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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

May 16, 2018

To: Committee on Energy and Commerce Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Full Committee Markup of Opioid Legislation

On **Thursday, May 17th, at 10:00 a.m., in room 2123 of the Rayburn House Office Building**, the full Committee will meet to markup 34 bills aimed at combatting the opioid crisis.

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;
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;

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;
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.

I. BACKGROUND

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-

to Provide Care for Patients.[3] From these legislative hearings, the Health Subcommittee held a markup on some of these bills on April 25, 2018.[4]

Please refer to the hearings and markup memoranda for background on the legislation under consideration. The information below summarizes any major changes made to prior versions of the legislation that were considered at previous legislative hearings, or at the Subcommittee on Health markup.

II. LEGISLATION

A. PUBLIC HEALTH SERVICE ACT

7. H.R. 5807, Substance Use Disorder Coordination, Access, Recovery Enhancement Act of 2018

H.R. 5807, introduced by Rep. Mullin (R-OK) and Rep. Blumenauer (D-OR) the draft legislation that incorporated the text of H.R. 3545, Overdose Prevention and Patient Safety Act considered at the May 8th Subcommittee on Health Hearing, "Improving the Coordination and Quality of Substance Use Disorder Treatment," and some of the provisions of H.R. 3692, the Addiction Treatment Access Improvement Act of 2017.

Like H.R. 3545, this legislation would take away the rights of individuals with substance use disorders to decide the extent to which their medical record from Part 2 programs can be shared. Like the Amendment in the Nature of a Substitute (AINS) to H.R. 3692 considered at the March 21st hearing, "Combatting the Opioid Crisis: Prevention and Public Health Solutions," this legislation would allow certain providers to treat up to 100 patients with buprenorphine in the first year after obtaining their DATA waiver.

Unlike H.R. 3962, the legislation does not allow all advanced practice registered nurses, including certified nurse midwives, certified registered nurse anesthetists, and clinical nurse specialists, to treat patients with buprenorphine. Further, unlike H.R. 3692, this legislation does not bestow nurse practitioners and physician assistants with permanent authority to treat patients with buprenorphine; instead extending the authority to October 1, 2028. Finally, H.R. 5807 also

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energycommerce.house.gov/committee-activity/hearings/hearing-on-combating-the-opioid-crisis-prevention-and-public-health).

[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, *Markup of Opioid and Other Public Health Legislation*, 115th Cong. (April 25, 2018) (https://democrats-energycommerce.house.gov/committee-activity/markups/markup-of-opioid-and-other-public-health-legislation-subcommittee-on).

does not codify the 275 cap on the number of patients physicians can treat, established by regulations included in H.R. 3692.

8. H.R. 5812, Creating Opportunities that Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies Act of 2018

H.R. 5812, introduced by Reps. Griffith (R-VA) and Pallone (D-NJ), would codify the Prevention for States Program and Enhanced Surveillance of Controlled Substance Overdose Program, which is administered by the Centers for Disease Control and Prevention. This legislation also updates the National All Scheduled Prescription Electronic Reporting (NASPER) Act and incorporates it into CDC's Prevention for States Program.

B. MEDICARE PART B

10. H.R. 5603, Access to Telehealth Services for Opioid Use Disorder

H.R. 5603, the Access to Telehealth Services for Opioid Use Disorders Act, introduced by Reps. Matsui (D-CA) and Johnson (R-OH), expands access to telehealth services for Medicare beneficiaries with opioid use disorders by giving the Secretary the authority to lift the originating site and rural health professional shortage area (HPSA) requirements for the treatment of opioid use disorders and co-occurring mental health disorders via telehealth. An AINS is expected that would make technical changes and would expand the program to treatment of substance use disorders more broadly.

11. H.R. 5605, Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act

H.R. 5605, introduced by Rep. Ruiz (D-CA) would create a demonstration project for an Alternative Payment Model for treating opioid use disorders. This model includes the development of measures to evaluate the quality and outcomes of treatment, and to reward coordinated care teams that provide high quality, evidence-based medication-assisted treatment in conjunction with appropriate psychosocial services. An AINS is expected that would make technical changes and would limit the number of beneficiaries that can participate to 20,000.

12. H.R. 5798, Opioid Screening and Chronic Pain Management Alternatives for Seniors Act

H.R. 5798, the Opioid Screening and Chronic Pain Management Alternatives for Seniors Act, introduced by Reps. Bucshon (R-IN) and Dingell (D-MI) would add a pain assessment and a screen for opioid use disorders to the Welcome to Medicare initial examination, as well as referral to treatment, where appropriate. The introduced bill makes technical changes from the discussion draft marked up in the Health Subcommittee on April 25, 2018, and would clarify that both the pain assessment and the screening would only apply to an individual with a current opioid prescription for chronic pain.

13. H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act Post-Surgical Injections as an Opioid Alternative Act

H.R. 5804, introduced by Reps. Shimkus (R-IL) and Krishnamoorthi (D-IL), seeks to incentivize post-surgical injections as a pain treatment alternative to opioids by reversing a reimbursement cut for these treatments in the Ambulatory Surgical Center (ASC) setting. The discussion draft marked up in the Health Subcommittee on April 25, 2018, would have fixed the reimbursement rate at 2016 levels through 2028. The introduced version that the full Committee is expected to take up would fix the reimbursement rate at 2016 levels for five years. The introduced version also requires the Department of Health and Human Services to conduct a study and submit to Congress a report on the extent to which the procedures are effective at preventing the need for opioids for individuals furnished such procedures. The bill would also require GAO to collect data and issue a report relating to the cost differential between these procedures performed in a hospital operating room as compared to an office setting within a hospital.

14. H.R. 5809, Postoperative Opioid Prevention Act of 2018

H.R. 5809, the Post-Operative Opioid Prevention Act of 2018, introduced by Reps. Bucshon (R-IN) and Peters (D-CA), would add two years to the current three -years of pass-through payment for non-opioid analgesics for post-surgical pain management in the Medicare Outpatient Prospective Payment System (OPPS). Under current law, new drugs receive three years of separate reimbursement in the OPPS before they are bundled into the cost of a procedure. This bill would extend pass-through status from three to five years, thereby allowing the manufacturers of these non-opioid analgesic drugs to obtain higher reimbursement for a longer period of time.

The introduced bill makes the following changes from the discussion draft marked up in the Health Subcommittee on April 25: 1) requires that the drug have demonstrated substantial clinical improvement in order to qualify for additional two years of pass through status; and 2) extends pass-through status not only for new drugs that are not currently receiving any reimbursement under the OPPS, but also to drugs that are currently on three -year pass through status.

C. MEDICARE PART D

15. H.R. 5715, Strengthening Partnerships to Prevent Opioid Abuse Act

H.R. 5715, introduced by Reps. Renacci (R-OH), Sewell (D-AL), Guthrie (R-KY) and Rep. Peters (D-CA), would create new program integrity transparency measures in Medicare Part C and Medicare Part D by establishing a program integrity portal for the purposes of increasing information sharing of cases of substantiated fraud, waste, and abuse. A discussion draft version of this bill was favorably reported out of the Health subcommittee by voice vote. It is expected that there will be a technical amendment offered at full Committee that would clarify that fraud hotline tips do not constitute sufficient evidence for substantiated fraud, waste, and abuse for the purposes of this bill without further evidence.

D. MEDICAID

19. H.R. 3192, CHIP Mental Health Parity Act

H.R. 3192, CHIP Mental Health Parity Act, introduced by Rep. Kennedy (D-MA) would require comprehensive mental health and substance use disorder services as a mandatory benefit under the CHIP program for pregnant women and children. An AINS will be offered to this bill that incorporates technical feedback by CMS to ensure better implementation of the policy.

20. H.R. 4005, Medicaid Reentry Act

H.R. 4005, the Medicaid Reentry Act, as originally introduced by Rep. Tonko (D-NY) 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 that will be offered 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 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.

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

H.R. 4998, the Health Insurance for Former Foster Youth Act, introduced by Rep. Bass (D-CA), would ensure that former foster youth are able to keep their Medicaid coverage across state lines until the age of 26. An AINS will be offered to this legislation that mandates that all states must adopt this policy in calendar year 2023 for individuals attaining the age of 18 that year, although a state may adopt the policy sooner at state option, and requires CMS to issues guidance to state Medicaid programs on best practices to ensure continuity of coverage across state lines for former foster youth within one year of enactment.

22. H.R. 5477, Rural Development of Opioid Capacity Services Act

This legislation authorizes a demonstration project to expand treatment capacity of current and new Medicaid providers, and expand technical assistance to Medicaid providers for Medicaid billing and SUD education, and allows states to receive enhanced matching dollars to raise reimbursement rates for providers delivering SUD services. The AINS would add planning grants for at least ten states to develop applications for the demonstration project and recruit

prospective Medicaid providers, limits the states participating in enhanced FMAP portion of the demonstration project to five states eligible to receive an 80 percent match for new spending on activities in the demonstration project, and strengthens evaluation requirements for the project.

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

H.R. 5789, the MOM IMD Act, introduced by Rep. Foster (D-IL), would add a state option for neonatal abstinence recovery centers, clarify that pregnant and postpartum women keep their full range of Medicaid benefits when in an IMD, require CMS to issue guidance on NAS treatment options under Medicaid, and require a GAO study on coverage gaps for pregnant women with SUD. An amendment is expected based on stakeholder, CBO, and stakeholder feedback that would strike paragraphs (a) and (b) of Section 1 of the bill.

25. H.R. 5797, IMD CARE Act

The discussion draft considered at the Subcommittee would have established 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 and maintain outpatient spending for certain SUD outpatient services.

H.R. 5797 as introduced by Rep. Mimi Walters (R-CA) would establish a five-year, state option to receive federal Medicaid reimbursement for up to 30 days within a 12 month period for an individual with a diagnosed Opioid Use Disorder (defined to generally include pain medication and heroin use disorder).

26. H.R. 5799, Medicaid DRUG Improvement Act

The initial 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 revised discussion draft marked up by the subcommittee would remove the penalty for noncompliance on state Medicaid programs, and makes other technical changes, including the removal of HIV/AIDS monitoring.

The introduced legislation by Rep. Blackburn (R-TN) that will be considered makes additional technical changes to align with current state practice-specifically, clarifying that while states must adopt safety edits for opioids fills and daily maximum morphine equivalent prescribed to individuals, such limits are for the purposes of screening and identifying

problematic patterns and do not trigger an automatic denial of claims, allowing for clinical judgement.

27. H.R. 5800, Medicaid IMD ADDITIONAL INFO Act

This legislation, which was introduced by Rep. Upton (R-MI) has changed from the subcommittee discussion draft to allow for MACPAC technical feedback.

28. H.R. 5801, Medicaid PARTNERSHIP Act

This legislation, which was introduced by Rep. Griffith (R-VA) makes significant changes from the discussion draft considered at the Subcommittee's markup. The discussion draft considered at Subcommittee 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.

This legislation makes significant changes from the discussion draft. All penalties are removed. The scope has been narrowed to only schedule II controlled substances. Requirements on data use agreements between the state PDMP and the state Medicaid program are optional, and privacy and beneficiary protections have been strengthened throughout the legislation.

29. H.R. 5808, Medicaid Pharmaceutical Home Act of 2018

The discussion draft would have required 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.

This legislation, introduced by Rep. Bilirakis (R-FL) makes significant changes from the discussion draft. The legislation makes clear that while states must operate a lock-in program for at-risk beneficiaries, similar to Medicare, whether such a beneficiary is assign to the program still allows for flexibility by the state and for clinical judgment. The scope has been narrowed,

and all FFS lock-in programs, which nearly all states have, are deemed to meet the requirements of the bill. In addition, all beneficiary appeals and protections have been significantly strengthened and for the most part, track appeals and beneficiary choice for lock-in under the Medicare program. In addition, all penalties have been removed.

E. FEDERAL FOOD, DRUG, AND COSMETIC ACT

31. H.R. 5228, Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act

An AINS will be offered to incorporate feedback from stakeholders regarding an order to cease distribution or recall drugs that present an imminent or substantial hazard to the public health. The amendment will align the standard with that of biologics, and outline a hearing process for manufacturers that is consistent with that available for other product areas. The SCREEN Act passed the Subcommittee by voice vote.

32. H.R. 5752, Stop Illicit Drug Importation Act of 2018

H.R. 5752 passed the Subcommittee by voice vote. An amendment is expected to be offered by Rep. Blackburn (R-TN) to make technical changes to the definition of articles to be treated as drugs, and to clarify the circumstances that could lead to debarment.

33. H.R. 5806, 21st Century Tools for Pain and Addiction Treatments

Following passage in the Subcommittee by a vote of 19-10, Rep. Burgess (R-TX) introduced the "21st Century Tools for Pain and Addiction Treatment Act." The introduced version of this legislation strikes annual reporting requirements directing FDA to disclose the requests received, requests granted, rationale for approving or denying requests, as well as timelines, metrics, and recommendations regarding how non-opioid, non-addictive pain treatments could be eligible for expedited programs. FDA had raised concerns about the resource burden such reporting would entail, and the impact it would have on staff being diverted from other activities to compile such reports. Further, the legislation did not include any resources to implement the new annual reporting requirements.

34. H.R. 5811, Long-Term Opioid Efficacy Act of 2018

Introduced by Reps. McNerney (D-CA) and Griffith (R-VA), the "Long-Term Opioid Efficacy Act of 2018" would provide FDA with authority to require post-marketing studies of manufacturers of controlled substances if there is reason to believe that a potential reduction in effectiveness or an increase in the serious risk of the drug. Such authority would enable FDA to require manufacturers of controlled substances, such as chronically administered opioids, to demonstrate that their products are effective or do not present serious risk.