Stakeholder Consensus Report

DEA Manufacturer, Importer, and Exporter Conference, September 23-24, 2015

Edward McGinley, President NABP, Member New Jersey Board of Pharmacy
NABP was founded in 1904 for the purpose of establishing interstate reciprocity of pharmacy licensure and to procure uniformity of legislation.

Today, NABP’s mission reads:

*NABP is the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health*
Accreditation

- VIPPS accreditation requires an Internet pharmacy to comply with the licensing and survey requirements of its state and each state to which it dispenses pharmaceuticals. There are 41 VIPPS-accredited sites.

- Vet-VIPPS provides assurance for consumers purchasing medications over the Internet for their pets. Currently, there are 23 Vet-VIPPS-accredited sites.

- The NABP e-Advertiser Approval Program targets Internet advertisers that offer limited pharmacy services. Search engines Google, Yahoo!, and Bing require entities advertising pharmaceutical services to be e-Advertiser approved in order to display ads. Currently, there are over 100 approved entities.
Accreditation

CMS deemed NABP an accrediting organization for pharmacies that supply durable medical equipment, prosthetics, orthotics, and supplies. To date, there are more than 500 accredited companies.
VAWD, VIPPS, Vet-VIPPS

• Complex Global Supply Chain for Prescription Drugs
  – 80% of Active Ingredients (Powder) for Prescription Drugs from Overseas
  – 40% of Finished Dosage Forms (capsules, tablets, liquids) from Overseas

• Accreditation Programs track drugs from start (manufacturer) to finish (patient or destruction of non-dispensed expired drugs)
VAWD

- VAWD was launched in 2005 and was developed due to concerns of counterfeit drugs affecting the US drug supply. FDA supported the development of the program.
- Wholesale distributors of prescription drugs and devices that are located in the US are eligible to apply for VAWD.
- 21 states recognize VAWD in some manner.
- There are currently over 532 VAWD-accredited wholesalers.
NABP as a Domain Name Registry

• In 2014, NABP received approval to operate the .pharmacy Top-Level Domain
• All registrants within the .pharmacy TLD are vetted prior to registration to confirm that they meet all applicable regulatory standards, including pharmacy licensure and valid prescription requirements, in the jurisdictions where they are based and where they serve patients
Controlled Substances Stakeholder Coalition
Controlled Substances Stakeholder Coalition

- Impetus
- Organizations
- Desired Outcomes
Controlled Substances Stakeholder Coalition

• **Patient Care Issues**
  – Drug abuse and impairment
  – Access
  – Pain management

• **Practice and Operational Issues**
  – Drug abuse and diversion
  – Corresponding responsibility
  – Practice operations
Controlled Substances Stakeholder Coalition

• Consensus document
• Red Flags Document
• Red Flags Video
Consensus Document

Stakeholders
American Academy of Family Physicians, American Medical Association (AMA), American Osteopathic Association, Cardinal Health, CVS Caremark, Federation of State Medical Boards (observer), National Association of Boards of Pharmacy (NABP), National Association of Chain Drug Stores, National Community Pharmacists Association, Pharmaceutical Care Management Association, Pharmaceutical Research and Manufacturers of America, Rite Aid, Walgreen Co.
Primary Agreement
The participants agreed that stakeholder coordination and collaboration must be improved in order to combat the serious public health issue of prescription drug abuse and diversion, while also complying with the “corresponding responsibility” requirements of federal and state laws and regulations.
Manufacturers Perspective

Manufacturers are actively engaged in a broad range of efforts with health care practitioners, law enforcement, patient groups, family advocates, and other stakeholders to support appropriate use of medicines, but also face significant challenges related to abuse of their analgesic drug products.
Manufacturers’ Perspective

- Extended-release or long-acting opioid analgesics subject to Risk Evaluation and Mitigation Strategy (REMS)
- Struggle to discern what constitutes a “suspicious order” to comply with monitoring of orders for products
Ultimate Goal

The goal of the stakeholder consensus document is to provide health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose as well as providing guidance on which red flag warning signs warrant further scrutiny.
Critical Next Steps

• Challenges faced by health care practitioners can be overcome through collaboration and communication
• Broader efforts to prevent the diversion of controlled substances while ensuring access to the medications for patients who need them for legitimate reasons
• Every individual taking responsibility
Prescription Drug Abuse Prevention

• NABP and the states have many programs that support efforts to prevent prescription drug abuse

• PDMPs

• NABP created PMP InterConnect, a system that allows for the transfer of prescription drug monitoring program data across state lines to authorized users. Currently, 30 states are live, and several states are in process
Prescription Drug Abuse Prevention

- The AWARxE Prescription Drug Safety program educates consumers about proper medication use, safely buying medicine online, and proper medication disposal.
- Tools for pharmacists
- Pharmacist Pledge
Questions

Pharmacist's Pledge: Fighting Prescription Drug Abuse

I pledge that I will make a difference, as a pharmacist and member of my community to help with the drug abuse epidemic. I will provide information about prescription drug abuse in my pharmacy, office, or other practice setting to make my patients and colleagues aware of the epidemic facing our nation. I will address prescription drug abuse as a pharmacist should by applying my knowledge, skills, and experience. I will be involved. I will take action. I will be a pharmacist who saves peoples’ lives!