Strengthening Efforts to Combat Prescription Drug Diversion, Fraud and Abuse

The impact of drug diversion goes beyond just the cost of the prescription drugs that have been diverted for illicit purposes. Prescription drug diversion not only results in increased costs to the health care system through doctor shopping and other forms of fraud, but it also results in increased burden on first responders and law enforcement who face the human toll of addiction and overdose and its devastating consequences.

While 94 percent of the prescription medicines most susceptible to abuse are generic,[1] the Pharmaceutical Research and Manufacturers of America (PhRMA) and its members are committed to supporting the appropriate use of prescription medicines and working with others to collectively address this complex public health challenge. As policies are considered to address this important public health issue, a careful balance needs to be struck to ensure that efforts aimed at minimizing the potential for diversion, misuse and abuse do not restrict access for patients with legitimate medical needs. Likewise, it is equally important that these efforts target the central routes by which diversion, fraud and abuse occur.

According to the Drug Enforcement Administration (DEA), most pharmaceuticals abused in the United States are obtained via doctor shopping, forged prescriptions, theft and rogue websites. Combatting these sources of diversion, fraud and abuse will take a multipronged approach across a broad range of stakeholders, including law enforcement and state and federal agencies and the private sector.

We support public policies to:

- *Expand law enforcement efforts to prosecute and shut down rogue online pharmacies,* which have been identified as a key source for diverted controlled substances. A recent National Association of Boards of Pharmacy review of online pharmacy websites found that more than 90 percent appeared to be operating in conflict with pharmacy laws and practice standards, highlighting the need to maintain a focus on addressing these illegal sites.[2]

[1] Among the most abused prescription medicines (opioids, CNS drugs, and stimulants) an estimated 93.7% of prescriptions at the retail level were for generic medicines in calendar year 2015. PhRMA analysis of IMS National Prescription Audit, April 29, 2016.

[2] National Association of Boards of Pharmacy. Buying Medicine Online. http://www.nabp.net/programs/consumer-protection/buying-medicine-online. Accessed 4/25/2016.

- *Support payment policies and technology solutions that prevent dangerous levels of drug utilization and detect potential doctor shopping behavior,* such as drug utilization review programs and mandated use of state prescription drug monitoring programs (PDMPs) when prescribing controlled substances. Tools such as these also facilitate appropriate decision-making and ensure patient access to needed medicines is not negatively impacted. The U.S. Centers for Medicare and Medicaid Services (CMS), for example, has credited policy changes directing Part D plans to implement improved drug utilization review and apply drug utilization controls for beneficiaries identified as "opioid overutilizers" with playing a key role in reducing opioid overutilization in the program. In fact, since implementing the policy change in 2013, CMS has regularly released data demonstrating a significant and consistent decline in the share of the program's opioid utilizers flagged as potentially problematic.

- *Expand efforts to facilitate coordination across federal public programs, state medical boards and other entities* to ensure that prescribers convicted of fraud and abuse are not able to simply relocate and allowed to continue their practices**.** Steps to improve coordination include:

  - *Mandate the use of PDMPs by all prescribers, including Medicare and Medicaid prescribers,* to detect potential doctor shoppers and inappropriate prescribing and to identify and refer potential fraud to appropriate authorities for further investigation, including with state medical boards.
  - *Assess the adequacy of existing efforts aimed at ensuring the accuracy and currency* of CMS assigned provider and beneficiary identifiers and DEA registrant identification and increasing penalties for illegal use of such identifiers.
  - *Support efforts to expand sharing of information on potentially problematic prescribing.* Some state medical licensing boards have expanded their efforts to obtain and share data with other entities regarding inappropriate prescribing.

- *Expand efforts to identify, shut down and prosecute those operating "pill mills."* These facilities inappropriately provide access to controlled substances and are identified through a set of behaviors driven by financial, not medical, interests and have no regard for therapeutic benefit or necessity (e.g., they generally don't require prescriptions and operate on a cash only basis). We support policies to:
  - *Clarify the regulations regarding legitimate pain management clinics* as this will help to ensure clear distinctions between "pill mills" and legitimate pain management clinics and facilitate law enforcement's ability to shut down these illegal operations while protecting the activities of legitimate health care providers. Key indicators of legitimate pain clinics and pill mills are included in the table below to inform the development of legislative definitions.
  - *Expand regulations to include references to relevant state statutes and regulations with which legitimate pain clinics must comply,* including, but not limited to, any specific training

requirements for persons practicing in pain clinics, clinic inspection requirements and state statutes or regulations related to the data and records that pain clinics are required to maintain.

Indicators of "Pill Mills" vs. Legitimate Pain Clinics	
Indicators of Pill Mills	*Indicators of Legitimate Pain Clinics*
• No maintenance of previous medical records • Physical exams are not required or inadequate exams are performed • Failure to screen for substance abuse disorders • The care provided is not individualized, e.g., there is no variance in scheduled visits, no referrals to other specialists or the combination of medications prescribed do not vary considerably • The primary mode of therapy provided is prescribing of controlled substances; • High volume of care • No appointments taken and walk-ins are the norm • Only cash payment accepted • "Patients" travel very long distances without any legitimate reason	• The clinic maintains appropriate registration, certification or licensure with DEA and appropriate state regulatory bodies • The clinic ensures appropriate ownership qualifications, i.e., holding certain licenses and/or board certifications • The clinic employs a medical director or clinical manager as a designee to bear certain responsibilities relative to clinic operation and compliance • The clinic adheres to state requirements concerning prescription drug monitoring programs • The clinic maintains certain records and/or collects certain data as required by law • The clinic is held responsible for administrative and/or clinical penalties and fees for violations relating to pain clinic provisions
Source: National Alliance for Model State Drug Laws and the National Safety Council, Prescription Drug Abuse, Addiction And Diversion: Overview Of State Legislative And Policy Initiatives: A Three Part Series Part 2: State Regulation Of Pain Clinics & Legislative Trends Relative To Regulating Pain Clinics, April 2014.	