

December 17, 2013

Dan Crippen, PhD
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National Governors Association
Hall of the States
444 North Capitol Street, Suite 267
Washington, DC 20001-1512

Re: American Medical Association comments on “Reducing Prescription Drug Abuse: Lessons Learned from an NGA Policy Academy”

Dear Dr. Crippen:

On behalf of the physician and medical student members of the American Medical Association (AMA), thank you for providing the AMA with the opportunity to outline possible ways to address the prescription drug abuse and diversion crisis. We have provided detailed comments below, but first let me commend the National Governors Association (NGA) for its work to bring together key stakeholders and leaders from the seven policy academy states and interested parties from many disciplines and professions. The willingness NGA has demonstrated to hear from so many has resulted in a very thoughtful “Lessons Learned” document that will serve future policy academy participants well as they work to identify and further augment best practices to combat this growing epidemic.

As we have stated in NGA roundtable discussions and elsewhere, physicians work hard to balance their ethical obligation to treat patients with legitimate pain management needs against the need to identify drug seekers and prevent abuse, overdose, and death from prescription drugs. Physicians must confront numerous challenges in their efforts to maintain that balance. Many of the NGA recommendations emphasize that balance, and others raise areas for additional consideration. Please know that the AMA welcomes the opportunity to work with the NGA to determine next steps, including how to most effectively engage the nation’s medical societies.

The AMA’s comments are organized per the seven areas highlighted by NGA:

- **Effective Leadership:** Advocating for comprehensive, public health focused solutions requires leadership that understands one-size does not fit all;
- **Prescriber Education:** Promoting educational opportunities for physicians and other prescribers to increase their knowledge must focus on information relevant to the patient populations they serve;

- **Safe Disposal:** Harmonizing and streamlining state and federal laws governing disposal of prescription drugs, including controlled substances, must include expanding awareness and access to local disposal sites;
- **Prescription Drug Monitoring Programs:** Using modernized, interoperable Prescription Drug Monitoring Programs (PDMP), has the potential to be a powerful clinical tool;
- **Public Education:** Enhancing public education efforts can provide key information throughout the community;
- **Expanding Treatment:** Expanding capacity of treatment and recovery programs, as well as considering strategies such as drug courts, needs to be part of strategic planning to facilitate access to existing programs; and
- **Data Sharing:** Increasing data sharing (including epidemiological) and evaluation is key to develop informed, targeted solutions based on local and regional needs.

Effective Leadership: Advocating for comprehensive, public health focused solutions requires leadership that understands one-size does not fit all.

The diversion and abuse of prescription drugs is a national epidemic – requiring leaders in government, medicine, public health and the community at-large to work together for effective solutions to curb abuse while preserving access to care. As NGA notes, several states have taken important, collaborative steps toward identifying policy solutions. Some states also have enacted and are implementing new laws and regulations intended to help communities combat abuse, diversion, overdose and death. Not all solutions, however well intended, achieve their goals. That is, despite all of our best efforts, the increase in abuse, overdose and death continue to rise at unacceptable levels. And at the same time, some efforts have had the unintended consequence of restricting patients’ access to care.

Like NGA, the AMA believes that “states can overcome” the challenges they face. Namely, the AMA believes that with a comprehensive, public health focus to evaluate all proposals, leaders will have the most effective lens through which to determine the most appropriate courses of action. This includes several of the policy options noted in the “Lessons Learned” document discussed in more detail below. But the AMA strongly cautions that proposals designed to legislatively mandate standards of care may unintentionally discourage physicians from appropriately treating pain or reduce access to prescription drugs for patients who are suffering.

Misuse, abuse, addiction and unintentional poisonings from prescription opioids are a serious public health problem and at the same time, a great deal of human pain and suffering remain inadequately treated. Pain is the most common reason patients seek medical attention; according to a 2011 Institute of Medicine report, 100 million Americans suffer from chronic pain. Although some of these chronic pain sufferers benefit from prescription opioids on a long term basis, others may not benefit or suffer harm. A multidisciplinary approach is often needed to manage these patients. Such an approach requires careful deliberation and nuanced implementation; one-size-fits-all solutions simply will not work in the short or long term.

As leaders, governors know too well how this crisis has affected their constituents. As physicians, we share that knowledge because physicians see the pain and suffering endured by patients with acute and chronic pain. We work hard to diagnose, treat and manage that pain, and we also work hard to treat patients who suffer from addiction – a disease that affects people of all walks of life, without distinction for income, race, gender or many other factors. That is why we believe effective leadership means working together to further develop best practices and avoid unintended consequences.

By working closely with medical societies, the AMA believes that such a public health, comprehensive approach can be achieved. For example, NGA highlighted the package of bills signed by Governor Robert Bentley, MD, in Alabama this past year. In fact, that package was strongly supported by the Medical Association of the State of Alabama. Specifically, Buddy Smith, MD, Chairman of the Medical Association of the State of Alabama Board of Censors commented: “Some states that have tried to combat prescription drug abuse have passed legislation that had disastrous effects on patient care and placed tremendous burdens on physicians. This package presents a workable solution. It comprehensively tackles this growing problem in our state.”¹ **It follows that the AMA urges NGA to include as a key recommendation that governors engage and collaborate with state and specialty medical societies. We welcome the opportunity to work with NGA and the nation’s governors in such a united effort.**

Prescriber Education: Promoting educational opportunities for physicians and other prescribers to increase their knowledge must focus on information relevant to the patient populations they serve.

The AMA strongly supports physicians and other prescribers relying on the most up-to-date education and training when it comes to pain management, prescribing opioid analgesics and other pain medications. A multitude of resources exist for physicians on these topics from state, specialty and other medical and health care organizations – including the federal government. For example, as part of the U.S. Food and Drug Administration’s (FDA) Risk Evaluation and Mitigation Strategy (REMS) for extended release and long-acting opioids, the FDA expects this voluntary program administered via accredited Continuing Medical Education (CME) providers to train 25 percent of the 320,000 prescribers of these drugs by the end of the first year following its implementation, 50 percent after two years and 60 percent within four years of the start of training. The AMA strongly supports the FDA’s efforts.

As for the AMA’s own efforts, over the past two years, the AMA has updated and progressively increased the education offerings available to physicians on best practices for managing pain while reducing the risk of prescription drug abuse. However, significant opportunities remain to educate practicing physicians on the scope of the crisis and provide them with appropriate educational opportunities to meet their needs. The AMA continues our communications and media efforts to increase awareness of these educational offerings to increase the awareness of “best practices,” new research and collaboration among professionals.

The initial launch of the AMA’s educational and awareness programs were undertaken at two AMA national meetings, our state meetings, our website, as well as widely accessible and consulted publications including *AMNews* and AMA journals.

¹ “Governor Bentley Signs Prescription Drug Abuse and Diversion Bills,” Press Release. August 5, 2013. Available at <http://governor.alabama.gov/newsroom/2013/08/governor-bentley-signs-prescription-drug-abuse-diversion-bills/>

Specifically, the AMA has offered a free online CME program since 2003 that underwent a revision this year and will be re-launched shortly. We have developed a new, 12-webinar series on topics related to responsible opioid prescribing as part of the collaborative for the Prescriber Clinical Support System for Opioid Therapies (PCSS-O).² This collaborative effort is led by the American Academy of Addiction Psychiatry and joined by the American Dental Association, American Osteopathic Academy of Addiction Medicine, American Psychiatric Association, American Society for Pain Management Nursing, the International Nurses Society on Addictions and the AMA. PCSS-O has many course offerings and other resources for physicians to choose from – depending on what fits best for their practice needs and patient population.

The AMA believes that improving physicians’ clinical decision-making and overall education on appropriate use of opioids and other pain-relieving modalities is best achieved by tailoring activities to physician practices rather than a one-size-fits-all mandate for physicians. We understand that many policymakers believe the only way to ensure appropriate prescribing behavior is to mandate physician training and education on a specific topic. The AMA believes that it would be more beneficial if programs were tailored to meet a physician’s practice and patient population needs. That simply cannot be done through legislative or other mandates, and we encourage NGA to highlight this nuance in the final document.

In addition, within the “Lessons Learned” document, NGA appears to appreciate the multiple ways that states have sought to increase education without resorting to a blunt mandate. That is why the AMA believes that positive incentives should exist for voluntary educational programs that help physicians understand current opioid drug labels, appropriate risk management and prescribing practices, as well as patient education and monitoring strategies to prevent abuse and diversion. **The AMA would strongly support legislation and grants that support development and deployment of voluntary CME that promotes appropriate prescribing for pain management and to combat diversion.**

Another area of potential policy and legislative activity could focus on waiving all or a portion of state licensing fees for prescribers who take relevant CME or have qualifying specialized training. This could extend to bonus payments under Medicaid or other targeted incentives. This ensures that underserved communities and vulnerable populations do not lose access to appropriate and medically necessary pain management. We believe that state medical societies would support these incentive-based voluntary efforts, and we urge NGA to include this recommendation in the final document.

Finally, the AMA believes that expertise for education and training lies with the appropriate licensing boards to work together to ensure that ample course offerings are readily available in each state, and that the boards work with the professional health care associations and other stakeholders to identify and promote the full range of CME offerings. In addition, the AMA notes that much of the legislative discussion in 2013 has focused on physician practices. The AMA recommends that this discussion be expanded to medical schools, nursing schools, physician assistant programs, dental programs and other appropriate schools to help prepare tomorrow’s health care professionals for combating this issue. This is another area NGA may wish to highlight in the final document.

Safe Disposal: Harmonizing and streamlining state and federal laws governing disposal of prescription drugs, including controlled substances, must include expanding awareness and access to local disposal sites.

² There are many online modules focused on increasing practitioners’ understanding of the current state of opioid-dependence treatment and improve clinical decision-making. Available at <http://www.pcass-o.org/online-modules>

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 proper disposal of unused prescription drugs that sit in their patients' medicine cabinets at home. Our children, teens and young adults, in particular, are able to access leftover medications in their home and this is an important source of initial exposure leading to diversion and substance misuse. But how do we dispose of all of the unwanted and unused prescription drugs in a safe and efficient manner?

Currently, we do not have a national infrastructure to safely and efficiently dispose of unused prescription drugs. This has not only contributed to the prescription drug diversion crisis, but raised very serious public health concerns as increasingly our drinking water has become contaminated with prescription drugs. In 2008, an investigation found that at least 46 million Americans were exposed to prescription drugs through their drinking water.³ 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 in your state, and the AMA encourages those discussions.**

As one potential solution, the AMA recently submitted formal comments in support of proposed rules from the Drug Enforcement Administration (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.⁴ In addition, the DEA Proposed Rules expand the category of entities authorized to offer these options and would 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 that do not have a registered pharmacy to participate in take-back events. NGA noted several of these options in the "Lessons Learned" document, and we believe that they deserve further consideration in the states.

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. To the extent that NGA can further those partnerships, the AMA strongly supports that effort.

Prescription Drug Monitoring Programs: Using modernized, interoperable Prescription Drug Monitoring Programs (PDMP), has the potential to be a powerful clinical tool.

The AMA agrees with NGA that PDMP have the potential to serve as a critical clinical tool in the fight against prescription drug abuse, misuse and diversion. Generally, however, physicians do not have access to reliable, real-time information about prescriptions patients have obtained (and filled) from other prescribers, particularly controlled substances. Thus, while we appreciate that NGA has identified several of the issues regarding PDMP use, the AMA believes that the emphasis on PDMPs should be to ensure that they are most *effectively* used to support clinical decision making rather than to focus on how much they are used.

³ Associated Press, Pharmaceuticals in water. Available at http://hosted.ap.org/specials/interactives/national/pharmawater_update/index.html. Last accessed May 16, 2013.

⁴ AMA letter to Administrator Michele M. Leonhart, Re: Disposal of Controlled Substances, RIN 1117-AB18, [Docket No. DEA-316], February 19, 2013.

In 2005, the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) was signed into law. Although \$52 million was authorized over a five-year period, it was not until 2009 that federal funds were appropriated to support the state adoption of PDMP. In theory, PDMPs were to provide reliable and actionable information.

In reality, however, it has been only in the past couple of years that most states have finally passed state legislation establishing PDMP, and the majority of PDMP are not real-time, interoperable or available at the point of care as part of a physician's workflow. Only five states provide data within 24 hours, according to the National Alliance for Model State Drug Laws (NAMSDL); one state provides data within three days, 32 states take up to a week to provide data and nine states take between two weeks and one month.⁵ With respect to interstate interoperability, NAMSDL reports that 43 states can legally share data across state lines, but only 20 can legally share data with other PDMPs. **NGA's continued support for interstate interoperability will help move this issue forward.**

Another area for NGA's attention is the need for PDMP to be adequately funded, maintained and modernized to ensure their long-term ability to help combat prescription drug abuse, misuse and diversion.⁶ The Congressional Research Service estimates that PDMP costs may vary widely, with start-up costs ranging from \$450,000 to over \$1.5 million and annual operating costs ranging from \$125,000 to nearly \$1 million.⁷ Despite AMA's advocacy, it appears improbable in the foreseeable future that Congress will appropriate sufficient funding even if NASPER is reauthorized to help states maintain and undertake much needed upgrades and modernization of PDMP. State leadership – as NGA notes – is sorely needed to ensure PDMP have the support they need. We urge NGA to highlight the need for appropriate funding, maintenance and modernization of PDMPs in the final document.

In the rare instances when PDMPs have been adequately maintained and funded, are available at the point-of-care with up-to-date information, and integrated into physician workflow, the efficacy of PDMPs is remarkable. As a pilot, Ohio place PDMP in emergency departments and found that 41 percent of prescribers given PDMP data altered their prescribing for patients receiving multiple simultaneous narcotic prescriptions. Of these providers, 63 percent prescribed no narcotics or fewer narcotics than originally planned.⁸ This indicates that PDMP data can help inform sound clinical decision-making to ensure prescriptions are medically-necessary, reducing illicit use of controlled substances.

Modernized PDMPs can provide physicians with a basic tool to make treatment determinations based on patient-specific needs. Governors and policymakers should use caution, however, that reducing drug use and preventing death cannot be fully achieved through well-meaning, but untested strategies such as requiring all prescribers to check an antiquated and poorly maintained PDMP for all patients as a condition of prescribing a controlled substance.

⁵ See, generally, National Alliance for Model State Drug Laws, www.namsdl.org

⁶ The funding piece deserves increased attention nationwide. A 2012 report from the Pew Charitable Trusts revealed that PDMP funding might come from grants, licensing revenue, licensing boards, general revenue, settlement funds, asset forfeiture and other areas.
http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/PDMP%20Update%201-31-2013.pdf

⁷ Report available at <http://www.fas.org/sgp/crs/misc/R42593.pdf>

⁸ Baehren, David F., M.D., et al. A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing Behaviors. *Annals of Emergency Medicine*, Vol. 56 No. 1, July 2010. Available at <http://download.journals.elsevierhealth.com/pdfs/journals/0196-0644/PIIS0196064409018125.pdf>

For example, while it makes sense for a pain medicine specialist to regularly consult a modernized PDMP that provides comprehensive, accurate data for his or her patients to review patient compliance and the potential for doctor shopping, it makes little sense for a pediatrician to consult a PDMP prior to giving a 10-year-old a sports physical. Similarly, it makes sense for a physician who is contemplating initiating treatment with opioids but believes the patient may be a risk for aberrant behavior or a physician who is treating patients with chronic pain with opioid analgesics, to consult the PDMP – if the PDMP data quality is high.

The key as to which physicians should be required to check a PDMP prior to prescribing a controlled substance is to carefully consider the type of practice and the patient population of the physician: e.g., the vast differences between providing care in an oncology practice, interventional radiology practice, emergency department – each raises different issues whose “solutions for prescription drug abuse and diversion” cannot be understood or achieved through a one-size-fits-all mandate to check the PDMP. In order for the NGA to help ensure PDMP can provide physicians with the type of clinical tool that will enhance clinical decision-making, the AMA strongly recommends the highest attention be paid to physician practice distinctions as well as data quality considerations that are outlined in this letter. The AMA recommends that NGA highlight these nuances in the final document.

In states that recently have enacted legislation requiring mandatory checks, there is impressive – but ultimately unsurprising data – showing that the supply of opioid analgesics has decreased.⁹ The AMA is glad that NGA also notes the rise in heroin as a growing problem. **Reductions in the supply of legal painkillers, however, may be a key factor in the unintended – yet tragic consequence of increases in illicit drug use – most commonly, heroin.**

Heroin is a less expensive yet more potent opiate.

According to the National Survey on Drug Use and Health, “[t]he number of persons who were past-year heroin users in 2011 (620,000) was higher than the number in 2007 (373,000).”¹⁰ This is why – as discussed in more detail below – the AMA strongly believes that as state leaders consider strategies to curb inappropriate use of prescription drugs, a simultaneous effort must be made to address the need for the prevention of illicit drug use and the treatment of those who are addicted. Just addressing the supply will not – by itself – solve the problem of demand and could drive an unintended increase in overdose and death. The AMA commends NGA for recognizing the need for that multipronged approach.

We raise two additional points regarding mandates on checking a PDMP in states where the PDMP is not real-time is unreliable, and is not available at the point of care or is not interoperable with other states and state agencies. First, consider that physicians welcome the opportunity to use best practices, regularly rely on evidence-based approaches to treatment and have been trained in how to analyze scientific information as part of their medical practice. This is why the AMA urges NGA to strongly support modernized PDMP so that physicians will be encouraged to adopt a reliable decision-making tool as part of their practice.

⁹ According to the Kentucky Office of Drug Control, “In the last six months since [mandatory PDMP checks] took effect, total doses of all controlled substances dropped 10.4 percent from the same time period a year earlier.” This included reductions in Hydrocodone and Oxycodone prescriptions by nearly 12 percent. Available at <http://odcp.ky.gov/> Last accessed May 16, 2013.

¹⁰ Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings. U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Available at <http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm#High>

Second, consider that physicians are only one piece of the puzzle to increasing PDMP use. That is why the AMA strongly supports NGA's call for discussions among all stakeholders – and all state agencies – to determine everyone in the health care chain, from prescriber to dispenser, who needs to be involved. With shared responsibility to provide information to the PDMP and to maintain and appropriately analyze that information, this duality provides the best environment for PDMPs to help combat prescription drug abuse and diversion – and prevent misuse, overdose and death.

Therefore, the AMA believes a more workable approach than mandates on prescribing practices or PDMP checks would involve governors working with appropriate medical, dental and other licensing boards to work with medical societies, the public health community and policy leaders to develop comprehensive recommendations to help guide prescribers and dispensers, rather than a one-size-fits-all approach. As noted by NGA, several policy academy states have taken this approach to positive effect, which the AMA believes is essential to curbing this epidemic.

Public Education: Enhancing public education efforts can provide key information throughout the community.

Another key area where the AMA agrees with NGA focuses on the need for comprehensive patient education and awareness efforts that highlight the risks of prescription drug abuse – and engages all stakeholders to help stop this epidemic. This can be achieved through, for example, targeted public service announcements, multimedia campaigns and other educational efforts in partnership with schools, business, health care organizations, government and medical societies that are tailored to each state. Some of the elements of this outreach might include:

- Facts that outline the nature and scope of the epidemic within each state;
- Health and other risks associated with illicit prescription drug use;
- The dangers of diversion, including practical tips on how prescription drugs can be safeguarded from children, visitors and others;
- Steps to take to dispose of unused prescription drugs, particularly pain medication; and most important
- Where to seek referrals or direct assistance for individual(s) seeking treatment programs and recovery.

While some of these issues would be covered as part of a physician's prescription for a medication, or a pharmacist's dispensing of the medication to a patient, this epidemic requires much broader, comprehensive community-based messages highlighting the appropriate role and use of prescription drugs, resources available for addiction treatment and prevention and where patients can safely dispose of unwanted and unused medications.

In addition, to help combat prescription drug abuse and diversion throughout each community in the nation, comprehensive public health education and awareness efforts also must reach family and friends so that they can learn how they can support efforts to stop this epidemic and help those suffering from addiction. Through its support for comprehensive public health education tools and resources to help all those affected by this crisis, including support for engagement with all stakeholders, NGA can play a major role in helping all states combat prescription drug abuse, diversion, overdose and death.

Expanding Treatment: Expanding capacity of treatment and recovery programs, as well as considering strategies such as drug courts, needs to be part of strategic planning to facilitate access to existing programs.

The AMA strongly supports the NGA’s call for an increased emphasis on treatment to break the cycle of addiction. Moreover, we urge NGA to continue to support data-driven, public health solutions to stemming prescription drug abuse, misuse and diversion. A public health focus emphasizes understanding the root causes of substance abuse disorders and the challenges inherent in developing effective treatment and recovery programs. A public health focus brings to bear the data necessary to develop targeted solutions and to make resources available in areas where they are needed most. Because we understand the tight fiscal restraints faced by many state legislatures, we believe that a public health focus would be the most efficient use of state resources to tackle this growing problem.

As part of the emphasis on treatment, to bring about real, meaningful change, we need a fundamental shift in how our nation discusses drug policy. This begins with the acknowledgement that our drug problem is a public health issue, not just a law enforcement issue. It means acknowledging that an ever-growing body of scientific research clearly demonstrates that addiction – the underlying cause of too much crime in this country – is a disease that can be prevented and treated successfully.”¹¹

Below, we discuss three specific strategies for NGA’s consideration and inclusion in the final document.

Naloxone saves lives.

We believe that additional national and state focus should be placed on strategies that go beyond combating diversion and misuse, and include policies that help physicians and other stakeholders to treat overdose and reduce deaths. **The AMA has endorsed state legislation to increase availability of naloxone in several states (including NGA policy academy states), which is a safe and effective FDA-approved medication that reverses opioid overdose.**¹² The AMA also has expressed its support to the FDA, Centers for Disease Control and Prevention (CDC) and the Secretary of the U.S. Department of Health and Human Services, and we welcome the opportunity to work with NGA and the nation’s governors to increase support for this proven, public health strategy.

Since the mid-1990s, community-based programs began offering naloxone and other opioid overdose prevention services to persons who use drugs, their families and friends, and service providers (e.g., health-care providers, homeless shelters, and substance abuse treatment programs). These services include education regarding overdose risk factors, recognition of signs of opioid overdose, appropriate responses to an overdose, and administration of naloxone.

A February 2012 report in the CDC’s Morbidity and Mortality Weekly Report summarized the findings from 48 such programs (representing 188 local sites). These programs reported training and distributing naloxone to 53,032 persons and receiving reports of 10,171 overdose reversals.¹³

¹¹ “Toward a Smarter Drug Policy” The Huffington Post, Posted: 02/14/2013 11:53 am, R. Gil Kerlikowske and Benjamin Todd Jealous. Available at http://www.huffingtonpost.com/r-gil-kerlikowske/toward-a-smarter-drug-pol_b_2687004.html

¹² See, for example, Colorado Senate Bill 13-014; New Jersey Assembly Bill 3095; and Oklahoma House Bill 1872.

¹³ Morbidity and Mortality Weekly Report (*MMWR*), Centers for Disease Control and Prevention, Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010, **February 17, 2012 / 61(06);101-105. Available at**

Increased emphasis is needed to remove barriers to addiction treatment and recovery programs.

While increased access to naloxone helps prevent death from overdose, we are deeply concerned by the barriers faced by physicians in finding and placing patients in addiction treatment and recovery programs. Emergency room physicians are on the frontlines of this dilemma because there is inadequate capacity to refer patients for detoxification and treatment and recovery programs. A profound need exists to address the workforce limitations and the lack of accessible and affordable treatment programs. If the ultimate goal is to stop addiction, overdose and death, a far greater effort is needed to focus on the treatment and recovery side of this crisis.

For example, the AMA strongly supports increased access to treatment for drug addiction and physician office-based treatment of opioid addiction. There are, however, federal barriers on the limits on the number of patients a physician may treat utilizing buprenorphine, a drug that can be used to facilitate recovery from opiate addiction. There is broad consensus in the medical community that buprenorphine is a major tool to fight addiction and does not have a high potential for misuse or fatal overdose. Lifting the cap would enable physicians to treat more patients with this highly-effective drug.

In addition, Suboxone®, a combination of buprenorphine (a potent synthetic compound that acts on the same opiate receptors as morphine and methadone) and naloxone (an inhibitor of the opiate receptor), is very safe when administered on an outpatient basis and is available for prescription by any licensed practitioner after completing training that focuses on the pathophysiology of opiate addiction, screening of patients, symptom identification and management and prescribing of the medication.

Suboxone® prescribers must pay a fee for completion of the course, registration with governmental entities and after a waiting period, the ability to prescribe Suboxone® to 30 patients for the first year. The prescriber may submit a waiver request to treat up to 100 patients after the first year.

There are two distinct advantages of Suboxone® treatment over methadone: (a) Suboxone® is safe for treating patients on an outpatient basis since the presence of the opiate inhibitor naloxone in the product makes Suboxone® extremely safe in the cases of overdose and diversion due to the co-presence of naloxone in the product; and (b) Suboxone® is extremely effective in the treatment of opiate addiction. The clear benefit of Suboxone® treatment is the fact that treatment can be offered as an outpatient, thereby reducing the stigma associated with participation in methadone clinic and being readily available to more patients.

The regulatory process for becoming a prescriber and the patient limits serve as barriers to increase capacity to treat opiate addiction and the availability of Suboxone® to opiate-addicted patients, particularly those patients in jurisdictions that have adopted a law enforcement approach (as opposed to a public safety approach) to combat prescription drug abuse. The advantages of reducing the regulatory burdens to prescribing Suboxone® would not only increase the availability of Suboxone® treatment for patients with opiate addiction, but would also increase clinical identification, awareness and acceptance of opiate addiction as a disease and reduce the stigma associated with opiate addiction.

There are several options to expand the current capacity to treat opiate addiction. First, Suboxone® training could be offered free-of-charge to prescribers with either renewal or initial application of a prescriber's DEA number. Second, the initial patient cap could be increased with a waiver option after

six months instead of one year. In addition, Medicare and Medicaid reimbursement rates for Suboxone® treatment and counseling could be increased as an incentive for prescribers to treat opiate-addicted patients. **To the extent that NGA and state legislators can review these barriers to effective treatment of patients addicted to opiates and determine whether there is an appropriate state role, the AMA stands ready to work with you.**

Administrative barriers interfere with physicians' clinical judgment.

Finally, one potential barrier to effective treatment and recovery that legislators could address is the requirement in many states for “fail first” and “step therapy” legislation that may inappropriately interfere with a physician’s preferred treatment for a patient. Specifically, if a third-party payer requires a drug to be ineffective before allowing the physician to use a preferred drug, this not only increases costs but reduces a physician’s ability, for example, to help treat a patient’s pain in the most effective manner possible with the least potential for abuse.

The ultimate takeaway is that physicians are best equipped to evaluate the medication needs of their patients. Third-party payers should not promote the adoption of policies that substitute physician clinical judgment with that of a plan’s without a process for engaging physicians and understanding a patient’s underlying medical needs.

Drug courts may offer additional state legislative strategies.

We continue to urge national and state policymakers to pursue a public health approach to combating addiction. To that end, the AMA supports the use of drug courts. **Specifically, the AMA encourages the establishment of drug courts at the state and local level as an alternative to incarceration and as a means of overcoming addiction for individuals with addictive disease convicted of nonviolent crimes.** We are pleased that NGA cited the efforts in New Mexico in this regard.

According to the National Association of Drug Court Professionals (NADCP), drug courts are an alternative to individuals with addictive disease, providing them with intensive treatment and regular drug testing. The NADCP has found that drug courts reduce crime, save money, help ensure compliance and restore families.¹⁴ The National Institute of Justice has similarly found that drug court participants had significantly fewer positive drug tests and reported better improvements in their family relationships.¹⁵

Individuals with an addictive disease require treatment, and when they are convicted of a nonviolent crime, drug courts can provide the medical attention, support, and accountability needed to help them conquer their addiction and turn their lives around.

Data Sharing: Increasing data sharing (including epidemiological) and evaluation is key to develop informed, targeted solutions based on local and regional needs.

There is no shortage of data showing the increasing numbers of Americans abusing prescription drugs and dying from unintentional overdose. And there are increasing data on the rise of neonatal abstinence

¹⁴ See, for example, <http://www.nadcp.org/learn/facts-and-figures>. According to the NADCP: “FACT: Nationwide, for every \$1.00 invested in Drug Court, taxpayers save as much as \$3.36 in avoided criminal justice costs alone. FACT: When considering other cost offsets such as savings from reduced victimization and healthcare service utilization, studies have shown benefits range up to \$27 for every \$1 invested. FACT: Drug Courts produce cost savings ranging from \$3,000 to \$13,000 per client. These cost savings reflect reduced prison costs, reduced revolving-door arrests and trials, and reduced victimization.”

¹⁵ See, for example, <http://www.nij.gov/nij/topics/courts/drug-courts/work.htm>

syndrome¹⁶ (NAS¹⁷). Despite these trends, no central or coordinated system exists for sharing the available data at the state or federal levels. During the course of national stakeholder meetings in 2012 and 2013 including the NGA, National Safety Council, National Conference of Insurance Legislators, National Conference of State Legislatures and others, the challenge of using all available data sources to combat prescription drug abuse and diversion was identified as representing perhaps the largest challenge facing legislators.

Currently, there are numerous entities that collect and store data on prescription drug use, misuse and diversion. At the state level, these include prescription drug monitoring programs, state Medicaid agencies, pharmacy benefit management systems, pharmacies, electronic health records, hospitals, private health insurers, law enforcement and more. At the federal level, data exist within Medicare and the Veterans Administration and data are collected and analyzed by the CDC, Substance Abuse and Mental Health Services Administration, the National Institute for Drug Abuse and more.

At a minimum, the AMA recommends that states identify all existing potential sources of data on prescription drug use, abuse and diversion within the state. This can occur either by interagency cooperation, administrative direction or through legislation directing the administrative branches to take specific action(s). Regardless of the process used, knowing what data are available would begin a conversation to determine the steps required as to how the data might be used, the privacy considerations that must be taken into account, and the technology and resources that would be required to make the data useful in terms of identifying prescription drug abuse, diversion, overdose and death. Taking these steps will require enormous commitment from all parties, but the AMA believes that solutions to the problems must begin with a clear understanding of the data.

For example, one clear need is to identify – in each state – the source of prescription drug abuse, misuse and diversion. Nationally, the Substance Abuse and Mental Health Services Administration survey data show that 54 percent of individuals admitting to nonmedical use of prescription pain relievers obtained them from friends or family. Of those drugs, 82 percent came from one physician.¹⁸ It is not possible to determine whether those medications were inappropriately prescribed based on the available data. It is clear, however, that the “medicine cabinet” plays a role in the nation’s prescription drug abuse and diversion epidemic. We need better prospective data to make informed decisions that will help guide effective policy interventions.

Once robust data are available, epidemiologists and other public health experts will be able to determine state-specific answers to questions, including: Who are the high prescribers? Are those prescribers prescribing appropriately – or are they in need of additional education? The data also would support enforcement actions to halt “pill mill” activities and rogue online pharmacies. In addition, the data would be able to support increased coordination with public health efforts to expand access to addiction

¹⁶ 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.

¹⁷ The AMA encourages NGA to consider adding NAS to the list of issues for states to address in future policy academy discussions.

¹⁸ See Figure 2.14, “Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2010-2011. Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings. U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Available at <http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm#High>

treatment and recovery in order to ensure that those suffering from addictions do not resort to illicit drug use, such as heroin.

Conclusion: Looking Ahead

There are many areas where additional legislation and policy development can play a powerful role in helping combat prescription drug abuse, misuse and diversion. And there are many other areas where governors and medical societies can play a powerful role in ensuring that all appropriate stakeholders work together. To effectively combat this epidemic, the AMA strongly encourages NGA to highlight the need to ensure access to appropriate pain management and support treatment for substance abuse and addiction in addition to legislative and other efforts to combat prescription drug abuse and diversion. We also strongly support efforts to ensure that all stakeholders are working together. We stand ready to work with NGA on both fronts.

If you have any questions, including state-specific efforts that have occurred this year, as well as efforts by state medical societies to combat this epidemic, please contact Daniel Blaney-Koen, Senior Legislative Attorney, Advocacy Resource Center at daniel.blaney-koen@ama-assn.org or 312-464-4954.

Sincerely,

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