# The Administration's Response to the Prescription Drug Epidemic: Action Items

As outlined in <u>Epidemic: Responding to America's Prescription Drug Abuse Crisis</u>, below are the action items identified in the Administration's action plan to prevent and reduce prescription drug abuse. These activities are part of the broader National Drug Control Strategy, a comprehensive approach to reducing drug use and its negative consequences.

#### 1. Education

a. Require Practitioners who Request DEA Registration to Prescribe Controlled Substances to be Trained on Responsible Opioid Prescribing

[ONDCP]

Work with Congress to amend Federal law to require practitioners (physicians, dentists, and others authorized to prescribe) who request DEA registration to prescribe controlled substances to be trained on responsible opioid prescribing practices as a precondition of registration. This training would include assessing and addressing signs of abuse and/or dependence.

b. Require Manufacturers to Develop Materials and Initiatives on the Appropriate Use of Opioid Pain Relievers

IHHS, FDA1

Require drug manufacturers, through the Opioid Risk Evaluation and Mitigation Strategy (REMS), to develop effective educational materials and initiatives to train practitioners on the appropriate use of opioid pain relievers.

c. Increase Continuing Medical Education on Proper Prescribing and Disposal of Prescription Drugs

[VA]

Federal agencies that support their own healthcare systems will increase continuing medical education for their practitioners and other healthcare providers on proper prescribing and disposal of prescription drugs.

d. Require Medical Education Curricula and Continuing Education for Safe and Appropriate Use of Opioids to Treat Pain While Minimizing the Risk of Addiction and Abuse [HHS. SAMHSA]

Work with appropriate medical and healthcare boards to encourage them to require education curricula in health professional schools (medical, nursing, pharmacy, and dental) and continuing education programs to include instruction on the safe and appropriate use of opioids to treat pain while minimizing the risk of addiction and substance abuse. Additionally, work with relevant medical, nursing, dental, and pharmacy student groups to help disseminate educational materials, and establish student programs that can give community educational presentations on prescription drug abuse and substance abuse.

e. Develop Methods of Assessing the Adequacy of Pain Treatment to Inform the Appropriate Use of Opioid Pain Medications

[HHS, CDC]

In consultation with medical specialty organizations, develop methods of assessing the adequacy of pain treatment in patients and in patient populations, to better inform the appropriate use of opioid pain medications

f. Develop Evidence-Based Clinical Guidelines for Opioid Prescribing in the Emergency Department

[HHS, CDC]

Work with the American College of Emergency Physicians to develop evidence-based clinical guidelines that establish best practices for opioid prescribing in the emergency department.

g. Develop Tools to Facilitate Appropriate Opioid Prescribing [HHS, FDA]

Work with all stakeholders to develop tools to facilitate appropriate opioid prescribing, including development of Patient-Provider Agreements and guidelines.

### h. Support and Promote an Evidence-Based Public Education Campaign on Appropriate Use, Secure Storage, and Disposal of Prescription Drugs

[ONDCP]

Enlist all stakeholders to support and promote an evidence-based public education campaign on the appropriate use, secure storage, and disposal of prescription drugs, especially controlled substances. Engage local anti-drug coalitions, and other organizations (chain pharmacies, community pharmacies, boards of pharmacies, boards of medicine) to promote and disseminate public education materials and to increase awareness of prescription drug misuse and abuse.

### i. Require Manufacturers to Develop Educational Materials for Patients on the Appropriate Use and Disposal of Opioid Pain Relievers

IHHS. FDA1

Require manufacturers, through the Opioid Risk Evaluation and Mitigation Strategy (REMS), to develop effective educational materials for patients on the appropriate use and disposal of opioid pain relievers.

#### Develop an Evidence-Based Media Campaign Targeted to Parents on the Risks of Prescription Drug Abuse

[ONDCP]

Working with private sector groups, develop an evidence-based media campaign on prescription drug abuse, targeted to parents, in an effort to educate them about the risks associated with prescription drug abuse and the importance of secure storage and proper disposal of prescription drugs (including through public alerts or other approaches to capture the attention of busy parents).

#### k. Expedite Research on the Development of Pain Medications with No Abuse Potential and Abuse-Deterrent Formulations

[HHS, NIDA]

Expedite research, through grants, partnerships with academic institutions, and priority New Drug Application review by FDA, on the development of treatments for pain with no abuse potential as well as on the development of abuse-deterrent formulations (ADF) of opioid medications and other drugs with abuse potential.

#### Advance the Design and Evaluation of Studies to Address Changing Patterns of Abuse [HHS, CDC]

Continue advancing the design and evaluation of epidemiological studies to address changing patterns of abuse.

### m. Provide Guidance on the Development of Abuse-Deterrent Drug Formulations and Post-Market Assessment

[HHS, FDA]

Provide guidance to the pharmaceutical industry on the development of abuse-deterrent drug formulations and on post-market assessment of their performance.

#### 2. Tracking and Monitoring

### a. Work with States to Establish PDMPs in Every State and to Require Prescribers and Dispensers to be Trained in Their Appropriate Use

[ONDCP]

Work with states to establish effective PDMPs in every state, including leveraging state electronic health information exchange activities, and to require prescribers and dispensers to be trained in their appropriate use. Encourage research on PDMPs to determine current effectiveness and identify ways to improve effectiveness.

### b. Support the National All Schedules Prescription Electronic Reporting (NASPER) Act Reauthorization in Congress

[HHS, SAMHSA]

Support the National All Schedules Prescription Electronic Reporting (NASPER) Act reauthorization in Congress. NASPER is a formula grant program administered by SAMHSA that funds state PDMPs. The program outlines specific, uniform criteria states must have in place to be awarded funding, which increases consistency among state PDMPs.

c. Work with Congress to Pass Legislation to Authorize the Sharing of VA and DOD Patient Information on Controlled Substance Prescriptions with State PDMPs

Work with Congress to pass legislation to authorize the Secretary of Veterans Affairs (VA) and the Secretary of Defense (DOD) to share patient information on controlled substance prescriptions with state PDMPs.

d. Encourage Federally Funded Healthcare Programs such as IHS and DOD and VA (when authorized to do so) to Provide Controlled Substance Prescription Information Electronically to the PDMPs in States in which They Operate Healthcare Facilities or Pharmacies

Encourage federally funded healthcare programs such as IHS and DOD and VA (when authorized to do so) to provide controlled substance prescription information electronically to the PDMPs in states in which they operate healthcare facilities or pharmacies. In addition, DOD, VA, and IHS are encouraged to evaluate the practice of having prescribers check PDMPs for patient controlled substance prescription histories before generating prescriptions for controlled substances.

e. Explore the Feasibility of Providing Reimbursement to Prescribers who Check PDMPs Before Writing Controlled Substance Prescriptions for Patients Covered Under Insurance Plans [ONDCP]

Explore the feasibility of providing reimbursement to prescribers who check PDMPs before writing controlled substance prescriptions for patients covered under insurance plans.

f. Evaluate Existing Programs that Require Doctor Shoppers and People Abusing Prescription Drugs to Use Only One Doctor and One Pharmacy. [ONDCP]

Evaluate existing programs that require doctor shoppers and people abusing prescription drugs to use only one doctor and one pharmacy. The PMP Center of Excellence at Brandeis University will convene a meeting in 2011 with private insurance payers to begin discussions on these topics.

g. Work with HHS and CMS to Evaluate the Utility of State PDMPs for Reducing Medicare and Medicaid Fraud

[HHS, CMS]

Work with HHS and CMS to evaluate the utility of state PDMPs for reducing Medicare and Medicaid fraud, as suggested in the 2009 GAO report—Medicaid: Fraud and Abuse Related to Controlled Substances Identified in Selected States.

h. Issue the Final Rule on DEA Electronic Prescribing of Controlled Substances [DOJ, DEA]

Issue the Final Rule on DEA Electronic Prescribing of Controlled Substances.

 Increase the use of Screening, Brief Intervention, and Referral to Treatment (SBIRT) Programs to Help Healthcare Providers Identify and Prevent Prescription Drug Abuse Problems [HHS, SAMHSA]

Increase the use of Screening, Brief Intervention, and Referral to Treatment (SBIRT) programs to help healthcare providers identify and prevent prescription drug abuse problems in primary healthcare settings by working with healthcare providers to increase awareness and training for these programs, and incorporating the use of Health Information Technologies (HIT) such as Electronic Health Records to enhance SBIRT programs.

Identify Ways in which Health Information Technologies (HIT) such as Electronic Health Records
Can Improve Prescription Drug Abuse Information

[HHS, ONC]

Identify ways in which Health Information Technologies (HIT) such as Electronic Health Records can improve prescription drug abuse information.

 Test the Usefulness of CDC's Real-Time BioSense Surveillance System for Generating Timely, Population-Based Measures of Prescription Drug Abuse in Selected Communities [HHS, CDC]

Test the usefulness of CDC's real-time BioSense surveillance system for generating timely, population-based measures of prescription drug abuse in selected communities. In addition, use information from

the NIDA Community Epidemiology Workgroup to monitor and detect locations where increased abuse is occurring to help target limited resources.

#### Assess the Usefulness of DAWNLive! Data for Use in Community Epidemiology [HHS. SAMHSA]

Assess the usefulness of the Drug Abuse Warning Network (DAWN) and how it can best be used for community epidemiology.

### m. Expand Upon DOJ's Pilot Efforts to Build PDMP Interoperability Across State Lines [DOJ, BJA]

Expand upon DOJ's pilot efforts to build PDMP interoperability across state lines, including leveraging state electronic health information exchange activities. Work to expand interstate data sharing among PDMPs through the Prescription Drug Information Exchange (PMIX).

# n. Evaluate Databases that Measure Prescription Drug Use, Misuse, and Toxicity, Clinical Use of Safe Opioid Prescribing Practices, and Access to High-Quality Pain Management Services [HHS]

Evaluate current databases that measure the extent of prescription drug use, misuse, and toxicity, clinical use of safe opioid prescribing practices, and access to high-quality pain management services, focusing on improving these databases and identifying new sources of data.

#### 3. Proper Medication Disposal

## a. Conduct Prescription Drug Take-Back Activities while DEA finalizes medication disposal regulations

[DOJ, DEA]

While the administrative process to establish the DEA medication disposal rule is underway, DEA and other Federal agencies shall conduct additional take-back activities. Information about the take-back events shall be distributed to local anti-drug coalitions, HIDTAs, and other organizations (chain pharmacies, boards of pharmacies, boards of medicine, environmental agencies, etc).

# b. Develop and Execute a Public Education Initiative to Increase Awareness and Provide Education on Safe and Effective Drug Return and Disposal

[ONDCP]

Once DEA regulations on controlled substance prescription drug disposal have been established, develop and execute a robust public education initiative to increase public awareness and provide education on new methods of safe and effective drug return and disposal.

# c. Engage PhRMA and Others in the Private Sector to Support Community-Based Medication Disposal Programs

[ONDCP]

Once DEA regulations have been established, engage PhRMA and others in the private sector to support community-based medication disposal programs.

#### 4. Enforcement

### a. Contribute to the Curriculum for the Pharmaceutical Crime Investigation and Prosecution Training Program

[ONDCP]

ONDCP, the National Methamphetamine and Pharmaceutical Initiative (NMPI), a law

enforcement training initiative funded by HIDTA, and DEA will contribute to the curriculum for the pharmaceutical crime investigation and prosecution training program sponsored by BJA in 2011. Target training to states with the highest need.

### b. Increase Training to Law Enforcement and Prosecutor Groups at National and Regional Conferences

[ONDCP]

Increase training to law enforcement and prosecutor groups at national and regional conferences.

# c. Continue Aggressive Enforcement actions Against Pain Clinics and Prescribers who are not Prescribing within the Usual Course of Practice and not for Legitimate Medical Purposes [DOJ, DEA]

Continue aggressive enforcement actions against pain clinics and prescribers who are not prescribing within the usual course of practice and not for legitimate medical purposes.

## d. Work with the Appropriate Groups to Write and Disseminate a Model Pain Clinic Regulation Law

[ONDCP]

Work with the appropriate groups to write and disseminate a Model Pain Clinic Regulation Law taking into consideration: 1) registration of these facilities with a state entity; 2) guidance for rules regarding number of employees, location, hours of operation; 3) penalties for operating, owning, or managing a non-registered pain clinic; 4) requirements for counterfeit-resistant prescription pads and reports of theft/loss of such pads; 5) disciplinary procedures to enforce the regulations; and 6) a procedure to allow patient records to be reviewed during regular state inspections.

# e. Increase HIDTA Intelligence-Gathering and Investigation of Prescription Drug Trafficking and Increase Joint Investigations by Federal, Sate, and Local Agencies

[ONDCP, HIDTA]

Increase HIDTA intelligence-gathering and investigation of prescription drug trafficking, and increase joint investigations by Federal, state, and local agencies.

## f. Identify and Seek to Remove Administrative and Regulatory Barriers to "Pill Mill" and Prescriber Investigations

[ONDCP]

Identify and seek to remove administrative and regulatory barriers to "pill mill" and prescriber investigations that impair investigations while not serving another public policy goal.

## g. Expand Use of PDMP Data to Identify Criminal Prescribers and Clinics by the Volume of Selected Drugs Prescribed

[DOJ, DEA]

Expand the use of PDMP data to identify criminal prescribers and clinics by the volume of selected drugs prescribed. Encourage best practices for PDMPs, such as PDMP reporting of such prescribers and clinics to pharmacies, law enforcement, and insurance providers.

## h. Use PDMP Data to Identify "Doctor Shoppers" by Their Numbers of Prescribers or Pharmacies

[DOJ, BJA]

Use PDMP data to identify "doctor shoppers" by their numbers of prescribers or pharmacies. Encourage best practices such as identifying such individuals to their prescribers and pharmacies, law enforcement and insurance providers.