



House Energy & Commerce Committee Markup of Opioid Legislation May 9, 2018

OVERVIEW

The House Committee on Energy and Commerce held a markup on Wednesday, May 9, 2018 of 26 bills related to combating the opioid crisis. While the actions were taken on a bipartisan basis, Democrats voiced concerns over cuts to Medicaid proposed in the FY18 and FY19 Trump budgets and repeal of the Affordable Care Act that would limit access to treatment for substance use disorders (SUD) and potential changes to essential health benefits that have expanded access to treatment.

All of the bills were favorably reported to the House floor by voice vote. Ranking Member Frank Pallone (D-NJ) requested the sole roll call vote of the health care portion of the markup for an amendment to the Over the Counter Monograph legislation that would shorten the period of patent exclusivity from 18 months to 12 months. The amendment was rejected 24-30.

In general, the bills focused on prevention, treatment, reducing diversion of opioids, and development of non-addictive painkillers. Multiple bills focused on improving addiction education and training. Bills also focused on creating opioid recovery centers and providing grant funding to emergency rooms that initiate MAT after a patient is admitted with an opioid overdose. Diversion bills focused on safe disposal of opioids in hospice settings and the use of electronic prescriptions to ensure prescriptions aren't misused. Multiple bills focused on seniors, including H.R. 5686, which would require Part D plans to distribute information about opioid addiction to beneficiaries and H.R. 5675, which will establish lock in programs under Medicare. H.R. 5009, Jessie's Law, requires the Secretary of HHS to develop guidance for healthcare providers on appropriate disclosure of information in emergency situations.

The full committee will hold another markup on May 17 to advance additional opioid measures on which the committee has held hearings and/or that were reported favorably out of the Health Subcommittee previously. The Committee has not yet specified which measures will be marked up at that session, but staff are continuing to engage in discussions and it's possible that around 30 or more bills will also be considered.

Chairman Walden (R-OR) stated that he hopes the full House can vote on an opioid package by Memorial Day or at least the first part of June.

MEMBER STATEMENTS

Chairman Walden (R-OR)

- Will consider 26 pieces of legislation related to opioid epidemic and hope these bills will receive bipartisan support.
- These bills will strengthen prevention efforts and payment issues.

Ranking Member Pallone (D-NJ)

- The opioid epidemic is a complex crisis that requires thoughtful consideration. I will evaluate proposals based on two principles — whether the proposal improves access to treatment and whether the bill helps prevent people from getting addicted in the first place.
- There are 25 small bills before us and I support them. At the same time, I am concerned that many of the bills that can help us resolve the crisis will not be discussed today.
- For instance, I support the legislation that Congresswoman DeGette is working on to exempt short supply of MAT from prior authorization requirements. That bill not included in this process.
- I also asked to include a bill that I introduced with Richard Neal that would extend Medicare coverage to methadone clinics. Seniors with opioid abuse disorder don't have access to treatment in methadone clinics.
- There are a number of substantial bills that were left off the table — most notable is Rep. Tonko's TREAT Act that would have impact on the number of providers treating opioid addiction and the Rural Docs Act which would have increased the treatment capacity for substance use disorder treatment.
- It is still unclear what Medicare and Medicaid bills will be marked up next week.

Congressman Fred Upton (R-MI)

- Legislation I introduced will allow FDA to use other transaction authority to partner with innovative companies to develop alternatives to opioids.

Subcommittee on Health Ranking Member Green (D-TX)

- Asked for support for over the counter monograph safety bill and Comprehensive Opioid Recovery Centers Act, which will fund designated opioid centers.

Congresswoman Marsha Blackburn (R-TN)

- The effort to develop non-addictive pain treatment is a timely issue and I appreciate the Committee's work.

Congresswoman Dianne DeGette (D-CO)

- Some of the issues related to the opioid epidemic: physician education, how we are distributing opioids, availability of MAT, alternatives to opioids, aid to states, and help with law enforcement. These are issues that we need to look at in a comprehensive way.

Congressman Robert Latta (R-OH)

- I'm pleased to advance several bills today, including the Over the Counter Monograph Safety Act would affect products Americans use every day as well as the INFO Act which would allow advocates to have better information and data on a nationwide basis.

Congressman Gus Bilirakis (R-FL)

- Proud of the work the committee has done. Glad we're marking up H.R. 5675, which reforms prescription drug sponsors under Medicaid to establish programs for at risk beneficiaries.

Congresswoman Janice Schakowsky (D-IL)

- 1.7 million people will lose coverage if Medicaid work requirements are instituted in the selected states. Medicaid is necessary for combating this epidemic.

Congresswoman Doris Matsui (D-CA)

- Even if these bills are passed, that will not cancel out the harm of cutting Medicaid.

Congressman Peter Welch (D-VT)

- We have to keep Medicaid intact and we have to support rural broadband.

Congresswoman Kathy Castor (D-FL)

- Should not be undermining Medicaid. Cannot solve this crisis without Medicaid.

Congressman Raul Ruiz (D-CA)

- I urge all to reconsider attempts to cut Medicaid and to eliminate essential health benefits.

Congresswoman Debbie Dingell (D-MI)

- We need to work on preserving safety net programs like Medicare, Medicaid.

Congresswoman Cathy McMorris Rodgers (R-WA)

- 21st Century Cures Act has given billions for combating this epidemic.
- This committee has worked on a bipartisan way to solve this epidemic.

LEGISLATION CONSIDERED

H.R. 449, Synthetic Drug Awareness Act [[PDF](#)]

- Congressman Collins (R-NY) read a statement from Congressman Jeffries (D-NY) which noted that Congress must act collaboratively to combat synthetic drugs.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 4284, Indexing Narcotics, Fentanyl, and Opioids (INFO) Act [[PDF](#)]

- Latta legislation extends the deadline to 6 months for creating a Substance Use Disorder dashboard and changes wording on interagency committee.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5002, ACE Research Act [[PDF](#)]

- Congressman Fred Upton (R-MI), Congresswoman spoke in support of the bill because it helps better understand the science of pain.
- Congresswoman Debbie Dingell (D-MI) noted that pain needs to be addressed because we cannot stigmatize people who suffer from pain.

- Congressman Jerry McNerney (D-CA) said he appreciates the Majority's commitment to combating the opioid epidemic but wishes there was an equal commitment to combating gun violence.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act [[PDF](#)]

- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5009, Jessie's Law [[PDF](#)]

- McKinley Amendment – requires Secretary of HHS to develop materials for healthcare providers with a clear explanation of permitted disclosures under HIPAA for emergency situations like overdoses.
 - Congressman Tim Walberg (R-MI) spoke favorably of the bill and amendment.
 - Adopted by voice vote.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5176, Preventing Overdoses While in Emergency Rooms (POWER) Act [[PDF](#)]

- Congressman David McKinley (R-WV) noted that this bill will provide grants to emergency rooms, especially in rural areas. Congressman Michael Doyle (D-PA) said that starting MAT in the hospital will lead to saving money and lives.
- Ruiz Amendment – Will remove a rule that restricts doctors from giving more than one day's worth of buprenorphine. Instead, they will be allowed to provide 3 days worth.
 - Congressman Michael Doyle (D-PA) spoke in support of the amendment and noted that Gov. Wolf (D-PA) had reached out to him in support of the amendment and bill.
 - Amendment was withdrawn.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5197, Alternatives to Opioids (ALTO) in the Emergency Department Act [[PDF](#)]

- Congressman David McKinley (R-WV) noted that St. Joseph's hospital in Paterson, New Jersey has reduced its opioid prescriptions by 60%.
 - Pallone Amendment – Makes technical changes to the bill.
 - Adopted by voice vote
- **The bill was favorably reported to the House floor.**

H.R. 5261, Treatment, Education, And Community Help (TEACH) to Combat Addiction Act [[PDF](#)]

- Congressman Bill Johnson (R-OH) said that the bill will correct the lack of addiction education. Congressman Paul Tonko (D-NY) noted that this bill will strengthen the tools to combating the epidemic.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5272, Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse [[PDF](#)]

- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5327, Comprehensive Opioid Recovery Centers Act [[PDF](#)]

- Guthrie Amendment – reflects technical changes to Comprehensive Opioid Recovery Center requirements. Clarifies that the service might be contracted out.
 - Adopted by voice vote.
- Lujan Amendment – Requires Centers to provide prevention services for family members of those suffering from opioid disorder and those suffering from chronic pain without a terminal illness.
 - Adopted by voice vote.
- Congressman Gene Green (D-TX) spoke in favor of the bill because it establishes centers which will be the gold standard.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5353, Eliminating Opioid-Related Infectious Diseases Act [[PDF](#)]

- **The bill was favorably reported to the House floor by voice vote.**

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 [[PDF](#)]

- Matsui Amendment – Makes technical changes to the bill to conform to the Senate version. We have added psychiatric nurse practitioners that would qualify for CMMI Demonstration.
 - Adopted by voice vote.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5685, Medicare Opioid Safety Education Act [[PDF](#)]

- **The bill was favorably reported to the House floor by voice vote.**

H.R. 3528, Every Prescription Conveyed Securely Act [[PDF](#)]

- Mullin Amendment – Makes technical changes.
 - Congressman Frank Pallone (D-NJ) supports that prescriptions under Medicare Part D will be electronically prescribed. This bill can reduce diversion.
 - Adopted by voice vote.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act [[PDF](#)]

- Johnson Amendment – Makes technical changes.
 - Adopted by voice vote.
- Congressman Bill Johnson (R-OH) said that traditional prior authorization uses fax and telephone which causes delays for the patient and is burdensome. Electronic Prior Authorization provides a fast pathway for determining clinical appropriateness.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5675, To amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries [[PDF](#)]

- Congressman Bilirakis (R-FL) noted that pharmacy lock in has been used for Medicare for years. This bill changes the requirement, so all Part D plans should

have a lock in program. Congressman Ben Ray Lujan (D-NM) spoke in favor of the bill for protecting seniors.

- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5686, Medicare Clear Health Options in Care for Enrollees (CHOICE) Act [[PDF](#)]

- Congressman Chris Collins (R-NY) noted that half of older Americans suffer from chronic pain, so it is important to ensure seniors understand the dangers of opioids and prevention options. The bill will require Part D plans to inform patients about dangers of opioids.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5582, Abuse Deterrent Access Act of 2018 [[PDF](#)]

- Carter Amendment – extends CMS deadline to complete the study to 1 year; includes term “pro drug” and “list prices” in the bill.
 - Adopted by voice vote
- Congressman Doyle (D-PA) noted that he supports the bill because it gives an idea of how many people have access to ADF drugs.
- Congresswoman Schakowsky (D-IL) noted that she still believes that we need to study the price of naloxone products to see how the “skyrocketing” prices for generic and name brand naloxone products have affected access to these drugs. Generic and brand name formulations have seen huge price increases in the past few years. The generic version now sells for double its price and EVZIO has increased its price 500%. With the increased demand of these drugs to equip police, medical providers, family and friends the burden on public programs has increased as well. We need to know how these price increases are affecting access. We should give Secretary of HHS every tool he needs to address this public health emergency, especially the authority to negotiate the price of naloxone. President Trump is announcing his plan to address rising drug prices on Friday. I hope he includes many things but one thing we should be unified on is lowering the price of naloxone through negotiations. We cannot allow pharmaceutical corporations to profit from this epidemic. I hope that as we move forward through next week’s markup we can discuss how we can lower the barriers to accessing naloxone because when we can’t afford naloxone and it isn’t available people die.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5684, Protecting Seniors from Opioid Abuse Act [[PDF](#)]

- Congressman Michael Burgess (R-TX) spoke in support of the bill, noting that medication therapy will be expanded by adding those at risk for opioid abuse. Rep. Doyle (D-PA) noted that the bill would expand medication therapy to those at risk of substance use disorder. This bill will help people understand the drugs they are taking.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018 [[PDF](#)]

- Latta Amendment◊Makes technical changes to the bill. Reflect guidance from FDA. Adds a provision that requires GAO to conduct a study on the effect of exclusivity on the OTC market and consumers.

- Adopted by voice vote.
- Congressman Green (D-TX) voiced support for the bill and the amendment.
- Congresswoman Diana DeGette (D-CO) said that the monograph system is outdated.
- Congresswoman Dingell (D-MI) said that the FDA should be allowed to act swiftly if it sees issues.
- Congressman Pallone (D-NJ) said that the monograph system oversees thousands of drugs with a staff of 30 people and a budget of \$8 billion so this bill is necessary. Remains concerned about the inclusion of the exclusivity award.
- Pallone Amendment – would offer over the counter drugs 12-month exclusivity.
 - Congressman Robert Latta (R-OH) pointed out that the bipartisan agreement was 18 months.
 - Congressman Michael Burgess (R-TX) noted that he opposes 12-month exclusivity.
 - Congresswoman Schakowsky (D-IL) said that she opposes 18-month exclusivity. In the underlying bill, a company could get 18-month exclusivity for a drug that isn't better than old drug but just provides a new method of providing the drug (for instance changing pills to gummies). Companies can stop selling their old OTC drug and only sell the overpriced, exclusive drug.
 - Amendment not adopted—24 Yes, 30 No.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5473, Better Pain Management Through Better Data Act of 2018 [[PDF](#)]

- Congressman Michael Burgess (R-TX) This bill will direct FDA to hold a public meeting and update guidance on opioid sparing data. This bill will facilitate information sharing to providers.
- Congressman Ben Ray Lujan (D-NM) noted that non-addictive pain treatment is necessary because pain is inevitable. All non-addictive pain medications must be affordable and accessible.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5687, Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging [[PDF](#)]

- Congressman Frank Pallone (D-NJ) spoke in favor of this bill, would provide packaging and disposal guidance for schedule 2 drugs.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act [[PDF](#)]

- Congressman Buddy Carter (R-GA) supports this bill, because it incorporates his amendment that changed origination of prescriber materials to the Secretary of HHS with consultation of DEA administrator.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5041, Safe Disposal of Unused Medication Act [[PDF](#)]

- Walberg amendment Incorporates technical comments from DEA. There is a change to employee definition which has been reviewed by Association of Hospice Care.

- Congressman Tim Walberg (R-MI) voiced support for the Pallone amendment which clarified that training would be provided by the hospice rather than federal government and that there would be a record keeping program to maintain information for patient's clinical charts.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5202, Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018 [\[PDF\]](#)

- Welch Amendment – One of the tools DEA has in order to keep opioids off the market is the issuing of immediate suspension orders. DEA said that they would like to update the substantial likelihood standard used for suspension orders to be amended to probable cause standard. In the House Judiciary Committee, the day before, Acting Administrator of DEA recommended using foreseeable standard. The amendment would incorporate the DEA recommendation into the act.
 - Amendment not germane.
- Congressman Ryan Costello (R-PA) supports the bill because it updates the law to reflect technological advancements. Pharmacies cannot dispense practitioner administered buprenorphine now. This bill allows pharmacies to dispense injectable and intrathecal buprenorphine to practitioners. Urges support for the bill.
- Congressman Morgan Griffith (R-VA) noted that DEA should have asked for probable standard to begin with.
- **The bill was favorably reported to the House floor by voice vote.**

H.R. 5483, Special Registration for Telemedicine Clarification Act of 2018 [\[PDF\]](#)

- Congressman Carter (R-GA) supports bill as it incorporates amendment that lengthened the time to 1 year for finalizing the special waiver process.
- Congressman Pallone (D-NJ) noted that while DEA has authority to establish special registration to treat patients through telemedicine it hasn't established such registration yet. We are urging them to establish such a path, but the bill also ensures that this new method of care doesn't exacerbate opioid epidemic.
- **The bill was favorably reported to the House floor by voice vote.**
