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OPIOID SUMMARY

# Opioid Legislation Passed by the U.S. House of Representatives -- June 2018

During the month of June, the House of Representatives passed more than 70 opioid related bills. One of AMCP's policy and advocacy focus areas for 2018 is opioid management. AMCP also approved a new policy digest statement on Opioid Management. As you review, this summary you will note that several of the bills passed are consistent with the AMCP policy statement. AMCP also took an active role in support of five bills: **H.R. 3528** – Every Prescription Conveyed Securely Act, **H.R. 4275** – Empowering Pharmacists in the Fight Against Opioid Abuse Act, **H.R. 4841** – Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018, **H.R. 5676 –** the SENIOR Communities Protection Act of 2018, and **H.R. 6082** (formerly H.R. 3545/H.R. 5795) – the Overdose Prevention and Patient Safety Act. The latter bill (H.R. 6082) was not included in H.R. 6 but passed as a separate bill (summary below).

AMCP members and staff played a key role in the passage of these bills! AMCP members sent letters to more than 120 Representatives in 32 states in support of the referenced bills. AMCP also sent letters, participated in Hill visits and actively engaged with the Partnership to Amend 42 CFR Part 2 (H.R. 6082), and co-sponsored a print ad in support of H.R. 6082. The State Advocacy Coordinators (S.A.C.), AMCP Affiliates and the California Pharmacy Association were instrumental in distributing the action alerts and made a significant contribution to member engagement.

Adding your voice through grassroots advocacy sent a strong message that resulted in overwhelming support for these bills as reflected in the voting record both in numbers of favorable votes and bipartisan support -- Your efforts sent these bills to the Senate with a clear call for ACTION! The bills have been received in the Senate and will be assigned to a committee for consideration. In the Senate, AMCP members' action will once again be necessary to seek favorable votes to ensure that these bills will become law.

Below is a brief summary of the provisions included in the bills.

**H.R. 6** – the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities" Act passed the House with a strong bipartisan vote of 396-14. It is designed to combat the opioid crisis by advancing treatment and recovery initiatives, improving prevention, protecting communities, and bolstering efforts to fight deadly illicit synthetic drugs like fentanyl. A brief summary of selected provisions follows – the entire bill is 460 pages.

**MEDICAID:**

- Requires CMS to carry out a demonstration project to provide an enhanced federal matching rate for state Medicaid expenditures related to the expansion of substance use treatment and recovery services targeting provider capacity. [H.R. 5477]
- Beginning in 2020, all state Medicaid programs must have a beneficiary assignment program that identifies at-risk beneficiaries for substance use disorder (SUD) and assigns them to a pharmaceutical home program, which must set reasonable limits on the numbers of prescribers and dispensers that beneficiaries may utilize. This includes restricting their controlled substance prescriptions to 1 to 3 prescribers and 1 to 3 pharmacies. Pharmacies that have multiple locations that share real-time electronic prescription data, all such locations, shall collectively be treated as one pharmacy. If a state has an existing drug management program it shall be treated as a qualified drug management program under this section. Managed care entities must have guidelines for how to transition at risk members

between Medicaid fee for service and managed care plans. This program does not apply to individuals receiving hospice or palliative care or treatment for cancer, residents of a long-term care facility or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy. [H.R. 5808]

- Medicaid and CHIP Payment and Access Commission in consultation with the National Association of Medicaid Directors, pharmacy benefit managers, managed care organizations, health care providers (including pharmacists), beneficiary advocates and other stakeholders, shall publish a report which includes best practices for operating a drug management program and a summary of experience with the appeals process, a summary of trends and effectiveness and recommendations on how improvements can be made in the operation of such programs.
- Requires managed care entities to have a claims review automated process that monitors when an individual enrolled is concurrently prescribed opioids and benzodiazepines or antipsychotics.
- Requires State Medicaid programs to have prospective or retrospective Drug Utilization Review edits in place for opioid refills, concurrent prescribing with other drugs, and monitor antipsychotic prescribing for children. [H.R. 5799]
- Instructs HHS to issue guidance on Neonatal Abstinence Syndrome treatment options under Medicaid and a study by the Government Accountability Office on gaps in coverage for pregnant women with SUD. [H.R. 5789]
- Extends the Federal Medical Assistance Percentage (FMAP) to payments for Medicaid Health homes for patients with SUD and includes coverage of medication assisted treatment for medical assistance.
- Temporarily eliminates the enhanced federal matching rate for Medicaid expenditures for specified medical services provided by certain managed care organizations.

**MEDICARE:**

- Encourages the use of non-opioid analgesics for the management of post-surgical pain by allowing a limited period of payments. [H.R. 5809]
- Requires a review of current opioid prescriptions for chronic pain and screening for opioid use disorder be included in the welcome to Medicare initial preventive physical examination. [H.R. 5798]
- Requires e-prescribing for coverage of covered Part D controlled substances, with limited exceptions. Examples of exceptions include: prescription issued when practitioner and dispenser are same entity, prescription cannot be transmitted under the most recently implemented version of the NCPDP SCRIPT standard and prescription for individuals in hospice care or resident of skilled nursing facility. Pharmacist not responsible for verifying that the prescriber has a waiver or is exempt from the requirement. Applies to drugs prescribed on or after January 1, 2021. [H.R. 3528 – AMCP supported]
- Requires for plan years beginning on or after January 1, 2021 that prescription drug plan sponsors must establish a drug management program for at-risk beneficiaries. [H.R. 5675 - currently establishing a drug management program is voluntary]
- Defines opioid use disorder treatment services and treatment programs. The program must have a certification by the Substance Abuse and Mental Health Services Administration (SAMHSA) and accredited by an accrediting body approved by SAMHSA. Requires coverage for certified programs.
- Requires FDA to hold at least one public meeting to address the challenges and barriers of developing non-addictive, medical products intended to treat pain or addiction. Requires the Secretary of HHS to issue one or more final guidance documents or update existing documents to help address the challenges identified.

**PUBLIC HEALTH**

- Requires Secretary of HHS to establish a grant program to support the establishment or operation of public health laboratories to detect fentanyl, its analogues and other synthetic opioids. Requires the Director of the Centers for Disease Control and Prevention to enhance its drug surveillance program which includes increasing and accelerating the collection of data on fentanyl. [H.R. 5580]

- Requires Secretary to establish a pilot program for point-of-use testing of illicit drugs for dangerous contaminants.
- Increases the maximum number of patients that health care practitioners may initially treat with medication – assisted treatment (under a buprenorphine waiver). Eliminates any time limitations for nurse practitioners and physician assistants to become qualifying practitioners. Imposes a time limitation for clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwifes to become qualifying practitioners. [H.R. 3692]

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**H.R. 6** also included the following provisions from "bills" previously passed by the House by voice vote. There are many other bills included in this section and a summary of all such bills can be found at: https://energycommerce.house.gov/opioids-legislation/

- Requires state Children's Health Insurance Programs (CHIP) to cover mental health benefits, including substance use disorder services for pregnant women and children. In addition, states would not be allowed to impose financial or utilization limits on mental health treatment that are lower than limits placed on physical health treatment. [H.R. 3192]
- Requires Medicaid providers to check the prescription drug monitoring program (PDMP) before prescribing a Schedule II controlled substance. Encourages Medicaid providers to integrate PDMP usage into a Medicaid provider's clinical workflow. 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 PDMP data and information. [H.R. 5801]
- Promotes the testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology. [H.R. 3331]
- Directs CMS to evaluate the use of abuse-deterrent opioids in Medicare plans. [H.R. 5582]
- Directs 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. [H.R. 5685]
- Creates a demonstration project for treating substance use disorder (SUD). This model includes the development of measures to evaluate the quality and outcomes of treatment. [H.R. 5605]
- Directs CMS to work with eligible entities, including Quality Improvement Organizations, to engage in outreach with prescribers identified as clinical outliers to share best practices to evaluate their prescribing behavior. [H.R. 5796]
- Combats opioid abuse through providing more resources to beneficiaries and improving program integrity in the Medicare Part D program and requires e-prior authorization. [H.R. 5773 included H.R. 4841 – AMCP supported]
- Requires the Medicare Payment Advisory Commission to report to Congress on: (1) how Medicare pays for opioid and non-opioid pain management treatments in inpatient and outpatient hospital settings; (2) current incentives for prescribing opioid and non-opioid treatments under Medicare inpatient and outpatient prospective payment systems, along with recommendations to address any identified adverse incentives; and (3) how opioid use data is currently tracked and monitored through Medicare claims data. [H.R. 5723]
- Directs HHS to study ways to improve access to non-opioid pain management treatments. [H.R. 6110]
- Requires CMS to: (1) publish guidance for hospitals on pain management and opioid-use disorder prevention strategies for Medicare beneficiaries, (2) convene a technical expert panel to recommend opioid and opioid-use disorder quality measures for possible use in value-based payment and reporting models under Medicare; and (3) publish and periodically update all guidance issued since January 1, 2016 related to the prescription of opioids for Medicare beneficiaries. [H.R. 5774]
- Allows the Secretary to authorize Medicare Prescription Drug Plans and MA-PD Plans to suspend payment of claims pending an investigation of credible allegations of fraud by pharmacies. A fraud hotline tip without further evidence shall not be treated as sufficient evidence of a credible allegation of fraud. A credible allegation of fraud is defined by the HHS Secretary. [H.R. 5676 – AMCP supported]
- Requires 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. [H.R. 5775]

- Requires HHS to develop and disseminate programs and materials for training pharmacists, health care provider and patients on circumstances under which a pharmacist may decline to fill a prescription for a controlled substance because the pharmacist suspects the prescription is fraudulent, forged or otherwise indicative of abuse or diversion. HHS will seek input from relevant stakeholders [H.R. 4275 – AMCP supported]
- Provides NIH with new, flexible authorities to conduct innovative research and spur urgently needed research on new non-addictive pain medications. [H.R. 5002]
- Ensures medical professionals have access to a consenting patient's complete health history when making treatment decisions by requiring HHS to develop and disseminate best practices regarding the prominent display of substance use disorder (SUD) history in patient records of patients who have previously provided this information to a health care provider. [H.R. 5009 – AMCP supported]
- Reduces the number of unused controlled substances at risk of diversion or misuse by allowing hospice employees to safely dispose of these medications on site after the death of a patient. [H.R. 5041]
- Provides 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. [H.R. 5176]
- Provides the FDA with stronger recall and seizure authority to disrupt the entry of counterfeit and illicit drugs through International Mail Facilities (IMFs). [H.R. 5228]
- Establishes Comprehensive Opioid Recovery Centers (CORCs) that will 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. [H.R. 5327]
- Authorizes CDC to undertake an injection drug use-associated infection elimination initiative and work with states to improve education, surveillance and treatment of injection drug-use associated infections, like human immunodeficiency virus (HIV) and hepatitis. [H.R. 5353]
- Directs the FDA to articulate clear data collection methods that could be used to inform opioid-sparing labeling claims for products that may replace, delay, or reduce or the use of opioid analgesics. [H.R. 5473]
- Streamlines and enhances 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. [H.R. 5752]
- Improves current federal support for state-run PDMPs. 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. [H.R. 5812]
- Directs the FDA to work with manufacturers to establish programs for efficient return or destruction of unused Schedule II drugs, with an emphasis on opioids. These methods could include mail-back pouches to secure facilities for incineration, or methods to immediately inactivate/render unattractive unused drugs. In addition, this bill will facilitate utilization of packaging that may reduce overprescribing of opioids. Finally, this bill will require the Government Accountability Office (GAO) to study new and innovative technologies that claim to be able to safely dispose of opioids and other unused medications. GAO would review and detail the effectiveness of these disposal methods. [H.R. 5687]
- Enhances the 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, and their overall place in the treatment of pain. [H.R. 5811]

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**H.R. 6082** [AMCP supported] – the "Overdose Prevention and Patient Safety" Act passed the House with a strong bipartisan vote of 357-57.

- Expands the circumstances under which medical records relating to substance use disorders (SUD) can be disclosed to healthcare providers, plans, and health care clearing houses
- Enables medical professionals to access that information when treating patients
- Requires disclosures to be made in accordance with the Health Insurance Portability and Accountability Act's (HIPAA) privacy regulations
- Prohibits any entity from discriminating against an individual on the basis of information contained in SUD records
- Uses the same model that other federal privacy laws use, which is that exchanging health care information within the health care system produces better outcomes for the patient