AMA
AMERICAN MEDICAL ASSOCIATION

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Candace Thorson
Deputy Executive Director
National Conference of Insurance Legislators
385 Jordan Road
Troy, NY 12180

Re: American Medical Association Comments on NCOIL's Continued Work to Combat Prescription Drug Abuse and Diversion

Dear Ms. Thorson:

On behalf of the American Medical Association (AMA), physician and student members, we appreciate the work that the National Conference of Insurance Legislators (NCOIL) has done to help develop tangible solutions to combat America's prescription drug abuse and diversion epidemic. The Recommended Best Practices document that NCOIL continues to develop can serve as a guide to policymakers throughout the United States in that they highlight the need for careful consideration of policies to avoid one-size-fits-all legislation that may have adverse, unintended consequences for patients and physicians.

As NCOIL continues to evaluate areas of future policy development, the AMA offers comments on three areas:

- **The need to consider and address state and federal programs, including existing challenges and barriers when developing comprehensive Take Back and disposal programs for unused and unwanted prescription medications;**
- **Needed attention to the privacy issues raised by increased use of prescription drug monitoring programs (PDMPs); and**
- **Support for evidence-based, public health practices to treat neonatal abstinence syndrome.**

Each of these topics – like all of the issues already contained in the NCOIL Best Practices – cannot and should not exist in a vacuum. Policies, legislation and regulation aimed at combating prescription drug abuse, misuse, diversion, overdose and death must be articulated in a combined, multifactorial fashion that requires physicians, elected leaders, law enforcement, public health officials and all other stakeholders to work together.

The AMA understands the immediate need to reduce the destructive and deadly effects of prescription drug abuse and diversion. We remain deeply concerned, however, that actions with too narrow of a focus may harm patients' access to necessary medications and fuel the increasing spread of heroin use in patients with substance use disorders, including addiction. Thus, while the AMA has limited its comment to those areas that NCOIL requested in its Request for Comment, we remain committed to working with NCOIL and others to develop a comprehensive, public health approach to help combat prescription drug abuse, diversion, overdose and death.

The need to consider and address state and federal programs, including existing challenges and barriers when developing comprehensive Take Back and disposal programs for unused and unwanted prescription medications

There is no question that a large supply of prescription drugs is dispensed in the United States. There also is no question that physicians face challenges when advising patients on the proper storage and disposal of unused prescription drugs. Our children, teens and young adults, in particular, are able to access medications in their home, and this is an important source of initial exposure leading to diversion and substance misuse.

The AMA supports the U.S. Drug Enforcement Administration's (DEA) efforts to promote National Take Back Day and similar efforts to provide a safe and legal way for people to dispose of prescription drugs they do not need. However, how can this be done safely and efficiently, in a convenient way and on a consistent basis?

Currently, a national infrastructure does not exist to safely and efficiently dispose of unused prescription drugs. This situation contributes to the prescription drug diversion crisis, and also raises serious public health concerns related to the increasing contamination of our drinking water with prescription drugs. In 2008, an investigation found that at least 46 million Americans were exposed to prescription drugs through their drinking water.[1] This included the water supplies of 24 major metropolitan areas and the water supplies of many of the nation's watersheds. **Removing unwanted and unused drugs is an important discussion that needs to occur between all stakeholders, and the AMA encourages those discussions.**

As one potential solution, the AMA submitted formal comments in support of proposed rules from the DEA that would expand the options available to collect controlled substances from ultimate users for purposes of disposal, including Take Back events, mail-back programs and collection receptacle locations.[2] In addition, the DEA Proposed Rules expand the categories of entities authorized to offer these options to include manufacturers, distributors, reverse distributors, local law enforcement and retail pharmacies. While the AMA supports the expansion of entities permitted to engage in collection of unused controlled substances, we urged the DEA to reconsider its decision to not allow hospitals without a registered pharmacy to participate in Take Back events.

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[1] Associated Press, Pharmaceuticals in water. Available at http://hosted.ap.org/specials/interactives/_national/pharmawater_update/index.html. Last accessed May 16, 2013.

[2] AMA letter to Administrator Michele M. Leonhart, Re: Disposal of Controlled Substances, RIN 1117–AB18, [Docket No. DEA–316], February 19, 2013.

However, even if the DEA successfully increases the flexibility of Take Back locations, there remains a host of disparate and complicated laws and regulations involving the storage, custody, transportation and ultimate disposal of drugs gathered in this fashion. Disparate federal and state agencies are involved including the Environmental Protection Agency, Department of Transportation, law enforcement, DEA, Occupational Safety and Health Administration and other public health and safety agencies. We have urged the DEA to take a lead in partnering with federal and state stakeholders to harmonize and streamline these requirements. NCOIL certainly can play a proactive and productive role in this regard.

At the same time, there are examples of work being done in many states in support of ongoing Take Back and disposal of unused and unwanted prescription medication. In Kentucky, there now are 172 drug disposal locations, covering 110 of the state's 120 counties.[3] The Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) implemented a new statewide drug Take Back plan several years ago that resulted in having more than 120 secure drop boxes installed throughout the state. Notably, the Oklahoma initiative has been a partnership with a Tulsa energy company that destroys the unused drugs.[4] In New Mexico, the city of Albuquerque, large chain pharmacies, radio and TV stations have Take Back programs in addition to county-based law enforcement activities. Pennsylvania's Department of Drug and Alcohol Programs has an interactive, online map[5] to help people find a Take Back location in the Commonwealth.

Furthermore, Take Back and disposal programs have garnered legislative activity in multiple states, including Wisconsin,[6] New Hampshire,[7] Rhode Island[8] and others. These statutes vary in their complexity and scope, but each point to the fact that states interested in taking action have legislative models to consider. Also key to success in each state was the fact that the state medical society helped enact the new law; many medical societies already work with state and local law enforcement in support of Take Back efforts and events. In short, the nation's physicians are ready to be your partner in this effort.

This is not to say that designing a best practice will address all challenges. Consider that some state Take Back sites may not always be convenient. That is, having a year-round program with broad access may be more useful than having a program only available during certain days for limited hours. In addition, many Take Back sites are located in courthouses and police stations – understandable due to the need for a secure location. Those locations, however, may cause some patients pause, as noted recently by the National Governors Association.[9]

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[3] Kentucky Office of Drug Control Policy, http://odcp.ky.gov/Kentucky+Prescription+Drug+Disposal+Sites.htm.
[4] Covanta Energy. Press Release. Octover 14, 2013. Available at http://www.marketwatch.com/story/a-million-thanks-to-the-state-of-oklahoma-for-exceptional-leadership-in-protecting-people-and-the-environment-from-improper-disposal-of-drugs-2013-10-14
[5] See http://www.portal.state.pa.us/portal/server.pt?open=514&objID=1677241&mode=2
[6] Drug Disposal Programs and the Disposal of Prescription Drugs. Wisconsin Legislative Council Act Memo. 2013 Wisconsin Act 198. Available at https://docs.legis.wisconsin.gov/2013/related/lcactmemo/ab448.pdf
[7] Controlled And Non-Controlled Pharmaceutical Drug Take Back Programs. N.H. Rev. Stat. § 318-E:1 (2014)
[8] See 2012 R.I. Gen. Laws. § 21-31-24.
[9] See, Reducing Prescription Drug Abuse: Lessons Learned from an NGA Policy Academy. The National Governors Association (NGA) Center for Best Practices. Available at http://www.nga.org/files/live/sites/NGA/files/pdf/2014/1402ReducingPrescriptionDrugAbuse-Paper.pdf (Note:

The AMA stands ready to work with NCOIL on further policy development for best practices concerning safe Take Back and disposal programs, and we would be pleased to connect NCOIL with representatives from state medical societies for additional information.

Needed attention to the privacy issues raised by increased use of prescription drug monitoring programs (PDMPs)

Many states in the 2013 and 2014 state legislative sessions have expended considerable energy on legislation concerning prescription drug monitoring programs (PDMPs). As the AMA has previously stated, we support the use of PDMPs as a clinical decision-making tool that can assist physicians when considering whether to prescribe controlled substances.

One area that is beginning to see increased attention is the extent to which law enforcement and others have access to the array of a patient's personal medical information contained within a PDMP. This includes debate over what legal or other standard or threshold must be met for accessing that information by law enforcement and others. According to the National Association of Model State Drug Laws,[10] 17 states require probable cause, search warrant, subpoena or other judicial process for law enforcement to access a PDMP. Twenty-nine states require that a search must be pursuant to an active investigation, but it is not always clear how "active investigation" is interpreted. Only Vermont[11] treats the information in a PDMP as confidential and available only to a professional licensing board – but the board may refer to law enforcement if illegal activity is suspected.

From the AMA's perspective, the information disclosed to a physician by a patient should be held in confidence – this includes information that goes into a patient's medical record. **Physician-patient confidentiality is bedrock to the patient-physician relationship.** Likewise, the physician should not reveal confidential information without the express consent of the patient, subject to certain exceptions which are ethically justified because of overriding considerations. This includes the disclosure of confidential information when it is required by law or court order. The confidential exchange and security of information is essential for patient trust and treatment.

There is considerable pressure, however, for states to use their PDMP to investigate alleged diversion and other illegal activity. The AMA is concerned, however, that if a patient's personal medication history was subject to unfettered access via a PDMP, it raises the possibility of a patient not being fully honest with his or her physician due to the potential fear of that information being used for other purposes. The AMA understands that the predominant focus surrounding PDMPs in current legislative sessions concerns opioids, but the privacy issues raised go far beyond opioids as there are many types of controlled substances that are entered into a PDMP.

The NGA Policy Academy only reviewed the efforts of seven states.) In Kentucky, there are 172 drop-off locations, covering 110 counties.

[10] Types of Authorized Recipients – Law Enforcement and Judicial/Prosecutorial Officials. National Association of Model State Drug Laws. Available at http://www.namsdl.org/library/28F73901-65BE-F4BB-A79C68B985DB458C/

[11] See Vt. Stat. Ann. tit. 18, § 4284 (2014).

For example, depending on the state, a PDMP may contain every prescription for a controlled substance, which could indicate that a patient is receiving treatment for many different conditions and situations, including cancer, hospice, HIV, sickle-cell anemia and mental health conditions such as attention deficit disorder, depression or anxiety. When a PDMP is subject to civil discovery or open investigations, many patient records may suddenly be cast into the open – subjecting an unknowing patient to undue scrutiny, embarrassment, humiliation and other harmful reactions.

These considerations also are being played out in the nation's courts, which are considering how to balance a patient's and physician's privacy interests against the need to protect public safety. These cases address limits for the release of PDMP information, and what standard must be met by the party seeking the information. Just as there are many views on how to address the nation's prescription drug abuse and diversion epidemic, the courts have delivered conflicting opinions:

- A federal district court in Oregon ruled that a warrant is required. The DEA had argued that an administrative subpoena was sufficient. The court held, however, that the prescription records "are protected by a heightened privacy interest rendering the use of administrative subpoenas unreasonable."[12]
- In California, separate cases are considering whether the state PDMP "adequately protect[s] patient privacy against governmental intrusion."[13] It should be noted that the state Department of Justice maintains the state PDMP and is the primary arbiter determining when an investigation and release of information is reasonable.
- In Florida, a state court considered the privacy issue from a physician's perspective. The court held that the "government's compelling interest in regulating controlled substances…justifies the intrusion into Plaintiff's privacy," and that "the warrantless search and seizure of the prescription records of Plaintiff and the other approximately 3,300 persons was reasonable," and not a violation of anyone's privacy rights.[14]

There is much more work to be done on the privacy issues raised by PDMPs and the AMA is pleased that NCOIL has added this for consideration.

Support for evidence-based, public health practices to treat neonatal abstinence syndrome

In addition to the increasing numbers of Americans abusing prescription drugs and dying from unintentional overdose, there are increasing data on the rise of neonatal abstinence syndrome (NAS).[15] Yet, states are only starting to act, sometimes with mixed results.[16]

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[12] *Oregon Prescription Drug Monitoring Program v. U.S. Drug Enforcement Administration.* U.S. District Court for the District of Oregon, Portland Division. Case No. 3:12-cv-02023-HA. Feb. 11, 2014.

[13] See *Michael Chiarottino, M.D. v. Linda Whitney as Executive Director, Medical Board of California*; and *Alwin Lewis, M.D. v. Superior Court of the State of California, County of Los Angeles.*

[14] *Michael H. Lambert v. R.J. LaRizza, as State Attorney for the Seventh Judicial Circuit of the State of Florida.* Circuit Court, Seventh Judicial Circuit, Florida. Case No. 12-31402-CICI. Feb. 13, 2014.

[15] Neonatal abstinence syndrome (NAS) is a condition affecting newborns whose mothers used opiates during pregnancy. As detailed in the April 30, 2012 issue of the *Journal of the American Medical Association*, NAS not only can have severe health consequences on fetuses and newborn babies, but NAS raises issues concerning Medicaid, appropriate treatment of pregnant women and the financial costs to the health care system.

As a starting point, it should be noted that substance abuse and addiction is a disease and should be treated as such. This goes for all patients, including women who are pregnant.

That is why, the AMA recommends that legislators turn their focus and support the work done by the nation's leading national medical specialty societies, including the American Academy of Pediatrics (AAP), the American Congress of Obstetricians and Gynecologists (ACOG) and the American Society of Addiction Medicine (ASAM). That is, the information from these – and other medical societies – can help legislators and public health officials design policies that put the interests of the pregnant woman and her baby first and foremost.

For example, among its resources, the AAP published "Neonatal Drug Withdrawal,"[17] a clinical report that contains important background on opioids; the clinical presentation of opioid withdrawal; differential diagnosis; assessment and nonpharmacologic treatment; and the rationale and comparative evidence for pharmacologic treatment. There also is information on managing patients, key clinical considerations and an extensive list of references. In short, the AAP report – while not a standard of care – does provide evidence-based information from which medical decisions are made.

Similarly, the AMA encourages NCOIL's members to work with the medical society in their state if legislative solutions are sought. If this path is chosen, two resources from ACOG's Toolkit on State Legislation[18] may be of interest. One document highlights the key terms and issues surrounding NAS, including that the "shared goal must be a healthy outcome for both mother and baby" rather than "punitive drug enforcement policies."

Finally, ASAM is developing resources as part of the Providers' Clinical Support System for Medication-Assisted Treatment (PCSS-MAT). One part of the PCSS-MAT program is scheduled 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 issues in addiction, according to ASAM officials.[19]

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[16] The Tennessee legislature, for example, enacted House Bill 277, The Safe Harbor Act of 2013, which emphasizes and prioritizes treatment for women misusing prescription drugs during pregnancy. In 2014, however, the Tennessee legislature enacted House Bill 1295, which essentially criminalizes substance abuse and may have the adverse effect of causing women misusing prescription drugs to avoid seeking treatment during pregnancy.

[17] Clinical Report: Neonatal Drug Withdrawal. Hudak, Mark L., Tan, Rosemarie C. The Committee on Drugs and The Committee on Fetus and Newborn. Pediatrics 2012; 129; e540. Jan. 30, 2012. Available at http://pediatrics.aappublications.org/content/129/2/e540.full.pdf+html

[18] The two documents are "Pregnant Women & Prescription Drug Abuse, Dependence and Addiction" and another document focused on suggested legislation. Both are available from the ACOG Government Affairs division.

[19] Med-Sci: ASAM Steps Up Efforts to Reduce Incidence of NAS. American Society of Addiction Medicine. April 17, 2014. Available at http://www.asam.org/magazine/read/article/2014/04/17/med-sci-asam-steps-up-efforts-to-reduce- incidence-of-nas

Conclusion

The AMA appreciates the opportunity to provide these comments. We look forward to continuing to work with NCOIL to combat the nation's prescription drug abuse and diversion epidemic.

If you have any questions about the policies and initiatives raised in this comment letter, including state-specific efforts that have occurred in recent legislative sessions, please contact Daniel Blaney-Koen, JD, Senior Legislative Attorney, Advocacy Resource Center, at daniel.blaney-koen@ama-assn.org or 312-464-4954.

Sincerely,

James L. Madara, MD