



## **Empowering Doctors and Pharmacists to Prevent Inappropriate Opioid Prescriptions**

### **The Problem**

The technology clinicians rely on to detect improper opioid prescriptions – known as Prescription Drug Monitoring Programs (PDMPs) – are available in most states and hold great promise, but vulnerabilities remain.

For example, PDMP data is not updated in real-time, may not include prescriptions filled across state lines, and likely does not include fill “attempts.” Additionally, PDMPs are not currently in the prescribing or dispensing workflow.

Doctors and pharmacists need real-time information on patient opioid history to inform their clinical judgement about whether to prescribe an opioid. Otherwise, those with abuse issues will gain access while those with cancer or other pain issues could be denied care.

### **The Solution**

The **Prescription Safety Alert System** provided for in H.R. 6688, the *ALERT Act of 2018* would complement PDMPs by providing real-time clinical data at the point of dispensing using already existing transaction data. This would limit doctor and pharmacy-shopping, identify cash transactions and attempts, not just fills, and help prevent inappropriate cross-state prescriptions that have long gone unnoticed.

The alert system delineated in the bill would be run by the private sector under contract with HHS and based on a model developed by the National Council for Prescription Drug Programs (NCPDP). The proposal includes the following elements:

- The legislation would direct the Secretary of HHS, acting through the FDA Commissioner and under Risk Evaluation and Mitigation Strategy (REMS) authority, to require that products deemed by the Secretary to be at risk for misuse, abuse, addiction, overdose, or drug-drug interactions be dispensed using a prescription safety alert system.
- The prescription safety alert system would be facilitated by use agreements with dispensers, allowing claims data to be used for clinical purposes.
- The alert system would use this prescription and dispensing data to review patient prescription history, including attempts to fill, and alert dispensers when a patient is at risk, in real-time and in workflow by utilizing the existing and in-use NCPDP Telecommunication standard.
- Importantly, this data would be made available only for clinical use, and with appropriate protections for patient privacy.

### **Benefits**

1. **Real time information will prevent inappropriate prescriptions.** Many individuals exhibiting signs of opioid misuse and abuse will shop pharmacy to pharmacy and doctor to doctor in the same day. Delays in data availability and accuracy can thus be deadly.
  - PDMP transactions are never real time – they are a retrospective look at patient medical history.

- By using real-time transactions as the data source, the information is real-time, allowing physicians and pharmacists to catch problems before they become worse.
2. **Reduced Burden from Current System:** This system uses the same transactions and standards every pharmacy uses today.
    - Because the information derives from the transactions used to order, fill and process claims for the prescription, it is available through physicians' e-prescribing systems and pharmacists' pharmacy management systems – transactions that are widely utilized currently every day.
    - The prescription safety alert system is a facilitator model based on technology that exists at every pharmacy counter today, and it exists in more than 80 percent of physician offices through the electronic health record system.
  3. **HIPAA Standards Improve Security and Safety:** Currently, many PDMP transactions do not use HIPAA standards, putting patients and providers at risk for breaches and penalties. This model uses HIPAA standards.
  4. **Lower Costs:** Better information will reduce opioid prescriptions and abuse, reducing pharmacy costs and spending associated with ER visits and hospitalizations. Savings could be in the billions every year.
  5. **Saves Lives:** Even the most conservative estimates confirm that these reforms would save lives.
    - A 2016 study from Vanderbilt University noted that if state PDMPs “enhanced their programs with robust features” we could save at least two lives per day – every day.
    - The President’s Opioid Commission recognized the integral role of PDMP enhancements in combating opioid misuse as well; calling for reforms to “further enhance the effectiveness and uptake of PDMPs across the nation” in its final report.
    - Enhanced PDMP funding and real time data is a win for patients, prescribers and pharmacists.