GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

MEMORANDUM

April 24, 2018

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Subcommittee Markup of Opioid Legislation and H.R. 5554, Animal Drug and Animal Generic Drug Amendments Act of 2018

On **Wednesday, April 25th, at 1:00 p.m., in room 2123 of the Rayburn House Office Building**, the Subcommittee on Health will meet to markup 63 bills, all aimed at combatting the opioid crisis. The Subcommittee will also markup legislation reauthorizing the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA):

Controlled Substances 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. 5580, Surveillance and Testing of Opioids to Prevent (STOP) Fentanyl Deaths Act;
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 Re-Entry 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 of 2018;
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 (SCREEN) 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 Treatment Act;
61. H.R. 5473, Better Pain Management through Better Data Act of 2018;
62. H.R. ____, FDA Packaging and Disposal;
63. H.R. ____, FDA Long-term Efficacy; and
64. H.R. ____, FDA Misuse/Abuse.

I. LEGISLATION

This year, the Health Subcommittee held a series of three hearings on legislation related to the opioid crisis, entitled *Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety*,[1] *Combatting the Opioid Crisis: Prevention and Public Health Solutions*,[2] and *Combatting the Opioid Crisis: Improving the Ability of Medicare and Medicaid*

[1] House Committee on Energy and Commerce, *Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety*, 115th Cong. (Feb. 28, 2018) (https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-combating-the-opioid-crisis-helping-communities-balance).

[2] House Committee on Energy and Commerce, *Combatting the Opioid Crisis: Prevention and Public Health Solutions*, 115th Cong. (Mar. 21-22, 2018) (https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-combating-the-opioid-crisis-prevention-and-public-health).

to Provide Care for Patients.[3] On March 14, 2018, the Subcommittee held a hearing on the *Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA*.[4]

Please refer to the memoranda from these hearings for background on the legislation under consideration. The information below summarizes major changes made to those versions of the legislation that were considered at previous legislative hearings.

A. Controlled Substances Act

1. H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act

An amendment will be offered that changes the lead agency charged with developing training and materials for identifying prescriptions that are fraudulent, forged, or indicative of abuse or diversion from the Drug Enforcement Administration (DEA) to the U.S. Department of Health and Human Services (HHS).

2. Discussion Draft of H.R. , the Improving Access to Remote Behavioral Health Treatment Act of 2018

The revised discussion draft expands registration for purposes of telemedicine under the Controlled Substances Act to community mental health facilities that meet the criteria under section 1913(c) of the Public Health Service Act, or to a facility that is a Certified Community Behavioral Health Clinic and is licensed, operated, authorized, or certified by a state government.

B. Public Health Service Act

1. H.R. 5272, Reinforcing Evidence-Based Standards under Law in Treating Substance Abuse (RESULTS) Act of 2018

An Amendment in the Nature of a Substitute (AINS) will be introduced. It would require the National Mental Health and Substance Use Policy Laboratory within the Substance Abuse and Mental Health Services Administration (SAMHSA) to issue specific guidance for entities applying for SAMHSA grants. That guidance would encourage the funding of evidence-based practices, encourage the replication of promising or effective practices, and inform applicants on how to best articulate the rationale for the funding of a program or activity.

---

[3] House Committee on Energy and Commerce, *Combatting the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients*, 115th Cong. (April 11-12, 2018) (https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-combating-the-opioid-crisis-improving-the-ability-of-medicare).

[4] House Committee on Energy and Commerce, *Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA*, 115th Cong. (Mar. 14, 2018) (https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-reauthorization-of-animal-drug-user-fees-adufa-and-agdufa).

C. Medicare Part B

1. Discussion Draft of H.R. ____, Welcome to Medicare

The previous draft would have added a pain assessment as part of the Welcome to Medicare Initial Preventive Physical Examination, the provision of information to the beneficiary regarding non-opioid treatment alternatives to manage chronic pain, as well as a referral to a pain management specialist. The revised discussion draft adds a review of current opioid prescriptions, and then in the case of an individual receiving prescription opioids, adds: 1) a screen for opioid use disorder; 2) a pain assessment; 3) the provision of information regarding non-opioid treatment options for the treatment and management of chronic pain; and 4) a referral to a specialist, as deemed appropriate by the provider.

D. Medicaid

1. H.R. 4005, Medicaid Re-Entry Act

This legislation would restart Medicaid coverage for otherwise eligible individuals that are incarcerated in the 30-day period preceding release. Incarcerated individuals are more than 13 times more likely to overdose in the first 30 days following release. The AINS strikes H.R. 4005 as drafted and replaces it with: 1) A requirement for CMS and DOJ to convene a multi-stakeholder group to address transitions from incarceration for justice-involved individuals at-risk for SUD; 2) A requirement that the stakeholder group convened issue a report on best practices for states to improve transitions from incarceration of justice-involved individuals, including ensuring continuity of health coverage; 3) A requirement for CMS to undertake work through the Innovations Accelerator Program with states to reform transitions from incarceration for individuals at-risk for SUD; 4) A requirement for CMS to issue, within 1 year of enactment, waiver guidance to states on best practices for transitions to the community, including systems for enrollment support, substance use treatment and related services for individuals who are inmates of a public institution in the transition period prior to their release and who are eligible for Medicaid; 5) A rule of construction stating that nothing prohibits a state from reclassifying/suspending coverage as an alternative to termination of coverage.

2. H.R. 4998, Health Insurance for Former Foster Youth Act

This legislation would ensure that former foster youth are able to keep their Medicaid coverage across state lines until the age of 26. The AINS would align the definition of former foster youth with that under the Affordable Care Act.

3. H.R. 5477, Rural Development of Opioid Capacity Services (Rural DOCS) Act

This legislation authorizes a demonstration project to expand treatment capacity of, and expand technical assistance to Medicaid providers, and increase reimbursement rates for providers. The AINS would add planning grants for states to develop applications for the demonstration project contemplated under the legislation and makes other technical edits.

4. H.R. 5562, to require the Secretary of Health and Human Services to develop a strategy to implement certain recommendations relating to the Protecting Our Infants Act of 2015; and for other purposes

More than 80 percent of Neonatal Abstinence Syndrome (NAS) treatment for infants is financed by Medicaid. This legislation would require HHS to submit a strategy to Congress, which among other things would implement GAO recommendations contained in an HHS report entitled, Protecting Our Infants Act: Final Strategy." An amendment will be offered that would add the maternal recommendations from the report.

5. Discussion Draft of H.R. ____, Provide IMD Services Up to 90 Days for Medicaid Beneficiaries with SUD

The discussion draft would establish a five-year, state option to receive federal Medicaid reimbursement for up to 90 days for any new impatient beds added by the state during the five-year period. States would be required additionally to maintain spending overall on inpatient costs. The revised discussion draft would require states to additionally maintain outpatient spending for certain SUD outpatient services.

6. Discussion Draft of H.R. ___, Medicaid Pharmaceutical Home Act of 2018

The discussion draft would require all states to have a "lock-in" program that identifies at- risk Medicaid beneficiaries based on certain criteria and sets limits on the number of prescribers and dispensers beneficiaries may utilize under both fee-for-service and managed care arrangements. States found to be not in compliance by January 2019, would be subject to a Federal Medical Assistance Percentages (FMAP) penalty. The draft bill would extend the effective date of the bill by one year, remove the penalty for states for non-compliance and make other changes related to the number of pharmacies and prescribers where a beneficiary can be "locked-in", and modifies the appeals process—narrowing appeals in certain instances and further defining the process in others.

7. Discussion Draft of H.R. ____, Medicaid DRUG Improvement Act

The discussion draft would require all state Medicaid programs to use drug utilization review (DUR) activities in both fee-for-service and managed care with respect to opioids prescribing, monitoring of antipsychotics, and specific monitoring of concurrent prescribing of opioids and certain conditions, including HIV/AIDS, benzodiazepines, and antipsychotics. States would be required to have state-determined limitations in place for opioid refills, a program in place to monitor antipsychotic prescribing for children, and at least one buprenorphine/naloxone combination drug on the Medicaid drug formulary. States would be subject to FMAP penalties for noncompliance as of January 2019. The AINS would remove the penalty for noncompliance on state Medicaid programs, and makes other technical changes, including the removal of HIV/AIDS monitoring.

8. Discussion Draft of H.R. ____, Medicaid PARTNERSHIP Act

The discussion draft would require each Medicaid state program to integrate prescription drug monitoring program (PDMP) usage into a Medicaid provider's (including pharmacists) clinical workflow. The bill establishes standard criteria that a PDMP must meet to be counted as a qualified PDMP for purposes of the Medicaid program. This bill would mandate that Medicaid providers- both prescribers and dispensers- check the PDMP before prescribing or dispensing controlled substances. The bill directs states to report to CMS on how their PDMPs are working, the number of covered providers who are using the PDMPs, and about statewide trends in controlled substance utilization. This legislation includes a FMAP implementation incentive that would be given to states at the Secretary's discretion, and a FMAP penalty for noncompliance. The AINS would extend the effective date to October 1, 2021, changes the enhanced FMAP eligibility to states that implement a system other states can use, and reduces slightly the FMAP penalty for noncompliance. The legislation makes other technical changes.

9. Discussion Draft of H.R. ____, Incentives to Create Medicaid Health Homes to Treat Substance Use Disorder

Medicaid health homes can be targeted under current law to substance use disorders (SUD). States receive a 90 percent match for the first eight quarters of a health home model for special care coordination and health management services. This legislation would provide an additional four quarters of the enhanced match for SUD-specific health homes. The AINS clarifies the extra incentive is available for new health home beneficiaries in states that already operate a SUD health home.

10. Discussion Draft of H.R. ____, Medicaid Graduate Medical Education Transparency Act

This legislation would require additional reporting from state Medicaid programs on dollars used towards GME. The revised discussion draft removes the penalty for noncompliance.

E. Federal Food, Drug, and Cosmetic Act

1. H.R. 5228, Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now (SCREEN) Act

H.R. 5228 aims to strengthen FDA's authority to detain, refuse, and destroy substances identified through international mail facilities, improve enforcement mechanisms, and provide funding to combat the influx of illegally manufactured opioids into the country.

2. H.R. 5554, Animal Drug and Animal Generic Drug Amendments Act of 2018

A manager's amendment will be offered, which adds three provisions to the prior version considered by the Subcommittee. First, the manager's amendment directs the Food and Drug Administration (FDA) to consider how to apply the drug development tools included in the 21st Century Cures Act to animal drugs, such as adaptive and novel clinical trial designs, real world evidence, and biomarkers and surrogate endpoints, among others. Another provision directs FDA

to issue recommendations related to expanding conditional approvals by September 30, 2019. The last provision requires FDA to consider foreign data in food additive decisions and to supply the supporting, scientific rationale for its decisions if it requires the sponsor to conduct more studies. The amendment directs FDA to report on the number of food additive petitions pending, how long they have been pending, and the number of study protocols that have been pending review for over 50 days. FDA would also have to provide guidance detailing the manner in, and the number of days by, which it intends to review and respond to existing petitions.

3. Discussion Draft of H.R. , 21st Century Tools for Pain and Addiction Treatment Act

The 21st Century Tools for Pain and Addiction Treatment Act is a revised discussion draft that would require FDA to hold, within one year of enactment, public meetings related to developing nonaddictive medical products intended to treat pain and addiction, including how novel clinical trial designs, use of real world evidence, and patient experience data could help with such efforts, as well as how the accelerated approval and breakthrough therapy designation pathways would apply to such treatments. The discussion draft further requires FDA, within one year of its enactment, to issue one or more final guidances, or update existing guidances regarding how the accelerated approval and breakthrough therapy designation pathways should apply to non-addictive medical products to treat pain or addiction, and the methods by which sponsors could use surrogate endpoints, intermediary endpoints, or real-world evidence.

4. Discussion Draft of H.R. , FDA Packaging and Disposal

The FDA Packaging and Disposal discussion draft has been revised to limit FDA's authority to require the use of one or more technologies related to packaging or disposal of schedule II or schedule III substances; incorporates a requirement that the Secretary must consult with experts and a broad range of stakeholders prior to issuing such an order; and provides the manufacturer with the ability to request additional time to implement such technologies, as well as the opportunity to dispute a determination.