



# NATIONAL DRUG CONTROL STRATEGY

2015



### Additional Monitoring Activities

Drug Utilization Review is a practice pharmaceutical benefit managers and others who pay for medicines use to examine prescription data for patterns or trends that suggest a patient might be at risk for health problems or to manage care. CMS has established a Medicare Opioid Overutilizer program under which prescription drug plans in Medicare part D to review patient opioid use and to notify prescribers by mail and phone when they suspect a plan member may be at risk of receiving opioids from too many providers or pharmacies. In some cases, plans may use a case management process to help ensure providers arrive at appropriate prescribing decisions.<sup>211</sup>

Medicaid and private insurers often use a second practice, Drug Utilization Review and Restriction (DURR) in which if a patient is identified at high risk following prescription history review, the insurer restricts the patient to receive services from a single primary care provider and/or a single pharmacy and refuses to reimburse claims made through other locations or providers. To date, at least 46 states and the District of Columbia Medicaid agencies use such programs.<sup>212</sup> At least one study has shown that states using these programs reduce high levels of controlled substance prescribing compared with states not using such programs.<sup>213</sup> DURR is not explicitly permitted by Medicare Part D Statute and would require a legislative change to enable its use by prescription drug plans in that program; the FY 2016 President's Budget included a proposal that would allow CMS to establish such a program.

VA has been a leader in reducing overuse and abuse of prescription opioids through the Opioid Safety Initiative. Despite seeing more overall outpatients, nearly 115,000 fewer Veteran patients are receiving opioids as of 2015 than in mid-2012. When Veteran patients require opioids for their medical needs, more Veterans now than in the past are receiving lower dosages to make sure the opioid prescriptions are safe but effective. In mid-2012, there were 59,499 Veteran patients receiving greater than or equal to a 100 morphine equivalent daily dose (MEDD); as of mid-2015, there are 45,768 patients receiving greater than or equal to a 100 MEDD, a reduction of 23%. In addition, VA is exploring cutting-edge alternative therapies to treat pain and reduce the need for opioids.

### Pillar 3: Disposal

Drug diversion contributes to non-medical opioid use. Proper storage and safe disposal are important as a means to secure opioids in the home and prevent them, as well as unwanted or unused opioids from being used for nonmedical reasons.

#### Increase Prescription Return/Take-Back and Disposal Programs

From 2010 to 2014, DEA prescription drug take-back events collected over 4.9 million pounds (2,411 tons) of drugs.<sup>214</sup> In September of 2014, the DEA held its ninth official Drug Take-Back Day.<sup>215</sup> Events occurred at 5,495 collection sites, including sites in the 50 states, the District of Columbia, Guam, Puerto Rico and the US Virgin Islands and collected a total of 309 tons of drugs.<sup>216</sup> On October 9th 2014, DEA's final Rule on the Disposal of Controlled Substances<sup>217</sup> authorized by the Secure and Responsible Drug Disposal Act of 2010<sup>218</sup> went into effect.

## Drug Deactivation Systems

Provided they meet the DEA rule's standard for disposal that drugs are rendered "non-retrievable" by the disposal method, ONDCP supports of innovative disposal methods such as drug deactivation. These systems may be helpful for disposal in locations where incineration is not permitted or take back is not within easy driving distance. In 2013, NIDA sponsored a Small Business Innovation Research contract solicitation<sup>219</sup> requesting proposals to develop system that would provide a simple way to safely inactivate and contain unwanted prescription drugs, thereby minimizing the potential for diversion or accidental exposure, and providing a safe and environmentally responsible way to properly dispose of pharmaceuticals. A disposal product was developed which exemplifies how the drug control interagency partners work together to use federal funds to address policy issues and how U.S. small business innovators can address public health and safety needs.

### Disposal Regulations

The new disposal regulations expand the options available to safely and securely dispose of potentially dangerous controlled substance prescription medications on a routine basis including options for take back programs by authorized collectors and law enforcement.<sup>220</sup>

The regulations authorize certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration with the DEA to become authorized collectors. All authorized collectors may operate a collection receptacle at their registered location, and collectors with an on-site method of destruction may operate a mail-back program. Anyone (not just authorized collectors) can hand out the pre-printed, pre-addressed mail-back packages in which patients and their caregivers can send their unused drugs to the mail-back program operators. Retail pharmacies and hospitals/clinics with an on-site pharmacy may operate collection receptacles at long-term care facilities.

Law enforcement continues to be able to collect controlled substance prescription drugs from patients or their caregivers, including by holding take-back events. Any person or entity - DEA registrant or non-registrant—may partner with law enforcement to conduct take-back events. Patients also may continue to use the guidelines for the disposal of pharmaceutical controlled substances listed by the FDA and the Environmental Protection Agency (EPA). Any method of patient disposal valid prior to these new regulations continues to be valid.

DEA, ONDCP and state experts have begun the process of increasing awareness and educating the public and communities about the new rule. In September and October of 2014, DEA conducted trainings for its diversion field agents in 20 different field divisions and headquarters. DEA, ONDCP and experts from the Alameda County California Superintendent's office held a webinar for community agencies on the new rule. Over 800 people registered for the program and 436 viewed it live. The webinar is archived on the ONDCP website as a resource for interested parties.<sup>221</sup> DEA has also trained registered distributors, reverse distributors, pharmacies, and multiple practitioner groups and associations regarding the disposal regulations. In September 2015, DEA will provide disposal training to registered manufacturers, importers, and exporters. Alameda County Supervisors developed a unique ordinance which permitted the county to charge industry for program support but resulted in a lawsuit against the county by the manufacturers.<sup>222</sup>

The U.S. District Court for the Northern District of California found for Alameda County, and on appeal, the Ninth Circuit Court of Appeals affirmed. This year, the U.S. Supreme Court refused to hear an appeal on this matter. Based on the decision of the Ninth Circuit upholding its constitutionality, the Alameda ordinance may become a useful model for other locales interested in funding disposal programs.<sup>223</sup> Additionally the VHA is offering disposal options to Veterans in alignment with the new regulations.<sup>224</sup> DOD has also begun to offer drug disposal opportunities at DOD facilities. In the next year ONDCP, EPA, DEA and HHS will develop and implement a plan for engaging communities to increase safe disposal. State and local governments remain essential players in expanding prescription drug disposal.

## Pillar 4: Enforcement

Although nonmedical prescription drug use is a public health problem, the 2011 *Prescription Drug Abuse Action Plan* recognized that unscrupulous prescribers, illegal pharmacies and those who illegally divert opioids for criminal gain or fraud should be addressed through enhanced enforcement activities.

### Assist States to Address Diversion and Pill Mills

Over the past several years, Federal, state and local law enforcement have undertaken significant enforcement actions against pill mills and pain clinics that practice outside the bounds of many clinical practice guidelines. Enforcement, together with legislative efforts to address pill mills, have led to some notable changes in health outcomes. Florida is a noteworthy example. In 2011, Florida enacted HB 7095, which banned physician dispensing, and changed wholesale distribution and reporting, pharmacy license regulations, physician standards of care, Department of Health (DOH) pharmacy inspections, and violation penalties. Initial analyses by the CDC indicate declines in the prescribing of drugs, especially those favored by Florida prescribing dispensers and pain clinics; from 2011 to 2012 overdose death involving those drugs declined 23 percent.<sup>225</sup> NIH funded a comprehensive policy analysis of HB 7095 that is using information collected via interviews with physicians and Drug Enforcement Strike Force personnel, DOH and crime records to determine whether HB 7095 altered practices and identify useful aspects of this legislation. NIH's research findings are anticipated in spring 2016.

One challenge to such efforts are increases in the number of clinics in border states where there has been high enforcement. For example, in the wake of legislative and enforcement efforts in Florida, DEA reports that Georgia now has over 150 registered clinics, many of which DEA data shows continue to serve patients without regard to practice standards.<sup>226</sup> Kentucky has also heightened enforcement, and DEA now estimates that Tennessee has over 300 clinics.<sup>227</sup> DEA and state authorities have been addressing this threat through a combination of enforcement actions, legislation, and education.

DEA also provides presentations at regional and national law enforcement conferences across the United States. These presentations inform the law enforcement community of the regional and national trends of diversion and abuse of controlled substance pharmaceuticals. As an active participant in the NMPI, DEA provides information to federal, state, local, and tribal law enforcement officials.