

Opioid Legislation Reaches Final Agreement-- September 2018

With a final compromise bill for the opioid package announced, AMCP would like to thank its members who acted to advocate for the inclusion of provisions which will help managed care combat the opioid crisis. Almost 300 AMCP members sent letters to 62 Senators to shine the spotlight on sections which needed to be included in a final compromise legislation. Without this impact, several of the sections would not have made it into the final bill. Congress is expected to vote on the compromise bill as early as today, September 27.

One of AMCP's policy and advocacy focus areas for 2018 is opioid management and along with our members action, we supported several bills which were included in the final opioid package of H.R. 6 – the SUPPORT for Patients and Communities Act. These include:

- H.R. 3528 – Every Prescription Conveyed Securely Act included as Section 2003. This provision requires Schedule II, III, IV, or V controlled substances covered under Part D or Medicare Advantage Drug Plans (MA-PD) to be transmitted using an electronic prescription drug program starting January 1, 2021.
- H.R. 4275 – Empowering Pharmacists in the Fight Against Opioid Abuse Act included as Section 3212. This provision directs HHS to help develop and disseminate materials which clarify circumstances when this is allowed based on suspected fraudulent, forged, questionable or suspicious origin of prescription.
- H.R. 4841 – Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018 included as Section 6062. This provision requires the Secretary of HHS to establish a standard, secure electronic prior authorization system no later than January 1, 2021 for use by Part D plans.
- H.R. 5676 – the SENIOR Communities Protection Act of 2018 included as Section 2008. This provision permits Part D plans and MA-PD plans to suspend payment and requires reporting of suspensions to the Secretary of Health and Human Services (HHS).

These measures together help prevent fraudulent prescriptions and curb potential opioid abuse while empowering pharmacists and health plans to act. These and several other sections that impact managed care are summarized below.

H.R. 6 will be a great step to combat the increase in overdose deaths reported by the CDC (72,000 overdose deaths in 2017).¹ However, AMCP is particularly disappointed that H.R. 6082 – the Opioid Overdose and Prevention Act, was not included in the compromise bill. AMCP, along with the [Partnership to Amend 42 CFR Part 2](#) will continue to advocate to eliminate barriers to patient centered coordinated care. This provision, 42 CFR Part 2 (Part 2), when aligned with the Health Insurance Portability and Accountability Act (HIPAA), would allow providers to access comprehensive substance use treatment records for patients and prevent dangerous drug-drug interactions and provide whole person coordinated care. Not only would this improve the care coordination for patients, H.R. 6082 contained protections for unlawful disclosure and requirements to notify patients of breaches. AMCP will continue to push the Senate to vote on this bill by the end of session, as it already passed the House by an outstanding 357-57 vote in June.

¹ Ahmad FB, Rossen LM, Spencer MR, Warner M, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2018. <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

[H.R. 6](#) – the “Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities” Act originally passed the House with a strong bipartisan vote of 396-14 in June and the Senate passed their version by a vote of 99-1 September 17. The final compromise bill, released Sept. 25, 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 660 pages.

Title I – Medicaid Provisions to Address the Opioid Crisis

- Section 1004 – Medicaid drug review and utilization. This provision builds on current state Medicaid drug utilization review activities by requiring programs to have safety edits in place for opioid refills, monitor concurrent prescribing of opioids and certain other drugs and monitor antipsychotic prescribing in children.
- Section 1016 – Better data sharing to combat the opioid crisis. This provision clarifies states’ ability to access and share data from prescription drug monitoring program (PDMP) including with providers and managed care entities, consistent with parameters in state law.

Title II – Medicare Provisions to Address the Opioid Crisis

- Section 2003 – Every prescription conveyed securely. This provision requires Schedule II, III, IV, or V controlled substances covered under Part D or Medicare Advantage Drug Plans (MA-PD) to be transmitted using an electronic prescription drug program starting January 1, 2021.
- Section 2008 – Suspension of Payments by Medicare prescription drug plans and MA-PD plans pending investigations of credible allegations of fraud by pharmacies. This provision permits Part D plans and MA-PD plans to suspend payment and requires reporting of suspensions to the Secretary of Health and Human Services (HHS).

Title III – FDA and Controlled Substance Provisions

- Section 3041 – Clarifying FDA post market authorities. This provision clarifies FDA’s post market authorities for drugs, such as opioids, which may have reduced efficacy over time, by modifying the definition of an adverse drug experience to include such situations.
- Section 3212 – Programs and materials for training on certain circumstances under which a pharmacist may decline to fill a prescription. This provision directs HHS to help develop and disseminate materials which clarify circumstances when this is allowed based on suspected fraudulent, forged, questionable or suspicious origin of prescription.

Title VI – Other Medicare Provisions

- Section 6062 – Electronic prior authorization for covered Part D drugs. This provision requires the Secretary of HHS to establish a standard, secure electronic prior authorization system no later than January 1, 2021 for use by Part D plans.
- Section 6063 – Program integrity transparency measures under Medicare Parts C and D. This provision requires the Secretary of HHS to establish a secure web portal that allows secure communication between the Secretary, Part D, MA plans and the Medicare Drug Integrity Contractor information on investigations or other actions taken by such plans related to providers who inappropriately prescribe opioids.
- Section 6064 – expanding eligibility for medication therapy management programs under Part D. This provision requires beneficiaries at risk for prescription drug abuse to be eligible for Medication Therapy Management (MTM) programs beginning January 1, 2021.

Title VII – Public Health Provisions

- Section 7051 – Inclusion of opioid addiction history in patient records. This provision requires HHS to develop best practices for displaying substance use disorder treatment information in EHRs, when requested by a patient.
- Section 7053 – Development and dissemination of model training programs for substance use disorder patient records. This provision requires HHS to identify model programs and materials to better train and educate providers, patients, and families regarding the permitted uses and disclosures of patient records related to treatment for SUD.

If you are interested in the entire text of the legislation, the entire bill can be found [here](#). Thank you again to all acted to support AMCP's work on opioid management. We look forward to continuing to fight for patients, families, and communities affected by the opioid epidemic.