repayment of up to \$250,000 for participants who agree to work as a SUD treatment professional in areas most in need of their services. The program will be available to a wide range of direct care providers, including physicians, registered nurses, social workers, and other behavioral health professionals. Serious workforce shortages exist for health professionals and paraprofessionals across the United States. According to SAMHSA, in 2012, the turnover rates in the addiction services workforce ranged from 18.5 percent to over 50 percent.<sup>4</sup> In a recent survey, nearly half of clinical directors in agencies specializing in SUD treatment acknowledged that they had difficulty filling open positions, primarily because of a lack of qualified applicants.<sup>5</sup>
14. **H.R. 5176, Preventing Overdoses While in Emergency Rooms (POWER) Act:** H.R. 5176, authored by Rep. David McKinley (R-WV) and Rep. Michael Doyle (D-PA), will provide resources for hospitals to develop protocols on discharging patients who have presented with an opioid overdose. These protocols would address the provision of naloxone upon discharge, connection with peer-support specialists, and the referral to treatment and other services that best fit the patient’s needs. The Substance Abuse and Mental Health Services Administration (SAMHSA) has identified individuals discharged from emergency medical care following opioid poisoning as a very vulnerable patient group in terms of opioid risks. For patients brought to the emergency room (ER) with uncontrolled blood pressure, asthma, or neglected diabetes, doctors often start treatment immediately. This is usually not the case for patients with SUD presenting with an opioid overdose. Having protocols in place that connect the patient to SUD treatment is a cost-effective way to treat patients in hospital emergency rooms.<sup>6</sup>
15. **H.R. 5197, Alternatives to Opioids (ALTO) in the Emergency Department Act:** H.R. 5197, authored by Rep. Bill Pascrell, Jr. (D-NJ) and Rep. David McKinley (R-WV), will establish a demonstration program to test alternative pain management protocols to limit the use of opioids in hospital emergency departments. According to the CDC, emergency

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<sup>4</sup> Substance Abuse and Mental Health Services Administration. “Workforce.” September 15, 2017. Available at <https://www.samhsa.gov/workforce>.

<sup>5</sup> Addiction Technology Transfer Center Network. “Vital Signs: Taking the Pulse of the Addiction Treatment Profession.” September 28, 2012. Available at <http://attcnetwork.org/documents/VitalSignsReport.pdf>.

<sup>6</sup> Busch SH, et al, Cost-effectiveness of emergency department-initiated treatment for opioid dependence. *Addiction*. 112: 2002–2010 (2017). Available at <http://onlinelibrary.wiley.com/doi/10.1111/add.13900/abstract;jsessionid=C64B00FAE33F1920471223B396D1FD53.f03t03>.

physicians have a “unique opportunity to engage in prevention of a future overdose, particularly for patients who may not have had other contact with the health care system.”<sup>7</sup> By promoting the use of non-opioid alternatives to manage pain, ERs can importantly serve as one of the first lines of defense against the opioid crisis.

16. **H.R. 5261, Treatment, Education, And Community Help (TEACH) to Combat Addiction Act:** H.R. 5261, authored by Rep. Bill Johnson (R-OH) and Rep. Paul Tonko (D-NY), will authorize HHS to designate and support Centers of Excellence, or institutions of learning that have championed SUD treatment and pain management education to improve how health professionals are taught about both SUD and pain. According to the National Academies of Sciences, Engineering, and Medicine, schools for health professional education, professional societies, and state licensing boards should develop evidence-based approaches to pain education and provide basic training in the treatment of opioid use disorder for health care providers.<sup>8</sup>
17. **H.R. 5272, Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse (RESULTS) Act:** H.R. 5272, authored by Rep. Steve Stivers (R-OH) and Rep. Eliot Engel (D-NY), will require that entities applying for Federal funding used to support programs or activities that address mental health or SUD submit materials to HHS demonstrating that the programs or activities are evidence-based. An amendment in the nature of a substitute will instead direct SAMHSA to provide guidance for entities applying for grants, including guidance on how best to articulate the rationale for a given program or activity; encourage the funding of evidence-based interventions; and encourage the replication of promising or effective practices.
18. **H.R. 5327, Comprehensive Opioid Recovery Centers Act:** H.R. 5327, authored by Rep. Brett Guthrie (R-KY) and Rep. Gene Green (D-TX), will help support the establishment of Comprehensive Opioid Recovery Centers (CORCs) to serve as models for comprehensive treatment and recovery. CORCs would utilize the full range of FDA-approved medications and evidence-based treatments, have strong linkages with the community, generate meaningful outcomes data, and dramatically improve the opportunities for individuals to establish and maintain long-term recovery as productive members of society.
19. **H.R. 5329, Poison Center Network Enhancement Act:** 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

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<sup>7</sup> Axeen S, Seabury SA, Menchine M, Emergency Department Contribution to the Prescription Opioid Epidemic. *Annals of Emergency Medicine*. (2018) DOI: 10.1016/j.annemergmed.2017.12.007.

<sup>8</sup> National Academies of Sciences, Engineering, and Medicine. “Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use.” July 13, 2017. Available at <http://nationalacademies.org/hmd/Reports/2017/pain-management-and-the-opioid-epidemic.aspx>

poisonings are reported annually to poison control centers.<sup>9</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>10</sup>

**20. H.R. 5353, Eliminating Opioid-Related Infectious Diseases Act:** H.R. 5353, authored by Rep. Leonard Lance (R-NJ), Rep. Joe Kennedy (D-MA), Rep. Chris Collins (R-NY), Rep. Anna Eshoo (D-CA), Rep. Joe Barton (R-TX), and Rep. Doris Matsui (D-CA), will authorize the Centers for Disease Control and Prevention (CDC) to undertake an injection drug use-associated infection elimination initiative and work with states to improve education, surveillance, and treatment of infections associated with injection drug use. Injection drug use is a well-known route for the transmission of blood borne infections, particularly human immunodeficiency virus (HIV) and hepatitis. According to the CDC, in the United States, approximately 7 percent of new HIV cases, 50 percent of new hepatitis C virus (HCV) cases, and 2 percent of hepatitis A cases are associated with illicit injection of drugs.<sup>11,12</sup> Within the course of one year in the state of Indiana, HIV infection was diagnosed in 181 patients, most of whom (87.8 percent) reported having injected the extended-release formulation of the prescription opioid oxymorphone, and 92.3 percent were coinfecting with HCV.<sup>13</sup>

**21. H.R. \_\_\_\_\_, To enhance and improve state-run prescription drug monitoring programs:** This discussion draft, 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 CDC 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.

**22. H.R. \_\_\_\_\_, To improve fentanyl testing and surveillance:** This discussion draft, 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.

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<sup>9</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>10</sup> American Association of Poison Control Centers. "Opioid Exposures." January 1, 2018. Available at <http://www.aapcc.org/alerts/opioids/>.

<sup>11</sup> Belani H, et al, Integrated Prevention Services for HIV Infection, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis for Persons Who Use Drugs Illicitly: Summary Guidance from CDC and the U.S. Department of Health and Human Services. *Morbidity and Mortality Weekly Report*. 61: 1-40 (2012). Available at [https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6105a1.htm?s\\_cid=rr6105a1\\_w](https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6105a1.htm?s_cid=rr6105a1_w).

<sup>12</sup> Spiller MW, Broz D, Wejnert C, Nerlander L, Paz-Bailey G, HIV Infection and HIV-Associated Behaviors Among Persons Who Inject Drugs — 20 Cities, United States, 2012. *Morbidity and Mortality Weekly Report*. 64: 270-275 (2015). Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6410a3.htm>.

<sup>13</sup> Peters PJ, et al, HIV Infection Linked to Injection Use of Oxymorphone in Indiana, 2014–2015. *The New England Journal of Medicine*. 375: 229-239 (2016). Available at <http://www.nejm.org/doi/full/10.1056/NEJMoa1515195>.



23. **H.R. \_\_\_\_\_, To support the peer support specialist workforce:** This discussion draft, 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 HHS 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 an 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.

*Medicare Part B*

24. **H.R. 3331, to amend title XI of the Social Security Act:** H.R. 3331, authored by Rep. Lynn Jenkins (R-KS), will promote the testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology.
25. **H.R. \_\_\_\_\_, CMS Action Plan:** This discussion draft 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, and meetings with stakeholders, for the purpose of addressing the opioid crisis.
26. **H.R. \_\_\_\_\_, Welcome to Medicare:** This discussion draft authored by Rep. Larry Bucshon (R-IN) and Rep. Erik Paulsen (R-MN) will add a pain assessment as part of the Welcome to Medicare initial examination, and provide intervention about non-opioid alternatives, as appropriate.
27. **H.R. \_\_\_\_\_, Adding Resources on Non-Opioid Alternatives to the Medicare Handbook:** This discussion draft will direct CMS to compile education resources for beneficiaries regarding opioid use, pain management, and alternative pain management treatments, and include these resources in the "Medicare and You" handbook.
28. **H.R. \_\_\_\_\_, Post-Surgical Injections as an Opioid Alternative:** This discussion draft, authored by Rep. John Shimkus (R-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.
29. **H.R. \_\_\_\_\_, Alternative Payment Model for Treating Substance Use Disorder:** This discussion draft, 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.
30. **H.R. \_\_\_\_\_, Use of Telehealth to Treat Opioid Use Disorder:** This discussion draft, authored by Rep. Doris Matsui (D-CA), will instruct CMS to evaluate the utilization of telehealth services in treating opioid use disorder.

31. **H.R. \_\_\_\_\_, Incentivizing Non-Opioid Drugs:** This discussion draft authored by Rep. Scott Peters (D-CA) and Rep. Larry Bucshon (R-IN) will create a temporary pass through payment to encourage the development of non-opioid drugs for post-surgical pain management in Medicare.

*Medicare Part D*

32. **H.R. 3528, Every Prescription Conveyed Securely Act:** H.R. 3528, authored by Rep. Katherine Clark (D-MA) and Rep. Markwayne Mullin (R-OK), will require e-prescribing, with exceptions, for coverage of prescribed controlled substances under the Medicare Part D program.
33. **H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act:** H.R. 4841, authored by Rep. David Schweikert (R-AZ), seeks to standardize electronic prior authorization for prescription drugs under Medicare Part D.
34. **H.R. \_\_\_\_\_, Mandatory Lock-In:** This discussion draft, authored by Rep. Gus Bilirakis (R-FL), Rep. Ben Ray Lujan (D-NM), and Rep. Peter Roskam (R-IL) will build off of work done in the Comprehensive Addiction Recovery Act (CARA), and will require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries.
35. **H.R. \_\_\_\_\_, Beneficiary Education:** This discussion draft, authored by Rep. Erik Paulsen (R-MN), will require prescription drug plans under Medicare Part D to include information on the adverse effects of opioid overutilization and coverage of non-pharmacological therapies and non-opioid medications or devices used to treat pain.
36. **H.R. 5582, Abuse Deterrent Access Act of 2018:** H.R. 5582, authored by Rep. Buddy Carter (R-GA), Rep. David Loebsack (D-IA), and Rep. Tom Reed (NY), will direct CMS to evaluate the use of abuse-deterrent opioids in Medicare plans.
37. **H.R. \_\_\_\_\_, Prescriber Notification:** This discussion draft, authored by Rep. Peter Roskam (R-IL), 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.
38. **H.R. \_\_\_\_\_, Prescriber Education:** This discussion draft will direct CMS to work with Quality Improvement Organizations to engage in outreach with prescribers identified as clinical outliers to share best practices.
39. **H.R. \_\_\_\_\_, Medication Therapy Management (MTM) Expansion:** This discussion draft, authored by Rep. Mike Kelly (R-PA) and Rep. Cathy McMorris Rodgers (R-WA), will add beneficiaries at risk for prescription drug abuse to the list of targeted beneficiaries to be eligible for MTM under Part D.

40. **H.R. \_\_\_\_\_, CMS/Plan Sharing:** This discussion draft, authored by Rep. James Renacci (R-OH) and Rep. Terri Sewell (D-AL), will help facilitate communication between Medicare Advantage (MA) organizations, Part D plan sponsors, and CMS relating to substantiated fraud, waste, and abuse investigations.

### *Medicaid*

41. **H.R.1925, At-Risk Youth Medicaid Protection Act:** This bill, authored by Rep. Tony Cárdenas (D-CA) allows Medicaid payment for medical services furnished to an incarcerated individual during the 30-day period preceding the individual's release.
42. **H.R. 3192, CHIP Mental Health Parity Act:** This 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.
43. **H.R. 4005, The Medicaid Reentry Act:** This 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.
44. **H.R. 4998, Health Insurance for Former Foster Youth Act:** The Patient Protection and Affordable Care Act 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, the ACA restricted foster youth from receiving Medicaid if they move out of their 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.
45. **H.R. 5477, Rural Development of Opioid Capacity Services Act:** This bill, authored by Rep. Tom O'Halleran (D-AZ), requires the Centers for Medicare and Medicaid Services 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.
46. **H.R. 5562, To require the Secretary of Health and Human Services to develop a strategy implementing certain recommendations relating to the Protecting Our Infants Act of 2015, and for other purposes:** This bill, authored by Rep. Evan Jenkins (R-WV), requires the Secretary of Health and Human Services (HHS) to submit to Congress a strategy for implementing recommendations from the HHS Behavioral Health Coordinating Council report, *Protecting Our Infants: Final Strategy*.
47. **H.R. \_\_\_\_\_, Limited repeal of the IMD Exclusion for adult Medicaid beneficiaries with substance use disorder:** The Subcommittee mark will be a discussion draft that, compared to the draft discussed in the legislative hearing, includes a maintenance of effort requirement to say states must continue to offer a continuum of care. The discussion draft allows state Medicaid programs from FY2019 through FY2023 to remove the IMD exclusion for Medicaid beneficiaries aged 21-64 with a substance use disorder. Medicaid would pay for up to 90 total days of care in an IMD during the

calendar year. Beneficiaries would need to be assessed after the first 30 days to determine if continued care (for the approval of up to 60 additional days) is medically necessary. The bill also requires states to maintain the level of funding and number of beds in IMDs in a state before a state adopts this option.

48. **H.R. \_\_\_\_\_, Medicaid Pharmaceutical Home Act:** The Subcommittee mark will be a discussion draft that, based on stakeholder feedback, includes improvements to the previous draft discussed in the legislative hearing. The discussion draft 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 pharmacy home program. The pharmaceutical home program must set reasonable limits on the number of prescribers and dispensers that beneficiaries may utilize, whether under a fee-for-service or managed care arrangement. The bill also codifies a requirement (currently, a regulation) that requires Medicaid managed care plans have a similar program.
49. **H.R. \_\_\_\_\_, Medicaid DRUG Improvement Act:** The Subcommittee mark will be a discussion draft that, based on stakeholder feedback, includes improvements to the previous draft discussed in the legislative hearing. The discussion draft requires all state Medicaid programs to use common sense DUR activities to help combat the opioid crisis. State Medicaid programs will be required to put limitations in place for opioid refills, monitor concurrent prescribing of opioids and other drugs (such as benzodiazepines and antipsychotics), monitor antipsychotic prescribing for children, and have at least one buprenorphine/naloxone combination drug on the Medicaid drug formulary.
50. **H.R. \_\_\_\_\_, Medicaid PARTNERSHIP Act:** The Subcommittee mark will be a discussion draft that, based on stakeholder feedback, includes improvements to the previous draft discussed in the legislative hearing. The discussion draft would require 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 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 a number of PDMP issues.
51. **H.R. \_\_\_\_\_, Incentives to Create Medicaid Health Homes to Treat Substance Use Disorder:** The Subcommittee mark will be a discussion draft that largely mirrors the previous draft discussed in the legislative hearing. To incentivize state Medicaid programs to use health home waivers for Medicaid beneficiaries with substance use disorder, the discussion draft extends the enhanced match from eight quarters to 12 quarters.
52. **H.R. \_\_\_\_\_, Medicaid IMD ADDITIONAL INFO Act:** The Subcommittee mark will be a discussion draft, using the same language as legislative hearing. The discussion draft directs the Medicaid and CHIP Payment and Access Commission (MACPAC) to conduct a study on IMDs. The study shall report on the requirements, standards, and oversight that State Medicaid programs have for IMDs. MACPAC, considering input from

stakeholders, shall summarize the findings and make recommendations on improvements and best practices. The report is due no later than January 2020.

53. **H.R. \_\_\_\_\_, Medicaid Graduate Medical Education Transparency Act:** The Subcommittee mark will be a discussion draft that, based on stakeholder feedback, includes improvements to the previous draft discussed in the legislative hearing. The discussion draft improves transparency in how Medicaid GME funds are being used to support physician training for providers who deliver care for patients with substance use disorder. The bill requires state Medicaid programs to report specific information on how physicians are trained in specialties that are essential in the opioid crisis (i.e., psychiatry, addiction medicine, etc.) and how GME recipients are using Medicaid funds to train physicians on substance use disorder.
54. **H.R. \_\_\_\_\_, HUMAN CAPITAL in Medicaid Act:** The Subcommittee mark will be a discussion draft, using the same language as was discussed in legislative hearing. Medicaid is the largest source of federal funding for behavioral health services—mental health and substance use disorder services—with nearly \$71 billion in projected 2017 spending. To strengthen the leadership of the Medicaid program who are helping combat the opioid crisis, the discussion draft provides enhanced federal medical assistance percentage to help recruit and retain talented leaders with specific expertise and capabilities. This approach helps ensure Medicaid has skilled and capable leaders to navigate this crisis and other public health crises.
55. **H.R. \_\_\_\_\_, Require Medicaid Programs to Report on All Core Behavioral Health Measures:** The Subcommittee mark will be a discussion draft, using the same language as was discussed in the legislative hearing. This bill 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.
56. **H.R. \_\_\_\_\_, 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:** The Subcommittee mark will be a discussion draft. This bill improves access to inpatient treatment services for women with substance use disorder who are pregnant or who are suffering from postpartum depression.

*FDA*

57. **H.R. 5228, Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act:** This bill, authored by Rep. Frank Pallone (D-NJ), will provide FDA with stronger recall and seizure authority, among other things, to disrupt the entry of counterfeit and illicit drugs through IMFs.
58. **H.R. 5554, To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs:** The Food and Drug Administration (FDA) collects user fees from the animal drug industry to accelerate the development of animal drugs, reduce application review times, and create a

more predictable, streamlined process for drug development and approval. This bill, authored by Rep. Markwayne Mullin (R-OK) and Rep. Kurt Schrader (D-OR), reauthorizes FDA's authority to collect fees from pioneer and generic animal drug manufacturers for a period of five years.

59. **H.R. \_\_\_\_\_, FDA and International Mail:** This discussion draft, 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 International Mail Facilities (IMFs) and pose serious public health threats to individuals across the country.
60. **H.R. \_\_\_\_\_, 21st Century Tools for Pain and Addiction Treatments:** This discussion draft will leverage existing pathways to help combat the opioid crises by directing FDA to issue or update existing guidance on ways these pathways can be leveraged 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.
61. **H.R. \_\_\_\_\_, FDA Opioid Sparing:** This discussion draft, authored by Rep. Barbara Comstock (R-VA), will direct the FDA to establish clear data collection methods for opioid-sparing labeling claims for products that may replace, delay, or reduce the use of opioid analgesics. While there may be alternatives to opioids for certain patients and conditions, there is a need for additional clarity and flexibility regarding what drug developers need to do to show that their products can spare certain patients from opioids as a part of their treatment regimen.
62. **H.R. \_\_\_\_\_, FDA Packaging and Disposal:** This discussion draft, authored by Rep. Richard Hudson (R-NC), will direct the FDA to work with manufacturers to establish programs for efficient return or destruction of unused Schedule II or III opioids. These methods could include mail-back pouches to secure facilities for incineration, or methods to inactivate immediately or render unattractive unused drugs. In addition, this bill will facilitate utilization of packaging that may reduce overprescribing, diversion, or abuse of opioids. Finally, the bill will require the Government Accountability Office (GAO) to study new and innovative technologies that claim to be able to dispose of opioids safely and other unused medications. GAO would review and detail the effectiveness of these disposal methods. According to SAMHSA, about 10.7 million people aged 12 or older misused prescription pain relievers annually. Of those who misused, over half surveyed indicated they obtained the pain relievers from a friend or relative.<sup>14</sup> Safe and proper

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<sup>14</sup> Lipari RN and Hughs, A. How People Obtain the Prescription Pain Relievers They Misuse. *National Survey on Drug Use and Health CBHSQ Report*. January 12, 2017. Available at [https://www.samhsa.gov/data/sites/default/files/report\\_2686/ShortReport-2686.html](https://www.samhsa.gov/data/sites/default/files/report_2686/ShortReport-2686.html).

disposal of opioids and other unused prescription drugs can prevent these substances from getting into the wrong hands.

63. **H.R. \_\_\_\_\_, FDA Long-term Efficacy:** This discussion draft, authored by Rep. Jerry McNerney (D-CA), 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.
64. **H.R. \_\_\_\_\_, FDA Misuse/Abuse:** This discussion draft, authored by Rep. Gene Green (D-TX), will strengthen FDA's authority to consider the misuse and abuse of a controlled substance when determining if its overall benefits outweigh the risks. Under current law, FDA evaluates drugs for safety and efficacy for their intended use when reviewing new drug applications. Clarifying FDA's authority to consider misuse and abuse as part of the drug approval and assessment process for opioids would augment the Agency's capacity to take necessary action to minimize the public health consequences of opioid misuse and abuse.

### **III. STAFF CONTACTS**

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