NATIONAL CONFERENCE OF INSURANCE LEGISLATORS (NCOIL)

EXPANDED VERSION:

NCOIL BEST PRACTICES TO ADDRESS OPIOID ABUSE, MISUSE & DIVERSION

Additional provisions—regarding PDMP privacy, neonatal abstinence syndrome/addiction during pregnancy, and drug take-back programs—are boxed and were adopted by the NCOIL Executive Committee on July 13, 2014.

The Best Practices were originally adopted by the NCOIL Executive Committee on November 24, 2013. Sponsored for discussion by Rep. Bill Botzow (VT)

1. BACKGROUND

In early 2012, NCOIL began a more than year-long investigation into causes and consequences of opioid abuse, giving particular consideration to impacts on the workers' compensation insurance market. Hours of expert testimony and committee discussion, as well as numerous written comments, laid the groundwork for the best practices framework offered below. The guidelines highlight the items addressed most frequently during NCOIL deliberations.

Opioid abuse is a national epidemic. According to the Centers for Disease Control & Prevention (CDC), enough prescription painkillers were prescribed in 2010 to medicate every American adult around-the-clock for one month.¹ Approximately three out of every four pharmaceutical overdose deaths in 2010 were due to opioid analgesics like oxycodone, hydrocodone, and methadone.²

Medicaid patients are prescribed painkillers at twice the rate of non-Medicaid patients and are at six times the risk of prescription painkiller overdose.³ And unintentional overdose deaths related to prescription opioids have quadrupled since 1999—and now outnumber those from heroin and cocaine combined.⁴ The statistics go on and on.

In the world of workers' compensation, there is significant proof that long-term opioid use leads to longer claim duration, longer-term disability, higher costs, and higher medical expenses.⁵ The use of long-acting opioids, for instance, has been found to increase the cost of a workers' compensation claim by nine times.⁶ And according to the California Workers' Compensation Institute, the top one percent of prescribing physicians accounted for 41 percent of all prescriptions for Schedule II drugs.⁷

The consequences of opioid abuse, misuse, and diversion are varied and far-reaching, meaning that an array of interested parties, from those who look at the supply-side of opioid use to those who address prevention, treatment, and recovery, have a hand in dealing with the problem and should be part of discussions regarding the development and implementation of effective state strategies—including the best practices suggested below.

2. PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)

2.1 Recognize essential role of PDMPs

Although states have made progress in recent years to establish PDMPs—statewide mechanisms that collect, monitor, and analyze prescribing and dispensing data related to controlled substances—more work is needed. Programs exist in some fashion in 49 states, but the PDMPs in four are not considered operational.⁸ It is worth noting that "operational" means a program collects data and reporting information. The term does not speak to the scope, funding, or effectiveness of a system.

2.2 Enhance interstate data sharing

Enhanced interstate data sharing is essential if a PDMP is to help identify sources of prescription drug abuse, misuse, and diversion and encourage early intervention and prevention, among other objectives—and certainly should be something that states work toward.

Currently, 18 states allow their PDMPs to exchange data with other PDMPs as well as with out-of-state entities that are authorized to use them. Eighteen other states allow sharing only with fellow drug monitoring programs, eight only with authorized users from different states—and five have no sharing rules in place at all.⁹

2.3 Work to expand categories of authorized users

There is significant variation in what states mean by "authorized user," and this may prevent a PDMP from realizing its full potential in recognizing trends and identifying atrisk individuals¹⁰. For instance, can Medicare and Medicaid access your state's PDMP? Do mental health and substance abuse professionals have access? Workers' comp specialists? State licensing boards? What rules are in place for law enforcement?

2.4 Consider circumstances of mandated use

When deciding whether to mandate physician use of a PDMP, states should take into account how operational a program is—e.g., accuracy and timeliness of data, ease-of-use, and physician accessibility—before requiring practitioners to check one. It's also important to consider how physician use of a PDMP would play out in a daily setting. There may be instances in which checking a PDMP is unnecessary, like when a doctor is performing a routine pediatric exam, or immediately before, during, and shortly after an operative or invasive procedure. There also may be medical disciplines, such as dental surgery, that may not lend themselves to mandated PDMP checks.

Because there is growing concern among medical professionals regarding an increasing frequency of neonatal abstinence syndrome, legislators may wish to strongly consider requiring all physicians to check a PDMP as part of prenatal care.¹¹ In doing so, states should consult with medical societies to ensure that any new requirements do not discourage pregnant women from seeking care.¹²

To help ensure that practitioners spend a maximum amount of time with their patients, rather than perform more administrative tasks, states might allow a practitioner to designate auxiliary staff to access the PDMP. Delegates who access a PDMP on behalf of a practitioner should be held to the same legal and ethical standards and penalties as practitioners and all other authorized users.

2.5 Encourage dispenser reporting

A fully functioning, effective PDMP should be a resource for a substantial body of accurate information, and so state legislators should give careful consideration to dispenser reporting requirements. In Kentucky, for instance, non-resident dispensers of controlled substances, including mail-order pharmacies, are among the entities that must report to the Kentucky All Schedule Prescription Electronic Reporting System (KASPER)—but not all states have a non-resident reporting mandate.¹³

(It is worth noting that since Kentucky's broad HB 1 reform law last year required all prescription providers of controlled substances—including non-resident dispensers—to register with KASPER, there has been a nearly three-fold increase in the number of registered KASPER accounts.)¹⁴

Dispensers should know for certain if a patient obtained a prescription, and so legislators might consider whether only dispensers, rather than prescribers, should report to a PDMP.¹⁵

2.6 Recognize benefits of real-time reporting

Real-time reporting in Oklahoma, the first state to implement such a requirement, means that the Oklahoma PDMP provides especially timely information. Also recognizing the benefits of a real-time system is New York, whose 2012 reform law called for "real-time" submissions, currently defined by the state Commissioner of Health as "daily" reporting. Six other jurisdictions require daily entries. All other states have longer data collection intervals—and in some states, much longer. The National Alliance of Model State Drug Laws (NAMSDL) reports, for instance, that four (4) states require only monthly data submission.¹⁶ If states are concerned that reporting to a PDMP in real time will prove costly for those who do, then officials may wish to establish a mechanism for compensating those who report.

2.7 Evaluate outcomes

Developing, implementing, and maintaining a drug monitoring program is complex and costly. It's crucial that states take the time to evaluate outcomes—through things like satisfaction surveys of physicians, pharmacists, and other users, as well as audits of how often a PDMP is used.

As time progresses, states should look at what's happened to the number of overdoses, emergency room visits, and other consequences of opioid misuse since the PDMP became operational. Among other things, the data may help to identify areas in a state where additional treatment and prevention services, as well as community-based outreach, may be appropriate. Although states may have limited staff to conduct such evaluations, universities and private research institutions may be of assistance.¹⁷

2.8 Consider state study approaches

Just recently, nearly one year after HB 1 became law, Kentucky officials announced that they would begin a year-long study into how the law, not just the drug monitoring program reforms, is playing out in order to determine successes and to remedy any unintended consequences. Wyoming, after beginning to use unsolicited reporting a few years back, began tracking the number of patients who met a certain threshold for being potential doctor shoppers. After two years, officials discovered that the number of such patients dropped significantly—indicating that the unsolicited reporting effort was successful. And, among other state efforts, Massachusetts recognized a need to develop an online portal for active investigations in response to survey responses from law enforcement PDMP users.¹⁸

2.9 Pursue various funding options

Funding—a word that elicits little enthusiasm among policymakers—for a PDMP must be sufficient and consistent if it is to be effective in both the short and long-terms. This admittedly may be an uphill climb. Current PDMP financing falls into four main categories: grants, licensing fees, general revenue, and board funds.¹⁹

Though grant²⁰ and other less common forms of funding—like settlements and private donations—certainly may be important and worth pursuing, these money sources may be temporary and inconsistent. A minor surcharge on state licensing fees, for instance, may be more reliable.²¹ Dedicated financing through a state's general fund—assuming that the money isn't directed elsewhere during times of financial stress—also may be stable and effective.

ADDITIONAL PROVISION — **PDMP PRIVACY** (corresponding footnotes on page 13)

2.10 Find balanced approach to ensuring data privacy

PDMPs have great potential to curtail opioid abuse, misuse, and diversion, and granting a variety of interested parties access to PDMP data may further that objective. However, the more entities that can review PDMP information the more important it becomes to develop standards for patient privacy.

Safeguards should be made clear in statute and/or regulation to avoid confusion and to help empower state officials to take action as needed. Safeguards may include (1) making PDMP data confidential and excluding it from open records or public records laws; (2) explicitly requiring PDMP administering agencies to adopt policies and procedures that reasonably assure that only those who are legally authorized to access the database actually do so; (3) imposing appropriate legal penalties and administrative sanctions, such as actions against someone's license, for violations and ensuring that the penalties/sanctions are enforced; (4) specifying who is authorized to access the data and for what purpose; and (5) implementing detailed authentication procedures to verify that a user is qualified to access the PDMP pursuant to state law. In conjunction with these safeguards, a state may wish to have its PDMP web site include clear instructions on how to report perceived privacy violations.

If prescribers and/or dispensers are allowed to choose delegates to access a PDMP on their behalf, a state may wish to require each delegate to use an individual password and login and to establish in law or regulation that the prescriber/dispenser is liable for the delegate's actions.²²

Education regarding proper uses and disclosures of PDMP data—including how HIPAA plays in—also is important. This may be especially true for criminal justice officials, who may be unaccustomed to viewing PDMP data as protected health information.

As states contemplate what privacy options they wish to pursue, legislators should keep in mind that an assurance of confidentiality is crucial to a patient-physician relationship. States should take care to ensure that—despite good intentions—criminal justice and other officials are not given access to a patient's medical history in a way that could expose the patient to arguably undue scrutiny and embarrassment and could discourage patients from being honest with their physicians. Though courts around the country are divided as to whether state efforts to regulate controlled substances outweigh a need for patient privacy²³, legislators should consider whether it is appropriate to in some way limit what entities other than the physician have a right to know about a person's medical conditions and treatment.

In addition to statutory and regulatory approaches, technology has a role to play in promoting safety of PDMP data. States may wish to require periodic safety checks to ensure that a PDMP is employing the most updated measures to ward against electronic attacks. Results of these audits could be included in a PDMP's annual report to government officials.²⁴

Interested parties who offered specific comments on best practices for PDMPs included:

• American Association of Oral and Maxillofacial Surgeons (AAOMS), written (April 2013, August 2013)

- American Insurance Association (AIA), comments at 2012 meetings/2013 Spring
- American Medical Association (AMA), written (May 2013, October 2013, May 2014) and presentations at 2012 Annual/2013 Spring Meetings
- American Pharmacists Association (APhA), written (October 2013)
- KY Office of Drug Control Policy, presentation at 2013 Spring Meeting
- KY Office of the Governor, presentation at 2012 Annual Meeting
- National Alliance of Model State Drug Laws (NAMSDL), presentations at 2012 Annual/2013 Spring Meetings, written (May 2014)
- National Council on Compensation Insurance (NCCI), comments at 2012 meetings
- Pharmaceutical Research and Manufacturers Association (PhRMA), written
- Property Casualty Insurers Association of America (PCI), comments at 2012 meetings/2013 Spring Meeting
- Sherry L. Green & Associates, LLC, written (May 2014)
- Work Loss Data Institute (WLDI), written (September 2013)

3. PRESCRIBING PRACTICES

3.1 Use consistent, evidence-based treatment guidelines

Consistent, evidence-based guidelines may be helpful in promoting appropriate use of opioids for managing pain and should be considered as legislators evaluate ways to rein in opioid-related workers' compensation costs, while still allowing a provider to use more than one type of treatment for an illness or injury. Guidelines in Washington State²⁵— which establish dosage thresholds, standards for drug testing and tapering, use of signed treatment agreements between physicians and injured workers, and consultations with pain management and other specialists, among other things²⁶—are credited with noticeably lowering mortality rates and containing costs.

3.2 Take care not to negatively impact clinical decision-making

When considering policy mandates for opioid treatment, however, legislators should work to ensure that the standards target inappropriate opioid use without negatively affecting clinical decision-making and legitimate treatment, and should seek input from medical and public health communities. For instance, limiting the duration of an opioid prescription—which may be appropriate following dental and certain other procedures— may have negative consequences for patients with serious illnesses like cancer, AIDS, end-stage emphysema, and heart failure who rely on these medications to ease chronic suffering. Exempting patients who are on hospice or are being managed by a palliative care provider may further help to ensure that seriously ill patients receive the relief they need.

Treatment guidelines also might address when it's appropriate to use an antiinflammatory like ibuprofen in lieu of a narcotic, as well as address concerns that prescribing opioids to younger patients might encourage future addiction.

3.3 Promote use of treatment plans

Legislators might promote use of written, individualized treatment plans, in which a practitioner documents alternatives to using a controlled substance along with reasons why the practitioner is or is not pursuing them.²⁷ The plans list treatment objectives that patients are measured against periodically. A physical exam, a screen for substance abuse, and a review of a patient's PDMP info for the previous 12 months are required before the practitioner prescribes an opioid.

3.4 Create a closed formulary and explore impacts

Legislators also might look into creating a closed formulary to control costs and limit unnecessary use of opioids in the workers' compensation system. A Texas formulary, in place for new claims since 2011, lists drugs that are not recommended as a first course of treatment and so require preauthorization. According to a July 2013 Texas Department of Insurance analysis of claims stemming from injuries that took place between 2009 and 2011, the number of claims involving use of not-recommended (also called "N") drugs—which include almost all opioids—dropped by 67 percent, while the total cost of "N" drugs fell by 82 percent.²⁸

Because there is no one-size-fits-all approach, however, legislators interested in establishing a formulary should explore how it might affect a physician's ability to make individual treatment decisions. States should keep in mind that physicians and pharmacists can play a critical role in developing cost containment programs—both formularies and alternatives, such as limiting quantities of off-formulary drugs—that directly affect patient care.

3.5 Regulate pain clinics to close down "pill mills"

"Pill mills"—as opposed to legitimate pain clinics in which specialized physicians evaluate, manage, and treat a person's pain—are a source of rampant wrongful prescribing that states should work to rein in. These clinics give people easy and illicit access to dangerous controlled substances and encourage a culture of addiction by promoting "doctor shopping" and other run-arounds to appropriate opioid usage.

Nine states have specific pill mill regulations.²⁹ They generally target clinics in which most patients in any given month are prescribed or dispensed specified drugs for pain management. Laws require certain licenses and registrations of the clinic and the owner and often require the owner or designated medical director to be on-site for a certain amount of time. Kentucky, for instance, requires on-site attendance 50 percent of the time that patients are at the facility.

Pill mill laws, among other things, also limit the actual prescribing and dispensing of a controlled substance. In Florida, the practitioner must document why he or she prescribed more than a 72-hour dosage—and the law also prohibits physicians from onsite dispensing of oxycodone, hydrocodone, and other commonly abused drugs. In West Virginia, pain clinics cannot distribute more than a 72-hour supply.³⁰

Regulating pain clinics in order to close down "pill mills" is critical, but legislators should take care to avoid rules that discourage physicians in lawful pain management clinics from prescribing opioids for legitimate purposes, as this may significantly burden patients with chronic pain and/or those who have no history of abuse.

ADDITIONAL PROVISION —

NEONATAL ABSTINENCE SYNDROME & ADDICTION DURING PREGNANCY

(corresponding footnotes on page 14)

3.6 Consider appropriate treatment for addiction during pregnancy/neonatal abstinence syndrome (NAS)

There are specialized concerns, which extend beyond the realm of workers' compensation insurance, related to evidence-based treatment for pregnant women addicted to opioids and for newborns suffering from neonatal abstinence syndrome (NAS). As defined by the American Congress of Obstetricians and Gynecologists (ACOG), NAS is an expected and treatable condition that results from prenatal exposure

to opioids and that, unlike exposure to maternal alcohol and tobacco use, reportedly has no long-term effects on child development.³¹ States looking to promote proven NAS treatments—which could be as simple as keeping the mother and child in the same room, rather than placing the baby in a neonatal intensive care unit (NICU) or treating with opioid replacement drugs—might consider guidelines developed by the American Academy of Pediatrics (AAP) and the ACOG.³² States may find that the most effective treatment approaches are also among the least expensive.

The American Academy of Pediatrics (AAP) guidelines, issued in 2012, establish a standard of care for the recovery of addicted newborns, providing background on opioids, as well as information on, among other things, the clinical presentation of opioid withdrawal, differential diagnosis, evaluating when drug-withdrawal medications are and are not needed, and the pros and cons of different types of withdrawal medications.³³

The ACOG's *Toolkit on State Legislation* offers a range of proposals on how to address pregnant women with drug problems—including guidelines on how states might study the issue; determine whether to require mandatory drug testing and reporting; set rules for prescribing drugs to counteract opioids used by pregnant women; facilitate access to treatment programs; and promote public awareness. The *Toolkit* asserts, among other things, that physician-prescribed and supervised use of opioid medications during pregnancy, known as medication-assisted treatment, improves outcomes for the mother and the baby when compared to no treatment or to withdrawal.

When evaluating pregnant women's access to addiction services, legislators should explore whether any obstacles prevent physicians from offering such care, including whether insurers are willing to reimburse obstetricians and gynecologists for doing so when they are well-trained in addiction medicine. Legislators should evaluate whether there are adequate facilities to treat pregnant women in the state and look at what officials might do to expand locations and opportunities.

Although some states and communities are taking punitive measures against pregnant women who abuse opioids—including potential criminal penalties or the involvement of child welfare agencies, which may remove the newborn from the mother's custody legislators should be careful when considering these approaches, as they can be detrimental though well-intentioned. A pregnant woman who wants treatment for opioid addiction but is afraid of legal and other penalties may be less likely to seek help that would benefit both her and her unborn child than a pregnant woman who feels comfortable disclosing her addiction to her physician.

In order to focus on preventative programs and services, Tennessee passed H.B. 277 in 2013, known as the *Safe Harbor Act*, establishing that a pregnant woman shall be a "priority user" of available drug abuse treatment at a facility that receives public funding. The law—strongly supported by medical societies—also establishes that the department of children's services cannot move to terminate the mother's parental rights simply because she abused prescription drugs while pregnant.^{34, 35}

Because drug abuse during pregnancy, as well as newborn opioid withdrawal, raises emotional, medical, and cost challenges, officials seeking a legislative response should take care to balance subjective and objective considerations.

<u>Interested parties</u> who offered specific comments on best practices for prescribing reforms included:

- American Academy of Hospice and Palliative Medicine (AAHPM), written (June 2013, September 2013)
- American Academy of Pediatrics, written (May 2014)
- American Association of Oral and Maxillofacial Surgeons (AAOMS), written
- American Congress of Obstetricians and Gynecologists (ACOG), written (May 2014)
- American Insurance Association (AIA), comments at 2012 meetings/2013 Spring
- American Medical Association (AMA), written (May 2013, October 2013, May 2014) and presentations at 2012 Annual/ 2013 Spring Meetings
- American Pharmacists Association (APhA), written (October 2013)
- Coalition Against Insurance Fraud, comments at 2012 meetings/2013 Spring
- Massachusetts Society of Addiction Medicine, written (May 2014)
- National Alliance of Model State Drug Laws (NAMSDL), presentations at 2012 Annual/2013 Spring Meetings
- National Association of Boards of Pharmacy (NABP), written
- National Association of State Controlled Substances Authorities (NASCSA), written
- National Council on Compensation Insurance (NCCI), comments at 2012 meetings
- Renee C.B. Manworren, PhD, APRN, BC, PCNS-BC, Connecticut Children's Medical Center, written (August 2013)
- Property Casualty Insurers Association of America (PCI), comments at 2012 meetings/2013 Spring Meeting
- Work Loss Data Institute (WLDI), presentation at 2012 Summer Meeting and written (September 2013)

4. EDUCATION & OUTREACH

4.1 Consider mandated CME requirement issues

It should go without saying that anyone who prescribes an opioid must understand its uses and ramifications, including potential for addiction. But one of the more controversial aspects of developing an anti-opioid abuse strategy is how to go about doing that.

If legislators choose to mandate certain opioid-related continuing medical education (CME) requirements, lawmakers should work with medical licensing boards and associations, including representatives of dentistry, in order to determine what courses are appropriate for specific medical disciplines—e.g., what should primary care doctors know as related to oncologists and other specialists—and that courses do not conflict or overlap with already-existing CME or other educational standards.³⁶ Among other things, legislators might wish to exempt certain specialities, such as hospice and palliative care, that already require substantial training in opioid prescribing. Boards and associations may have a handle on how to address potential cost and other impediments.

At least nine states have CME mandates that focus on pain management/prescribing controlled substances.³⁷

Concerns regarding the effectiveness of a voluntary system might be overcome by creating incentives to encourage physician participation, such as waiving all or part of state licensing fees.

4.2 Implement media and education programs

A need for education is not limited to practitioners. There is a vast misperception in the general public regarding the safety of prescription painkillers. After all, unlike heroin,

cocaine, and other illicit drugs, prescription narcotics come from a trusted source—a doctor.

Utah kicked off an innovative media and education campaign in 2010 with funding from the Utah Commission on Criminal & Juvenile Justice and a federal grant awarded to the Utah Division of Substance Abuse & Mental Health. The "Use Only as Directed" program³⁸—which is a partnership of substance abuse, business, and other entities—includes an interactive, easy to navigate web site featuring short, creative video clips; statistics regarding how prescription painkillers directly affect Utah; a FAQs section that gives answers to commonly asked questions; articles and other resources; a chat room where people can share their stories and seek help; and tips on using, storing, and disposing of drugs safely.

4.3 Encourage safe, environmentally responsible drug disposal

The "Use Only as Directed" web site notes that more than half of the people in Utah who abuse painkillers get the drugs free from friends or relatives. Nationally, the CDC reports that more than three out of four people who misuse prescription painkillers use drugs prescribed to someone else.³⁹ One way that Utah and other states are trying to encourage safe, environmentally responsible drug disposal is through permanent <u>drop-off</u> bins, which are proving helpful and cost-efficient in the communities that have them.

Drug <u>take-back programs</u> are another, more complicated option. The U.S. Drug Enforcement Agency (DEA) has established National Prescription Drug Take-Back Days that are manned by local law enforcement authorities at thousands of locations around the country. Maine, which has the oldest population in the nation, has been a leader in drug take-back efforts, counting the quantities of drugs returned to determine what prescriptions are returned most often. Based on the data, the state reduced costs in its Medicaid program by imposing 15-day limits on initial prescriptions of the most wasted drugs, including opioids.⁴⁰

The rules regarding take-back events can be complex, since a web of state and federal agencies apply regulations related to hazardous waste, controlled substances, public safety, privacy, and other items, and boards of pharmacy may have their own requirements. State legislators might seek opportunities to work with federal authorities to develop a more comprehensive, harmonized approach, as well as to allow related take-back options—such as permitting pharmacies to accept unused prescriptions—that might improve take-back efforts.⁴¹

ADDITIONAL PROVISION — DRUG TAKE-BACKS/SAFE DISPOSAL (corresponding footnotes on page 15)

Unique approaches to drug disposal can be found in states like Oklahoma, where the Bureau of Narcotics and Dangerous Drugs has teamed up with a Tulsa-based energy company that takes unused drugs left in permanent drop-off bins and uses the substances to produce clean energy. According to the company, it has safely destroyed one million pounds of unwanted medications.⁴² In Albuquerque, New Mexico, large chain pharmacies and radio and TV stations have established take-back programs in addition to county-based efforts.

In Pennsylvania, the Department of Drug and Alcohol Programs' web site includes an online map in which individuals can click on the county in which they live to access a list of drug disposal locations and their hours of operation.⁴³

Several states—with the assistance of their medical societies—have enacted laws in recent years to address drug take-back and disposal. In 2013, for instance, Wisconsin set

forth rules for operating take-back programs approved by the Wisconsin department of justice or by a political subdivision, as well as rules for authorization to dispose of prescription drugs.⁴⁴ In New Hampshire, a 2013 law authorizes governmental and private entities to organize pharmaceutical drug take-back programs in consultation with local law enforcement. The law—addressing concerns over the patchwork of regulations related to take-back events—requires the department of justice, pharmacy board, department of safety, and department of environmental services to develop joint guidelines.⁴⁵

Of course, the more convenient and available that a drug disposal location is the more likely it will be successful. Police stations and courthouses are common sites because they are easy to locate and they are secure. However, legislators should consider whether to establish disposal locations that are outside the realm of law enforcement, as not everyone inclined to return an unused drug may feel comfortable in a criminal justice environment.

In addition to trying to discourage inappropriate opioid use, there are environmental inducements to safe drug disposal. Promoting the use of drop-off bins and take-back programs hopefully will reduce the quantity of unused medications that make their way down toilets and into a community's drinking water supply. Including lists of flushable versus non-flushable drugs in local educational campaigns could help. The health risks of pharmaceutical contamination in water to both humans and wildlife are still being evaluated, but studies indicate that even low levels of drug contamination can affect cellular activity.⁴⁶ According to one estimate, at least 46 million Americans are drinking water that contains trace amounts of a wide variety of pharmaceuticals.⁴⁷

<u>Interested parties</u> who offered specific comments on best practices for education and outreach included:

- American Academy of Hospice and Palliative Medicine (AAHPM), written (June 2013, September 2013)
- American Academy of Pediatrics, written (May 2014)
- American Association of Oral and Maxillofacial Surgeons (AAOMS), written (August 2013)
- American Insurance Association (AIA), comments at 2012 meetings/2013 Spring
- American Medical Association (AMA), written (May 2013, October 2013, May 2014) and presentations at 2012 Annual/ 2013 Spring Meetings
- National Alliance of Model State Drug Laws (NAMSDL), presentations at 2012 Annual/2013 Spring Meetings
- National Council on Compensation Insurance (NCCI), comments at 2012 meetings
- Property Casualty Insurers Association of America (PCI), comments at 2012 meetings/2013 Spring

5. TREATMENT & PREVENTION

5.1 Encourage and enhance treatment and prevention initiatives

One aspect of an opioid strategy that legislators must not ignore is how to care for people suffering from drug overdose and addiction. The need to address such concerns is clear. Just one statistic: between 1999 and 2009, there was a 430 percent rise in the rate of treatment admissions for the abuse of prescription pain killers.⁴⁸

5.2 Encourage use of certain drug treatments

Lawmakers might consider encouraging use of <u>naloxone</u>, an FDA-approved drug that serves as an antidote to opioid overdose. Naloxone has been used by community-based programs since the mid-1990s and, according to a 2010 Centers for Disease Control & Prevention (CDC) survey of 48 such programs, the drug reversed more than 10,000 overdoses.⁴⁹ Sixteen states—California, Colorado, Connecticut, Illinois, Kentucky, Maryland, Massachusetts, New Jersey, New Mexico, New York, North Carolina, Oregon, Rhode Island, Vermont, Virginia, and Washington State—as well as the District of Columbia have enacted laws that expanded naloxone availability.⁵⁰

To help remove barriers that physicians face when trying to address a patient's treatment and recovery needs, states might work to remove federal limits on the number of patients a physician may treat with <u>buprenorphine</u>, which is broadly supported by the medical community as a way to facilitate recovery from opioid addiction.

Legislators also might explore practitioners' ability to use <u>Suboxone</u>. The drug helps to treat addiction on an outpatient basis and, as with buprenorphine, is subject to federal limits on how many patients a doctor can treat using the drug. Physicians also have concerns regarding the regulatory requirements for becoming an authorized Suboxone prescriber.

5.3 Establish/expand use of drug courts

In addition, there may be opportunities for legislators to promote use of drug courts, which studies show are a cost-effective way to reduce drug use and crime rates. Addicts who are non-violent offenders receive intensive treatment for at least one year and are subject to random drug tests and requirements that they meet certain obligations to the court, their families, themselves, and others. According to the National Association of Drug Court Professionals (NADCP), these courts, which are endorsed by the Office of National Drug Control Policy (ONDCP), have a 75 percent success rate and save at least \$6,000 per participant as compared to using the criminal justice system.⁵¹

<u>Interested parties</u> who offered specific comments on best practices for treatment and prevention included:

- American Medical Association (AMA), written and presentations at 2012 Annual/ 2013 Spring Meetings
- National Alliance of Model State Drug Laws (NAMSDL), presentations at 2012 Annual/2013 Spring Meetings

6. CONCLUSION

State legislatures deserve a great deal of credit for their wide-ranging efforts to tackle the opioid epidemic, particularly their work in recent years. Opportunities exist, though, to establish additional and perhaps even more successful reforms. Best practices are not intended to be a final word on how states should approach a multi-faceted opioid strategy, but they hopefully do provide a starting point for legislative discussion and decision-making. The statistics of abuse are disturbing. States may have little time to waste.

¹ "Policy Impact: Prescription Painkiller Overdoses," Centers for Disease Control & Prevention, November 2011.

² "Opioids drive continued increase in drug overdose deaths," Centers for Disease Control & Prevention press release, February 20, 2013.

- ³ "Policy Impact: Prescription Painkiller Overdoses," Centers for Disease Control & Prevention, November 2011.
- ⁴ "Topics in Brief: Prescription Drug Abuse," National Institute on Drug Abuse, December 2011.
- ⁵ Paduda, Joseph. "Wasted Dollars, Wasted Lives—How Opioid Overprescribing and Physician Dispensing Are Harming Claimants and Employers," Workers' Compensation 2012 Issues Report.
- ⁶ "The Effect of Opioid Use on Workers' Compensation Claim Cost in the State of Michigan," Journal of Occupational and Environmental Medicine, August 2012.
- ⁷ "Prescribing Patterns of Schedule II Opioids in California Workers' Compensation," California Workers Compensation Institute (CWCI), March 2011.
- ⁸ In most states, the Board of Pharmacy or Department of Health administers the PDMP, though law enforcement agencies, among other entities, sometimes do so. <u>http://www.namsdl.org/IssuesandEvents/NAMSDL%20With%20the%20National%20Safety%20Council%</u> <u>20Part%201%20State%20PMPs%2C%20May%202013.pdf</u> (accessed June 2013)
- ⁹ AZ, CT, IN, KY, LA, MI, NJ, NM, NY, ND, OH, OR (practitioner access limited to those in CA, ID, and WA), SC, TN, VT, VA, WA, and WV allow data sharing between their PDMPs and <u>both out-of-state</u> <u>PDMPs and authorized users</u>. States that allow access <u>only for out-of-state authorized users</u> are AK, CA, CO, ID, IA, MN, TX, and WY. States that allow access <u>only for other PDMPs</u> are AL, AR, DE, HI, IL, KS, MD, MA, ME, MS, MT, NV, NH, NC, RI, SD, UT, and WI. The following states have <u>no sharing rules</u> in place: FL, GA, NE, OK, and PA. MO does not have a PDMP. <u>http://www.namsdl.org/library/17A9675F-1C23-D4F9-742C62EED4805F68/</u> (accessed December 2013)
- ¹⁰ A state may wish to require that individuals who are identified as at-risk for opioid dependence have their prescriptions filled by a single pharmacist or prescribed by a single physician. (*National Alliance of Model State Drug Laws*)
- ¹¹ Letters to NCOIL from the American Medical Association (AMA), May 30, 2013; National Association of Boards of Pharmacy (NABP), May 31, 2013; and National Association of State Controlled Substances Authorities (NASCSA), June 2, 2013.
- ¹² The American Academy of Pain Medicine, American Academy of Pediatrics, American Congress o Obstetricians and Gynecologists, American Medical Society, and American Society of Addiction Medicine may be of assistance in addressing PDMP requirements related to neonatal abstinence syndrome (NAS).
- ¹³ National Alliance of Model State Drug Laws (NAMSDL), States with Statutory Authority to Require Nonresident Pharmacies to Report to Prescription Monitoring Program. <u>http://www.namsdl.org/library/8573B7C9-19B9-E1C5-31F3C2D5B041C157/</u>
- ¹⁴ Kentucky Office of Drug Control Policy, <u>http://odcp.ky.gov/</u> (accessed June 2013)
- ¹⁵ During a Nov. 22, 2013, NCOIL meeting in which legislators adopted these best practices, the American Insurance Association (AIA) raised the following concern: "On the final sentence in 2.5 our concern was that while at this time [in the best practices document], only dispensers report prescription information to PDMPs, the language is overly restrictive and does not allow for likely technological innovation. It is conceivable that when electronic prescriptions for controlled substances are implemented more fully that prescribers could send a copy of each prescription issued to the PDMP simultaneous with sending it to the pharmacy—an ideal situation. Suggesting states limit reporting requirements to dispensers only does not leave space for such a situation. Further, some prescribers not only prescribe, but also dispense. In this circumstance, most but not all states require the dispensing prescriber to report to the PDMP the dispensing of the controlled substance. Limiting the language to dispensers only does not fully encompass the dispensing prescriber."
- ¹⁶ New York switched to real-time reporting as of August 27, 2013. Delaware, Kansas, Kentucky, Minnesota, North Dakota, and West Virginia require daily/24-hour reporting. National Alliance of

Model State Drug Laws (NAMSDL), <u>http://nationalrxdrugabusesummit.org/wp-content/uploads/2013/03/Green-pt1_STATE_PMP.pdf</u> (accessed June 2013)

¹⁷ Pew Charitable Trusts report, Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices, September 20, 2012, available at http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report_final.pdf

¹⁸ Ibid.

¹⁹ Ibid.

²⁰ The National All Schedules Prescription Electronic Reporting (NASPER) Act established a formula grant program administered by the Substance Abuse and Mental Health Services Administration (SAMHSA) to help fund state PDMPs. NASPER has not been reauthorized, however, and currently is not providing grants. Harold Rogers Prescription Drug Monitoring Program grants, offered through the U.S. Department of Justice, are currently available.

²¹ Twelve (12) states, however—Arizona, California, Florida, Kansas, Kentucky, Maryland, Nebraska, New Hampshire, New York, Ohio, Vermont, and Washington—explicitly exclude licensing and other fees from funding. (National Alliance of Model State Drug Laws, http://www.namsdl.org/documents/FundingProvisionsofPMPs07312012.pdf)

ADDITIONAL FOOTNOTES — **RE: PDMP PRIVACY** (corresponds to PDMP privacy language on page 4)

- ²² If a state establishes that a prescriber or dispenser is liable for the activity of its delegate(s), the state may wish to allow the prescriber/dispenser to access a PDMP for the purpose of checking the delegates' history of pulling PDMP data on behalf of the prescriber/dispenser. (Sherry L. Green & Associates, LLC)
- ²³ A federal district court in Oregon ruled that the Drug Enforcement Agency (DEA) needs a warrant, rather than just an administrative subpoena, to access patient PDMP info. In Florida, a state court determined that the government's interest in regulating controlled substances justified an intrusion into privacy. In addition, as of May 2014, separate cases in California were looking at whether the state PDMP, which is maintained by the state's Department of Justice, adequately protects patient privacy against government intrusion. (*American Medical Association*)
- ²⁴ Although not directly related to PDMP privacy issues, legislators may wish to consider how states "deidentify" PDMP data for private and public entities to conduct certain research and education efforts. In particular, states should consider the importance of removing identifying information for physicians and prescribers—as well as for patients. (*Sherry L. Green & Associates, LLC*)
- ²⁵ California also has chronic pain medical treatment guidelines, available at <u>www.dir.ca.gov/dwc/DWCPropRegs/MTUS_Regulations/MTUS_ChronicPainMedicalTreatmentGuidelines.pdf</u> The Work Loss Data Institute's *Official Disability Guidelines* may be another resource, as well as guidelines produced by the American Pain Society (APA). Legislators may wish to consider funding opportunities that could help certain entities develop and update evidence-based treatment guidelines, as well as encourage research into pain management.
- ²⁶ "Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain," Washington State Agency Medical Directors Group, 2010. (Effective July 1, 2013, the guidelines were expanded to address acute as well as chronic pain, among other things.)
- ²⁷ Legislators may wish to consider how a practitioner's use of alternative treatments (e.g., physical therapy, cognitive behavioral therapy, guided imagery, massage, hypnosis, and other items) may be affected by third-party payers' willingness to pay for such treatments. (*Renee C.B. Manworren, PhD, APRN, BC, PCNS-BC, Connecticut Children's Medical Center*)
- ²⁸ Texas Department of Insurance report available at

<u>http://www.tdi.texas.gov/reports/wcreg/documents/Pharma_070913.pdf</u> The report looked at injuries with nine-month maturities. (The Texas formulary kicked in for older claims in September 2013.)

- ²⁹ Florida, Georgia, Kentucky, Louisiana, Mississippi, Ohio, Tennessee, Texas, and West Virginia have specific "pill mill" regulations (as of August 2013). (National Alliance of Model State Drug Laws, <u>http://www.namsdl.org/library/42E4C1F1-19B9-E1C5-3192D3E0E2DA16E7/</u>)
- ³⁰ In some other jurisdictions, policymakers have prohibited medical practitioners in emergency rooms from prescribing long-acting opioid painkillers.

(corresponds to provision on pages 6 and 7)

- ³¹ "Pregnant Woman & Prescription Drug Abuse, Dependence and Addiction," *Toolkit on State Legislation*, The American Congress of Obstetricians and Gynecologists (ACOG).
- ³² The American Society of Addiction Medicine (ASAM) also is developing resources as part of its Providers' Clinical Support System for Medication-Assisted Treatment (PCSS-MAT) program to encourage physicians trained in addiction medicine to serve as mentors to other physicians, such as primary care physicians, pediatricians, and obstetrician/gynecologists, who may deal with women's addiction issues. More information is available at http://pcssmat.org.
- ³³ Clinical Report: Neonatal Drug Withdrawal, American Academy of Pediatrics, January 2012.
- ³⁴ The Tennessee legislature has enacted two divergent laws related to pregnant women with substance abuse problems. Although the 2013 Safe Harbor Act prioritizes treatment for such women and offers protection against loss of parental rights, 2014 H.B. 1295 provides that a woman may be prosecuted for assault for the illegal use of a narcotic drug while pregnant, if her child is born addicted to or harmed by the narcotic, unless the woman actively enrolled in an addiction recovery program before the child's birth and remained and successfully completed the program after delivery. The 2014 law expires on July 1, 2016.
- ³⁵ The Guttmacher Institute provides monthly updates on state policies related to substance abuse during pregnancy. Reports are available at <u>http://www.guttmacher.org/statecenter/updates/index.html</u>.
- ³⁶ One resource may be a Prescriber Clinical Support System for Opioid Therapies (PCSS-O), which offers a series of educational webinar courses. PCSS-O is a collaborative project funded by a three-year grant from The Substance Abuse and Mental Health Services Administration (SAMHSA). The project is led by the American Academy of Addiction Psychiatry and also includes the American Dental Association, American Medical Association, American Osteopathic Academy of Addiction Medicine, American Psychiatric Association, American Society for Pain Management Nursing, and International Nurses Society on Addictions. http://www.pcss-o.org/
- ³⁷ Krupa, Carolyne. "Hot-button issues drive state CME mandates," amednews.com, February 13, 2012. California, Florida, Iowa, Massachusetts, Oklahoma, Oregon, Rhode Island, Tennessee, and West Virginia have pain management/prescribing controlled substances mandates.
- ³⁸ <u>http://www.useonlyasdirected.org</u> (accessed June 2013)
- ³⁹ "Policy Impact: Prescription Painkiller Overdoses," Centers for Disease Control & Prevention, November 2011.
- ⁴⁰ A proposed DEA rule that would expand the kinds of entities that could collect unused prescription drugs would ultimately, in an effort to prevent drug diversion, put an end to tabulating efforts like those in Maine. "New Rules Could Hurt Maine Drug Takeback Programs," Maine Sunday Telegram, January 27, 2013.

⁴¹ Legislators also might direct state agencies to identify programs in other jurisdictions that could be used as models for the state (*American Medical Association*) and/or wish to consider how implementing a drug take-back program affects the daily operations, health, and security of providers, including pharmacists, and whether reimbursement is appropriate (*American Pharmacists' Association*).

ADDITIONAL FOOTNOTES — RE: DRUG TAKE-BACKS/SAFE DISPOSAL (corresponds to provision on pages 9 and 10)
⁴² Covantra Energy press release, October 14, 2013.
⁴³ Online map of Pennsylvania safe drug disposal locations available at http://www.portal.state.pa.us/portal/server.pt?open=514&objID=1677241&mode=2
⁴⁴ Wisconsin Act 198 set rules for take-back programs/ prescription drug disposal in the state.
⁴⁵ New Hampshire Rev. Stat. §318-E:1 authorized/established requirements regarding governmental-private entity drug take-back events in the state.
⁴⁶ "Research shows pharmaceuticals in water could impact human cells," Associated Press. Article available at http://hosted.ap.org/specials/interactives/pharmawater_site/day1_03.html
⁴⁷ "AP INVESTIGATION: Scant advice on disposal of meds," Associated Press. Article available at http://hosted.ap.org/specials/interactives/pharmawater_site/sept15a.html
⁴⁸ Carnevale, Ph.D., John T. Presentation before NCOIL, November 15, 2012.
⁴⁹ "Community-Based Opioid Overdose Prevention Programs Providing Naloxone – United States, 2010," <i>Morbidity and Mortality Weekly Report (MMWR)</i> , February 17, 2012 / 61(06); 101-105. Centers for Disease Control and Prevention (CDC). <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6106a1.htm</u>
⁵⁰ "Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Good Samaritan Laws," The Network for Public Health Law, July 2013.

⁵¹ National Association of Drug Court Professionals (NADCP), <u>http://www.nadcp.org/nadcp-home</u>

The following interested parties have submitted written comments offering specific best practice recommendations:

American Academy of Hospice and Palliative Medicine (AAHPM) American Academy of Pediatrics (AAP) American Association of Oral and Maxillofacial Surgeons (AAOMS) American Congress of Obstetricians and Gynecologists (ACOG) American Medical Association (AMA) American Pharmacists Association (APhA) Massachusetts Society of Addiction Medicine National Alliance of Model State Drug Laws (NAMSDL) National Association of Boards of Pharmacy (NABP) National Association of Chain Drug Stores (NACDS) National Association of State Controlled Substances Authorities (NASCSA) Renee C.B. Manworren, PhD, APRN, BC, PCNS-BC, Connecticut Children's Medical Center Pharmaceutical Research and Manufacturers Association (PhRMA) Sherry L. Green & Associates, LLC Work Loss Data Institute (WLDI)

The following contributed more generally to NCOIL discussions regarding opioid issues and state reforms:

American Insurance Association (AIA) Carnevale Associates LLC (John T. Carnevale, PhD) Coalition Against Insurance Fraud International Association of Industrial Accident Boards & Commissions (IAIABC) Kentucky Office of Drug Control Policy Kentucky Office of the Governor National Council on Compensation Insurance (NCCI) Property-Casualty Insurers Association of America (PCI)

"PARKING LOT" ISSUES:

NCOIL believes that these best practices should evolve in response to emerging state needs, trends, and other opioid-related concerns—in order to be of greatest assistance to states. In keeping with that commitment, legislators at the 2013 Annual Meeting determined to explore the following items, among others, in a future version of the Best Practices to Address Opioid Abuse, Misuse & Diversion:

- Good Samaritan/Safe Harbor Laws for drug overdose reporting
- development by medical and hospital associations of policies aimed at limiting inappropriate use of opioids
- expanded/enhanced guidance regarding opioid treatment, prevention, and recovery
- · governmental entities (in addition to the DEA) that deal with drug take-back programs
- information regarding the relative effectiveness of various painkillers

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