

#### Steven C. Anderson, IOM, CAE President & Chief Executive Officer

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President Donald J. Trump The White House 1600 Pennsylvania Avenue N.W. Washington, DC 20500

Dear President Trump:

Given your commitment to declare a national emergency amid the opioid abuse epidemic, the National Association of Chain Drug Stores (NACDS) is writing to highlight new public policy positions that the Association has adopted after careful consideration over the past several months. These public policy positions reflect further steps that are important to continue to build the comprehensive and collaborative response that this complex epidemic requires. They also build on substantial efforts that pharmacies have taken to foster a zero-tolerance for abuse and a 100-percent commitment to patient care. We remain committed to working with you and members of your Administration to turn the tide on the opioid epidemic.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies. Chains operate 40,000 pharmacies, and NACDS' more than 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 178,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners.

As public health authorities have indicated, face-to-face interactions between pharmacists and patients have made pharmacists keenly aware of the extreme challenges and complexities associated with this epidemic. Based on this first-hand experience and our commitment to the patients and communities we serve, NACDS remains steadfast in our efforts to partner with law enforcement agencies, policymakers, and others to work on viable strategies to prevent prescription drug diversion and abuse, including prescription opioids. Chain pharmacies engage daily in activities with the goal of preventing drug diversion and abuse.

One encouraging statistic is the decrease in the number of opioid prescriptions dispensed annually over the past few years. The number of opioid prescriptions dispensed at retail pharmacies declined almost 15% from 2013-2016. Since chain pharmacies operate in almost every community in the U.S., we support policies and initiatives to combat the prescription drug abuse problem nationwide and believe that holistic approaches must be implemented to achieve this. To this end, we also support enhancing access to critical treatment programs for patients suffering from substance abuse disorders as well as

<sup>&</sup>lt;sup>1</sup> Source: Xponent, QuintilesIMS, Danbury, CT, 2017.

federal efforts to stop illegal drugs from entering the country. We are effectively contributing to efforts to address the opioid abuse problem.

# I. <u>Chain Pharmacy Is Pursing Key Policies to Help Curb Prescription</u> <u>Opioid Abuse</u>

### A. Limiting Initial Opioid Prescriptions for Treatment of Acute Pain

NACDS supports the enactment of legislation to establish a 7-day supply limit for initial opioid prescriptions issued for acute pain. This policy aligns with the Guideline for Prescribing Opioids for Chronic Pain developed by the Centers for Disease Control and Prevention (CDC), and serves to reduce the incidence of misuse, abuse, and overdose of these medications.

A clinical evidence review performed by the CDC revealed that a greater amount of initial opioid exposure is associated with greater risk for long-term use and addiction.<sup>2</sup> Notably, the average day supply per opioid prescription has increased in recent years, growing from 13.3 to 18.1 days per prescription between 2006 and 2016.<sup>3</sup> Considering this trend and the risk of initial exposure to higher amounts of opioids, it is imperative that lawmakers adopt policies to promote careful prescribing practices for prescription opioids.

So far, nearly twenty states have adopted laws or other policies limiting the maximum day supply that can be authorized on an initial opioid prescription for acute pain (with appropriate exemptions, such as patients with pain due to cancer care, hospice, or other end-of-life care, etc.) Chain pharmacy encourages lawmakers to enact legislation to standardize these dispensing limits across states which will promote consistent patient care and implementation.

## B. Pursue Policy Changes to Encourage Utilization of E-Prescribing

Chain pharmacy supports the adoption of laws and policies that promote the use of electronic prescribing to transmit prescription information between prescribers and pharmacists. For controlled substances in particular, use of this technology adds new dimensions of safety and security in the prescribing process. Prescribers can more easily track the controlled substance prescriptions that a patient has received. Additionally, electronic controlled substance prescriptions cannot be altered, cannot be copied, and are electronically trackable, whereas paper prescriptions are more vulnerable to forgery and alteration. Furthermore, the federal DEA rules for electronic controlled substance prescriptions establish strict security measures, such as two-factor authentication, that

<sup>&</sup>lt;sup>2</sup> https://www.cdc.gov/drugoverdose/prescribing/guideline.html

<sup>&</sup>lt;sup>3</sup> https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf

reduce any potential for fraudulent prescribing. Notably, the state of New York saw a 70% reduction in the rate of lost or stolen prescription forms after implementing its own mandatory e-prescribing law.<sup>4</sup>

NACDS has long served as a pioneer and advocate for e-prescribing and for the numerous advantages it presents for patients and for the healthcare delivery system. NACDS and the National Community Pharmacists Association partnered to help create the health information network that ultimately merged with RxHub and that now operates as Surescripts. The pharmacy community has supported federal and state policies over the years that have encouraged the widespread adoption of electronic prescribing technologies and practices, including DEA rulemaking and state law changes that finally allowed for the electronic transmission of controlled substance prescriptions. As of September 2015 when Vermont adopted policies to permit electronic prescribing of controlled substance prescriptions, this beneficial practice is legal nationwide.

In recent years, the adoption of electronic prescribing has increased dramatically. According to the most recent data available, 1.6 billion prescriptions were issued electronically in the United States last year, which equates to more than 4.3 million prescriptions per day. <sup>5</sup> While that number continues to grow, there is room to further improve the rate of electronic prescribing, particularly with controlled substance prescriptions, which lag behind overall adoption of this beneficial technology. Currently, only 14 percent of controlled substance prescriptions are issued electronically.

To enhance healthcare providers' utilization of this technology, chain pharmacy urges lawmakers to enact laws requiring that all prescriptions be issued electronically, with limited exceptions.

#### C. Nationwide Prescription Drug Monitoring Program

NACDS supports the important role of prescription drug monitoring programs (PDMPs) in helping to prevent drug abuse and diversion. Over the years, PDMPs have been established throughout the country as tools to curb diversion and abuse of controlled substance prescriptions. At this time, nearly every state has implemented their own program designed to assist in the identification and prevention of drug abuse and diversion at the prescriber, pharmacy, and patient levels. However, there are significant variances across state programs which, altogether, impede optimal use of PDMPs to their fullest extent.

<sup>&</sup>lt;sup>4</sup> Remarks of Anita Murray, Deputy Director, New York State Department of Health at the Harold Rogers Prescription Drug Monitoring Program National Meeting (September 6, 2017)

<sup>&</sup>lt;sup>5</sup> The Surescripts 2016 National Progress Report is available here: http://surescripts.com/newscenter/national-progress-report-2016/

NACDS is calling upon stakeholders to work together to develop and implement a nationwide PDMP solution to harmonize state requirements for reporting and accessing PDMP data. Our goal is to establish one system with unified expectations for appropriate use of PDMP data by prescribers, pharmacies, law enforcement, and others. Such a system should leverage electronic prescribing systems to provide timely, in-workflow analyses of real-time data with actionable point-of-care guidance for prescribers and dispensers. We urge the participation of federal policymakers, healthcare providers, and other stakeholders on this important initiative to create a national PDMP solution.

#### D. Take Back and Disposal of Consumer's Unused Controlled Substances

To stem the abuse of opioids and other controlled substances, pharmacies are committed to creating programs that provide patients with safe and effective ways to dispose of unwanted controlled substances that are workable in the communities they serve. To this end, NACDS supports policies that accommodate broad controlled substance drug disposal programs that allow pharmacies to facilitate at least one of a variety of DEA authorized options for drug disposal. These options include, but are not limited to: takeback kiosks in pharmacies, mail-back envelopes made available by manufacturers or pharmacies, community drug take-back events hosted at pharmacies, in-home disposal products, take-back kiosks at law enforcement locations, and vouchers to patients to obtain mail-back envelopes from manufacturers or pharmacies. Many pharmacies have implemented one or more of these types of take-back programs.

Recognizing that the entire drug supply chain has a role in drug disposal, we further support a program of manufacturer-funded mail-back envelopes for unused opioid drugs, wherein manufacturers make mail-back envelopes available to pharmacies to provide to patients upon request for opioid prescriptions. Combating prescription drug abuse requires collaboration. Chain pharmacy seeks collaborative efforts, including working with manufacturers to help customers safely and effectively dispose of their unwanted opioid drugs. We support state legislation to promote such programs.

To promote public awareness and use of the available disposal options, we encourage federal and state government and/or pharmaceutical manufacturer stewardship organizations to develop and provide drug disposal educational materials to consumers. Ideally, such materials should focus upon controlled substances, including the dangers of misuse and the potential for addiction to prescription controlled substances, treatment resources available, and the proper way to dispose of unused prescription controlled substances. These educational materials should be posted on government websites and be made available to pharmacies to provide to customers filling controlled substance prescriptions, with each pharmacy determining the best method for making those materials available to its patient population in a written and/or electronic format.

## II. Additional Ways that Chain Pharmacies Work to Fight Prescription Opioid Abuse and Diversion

#### A. Chain Pharmacy Initiatives

Chain pharmacies extensively train their personnel and have strict policies and procedures to prevent prescription drug diversion. Our members rigorously comply with state and federal laws and regulations. Pharmacies and pharmacy personnel are among the most highly regulated industries and professions in the nation.

Chain pharmacies have created a variety of extensive and robust loss prevention and internal security systems that are in place everywhere from our prescription drug distribution centers right down to the point of dispensing to the patient. We undertake initiatives to ensure that prescription drugs are accounted for every step along the way. We work closely with law enforcement to see that perpetrators are brought to justice.

Chain pharmacies have zero tolerance for prescription drug diversion. In addition to developing, implementing, and maintaining our own policies and procedures, we support numerous other initiatives to mitigate and reduce the scourge of prescription drug diversion. Chain pharmacies are committed to ensuring that prescription drugs remain under tight control for the purposes of providing care to their patients and are not diverted for nefarious purposes. Our members' efforts are evidence of this commitment.

#### B. DEA Regulations

According to DEA regulations, the responsibility for the proper prescribing and dispensing of controlled substances is on the prescribing practitioner, but a corresponding responsibility also rests with the pharmacist who fills the prescription.

DEA requires pharmacists to take on diverse and sometimes conflicting roles. On the one hand, pharmacists have a strong ethical duty to serve the medical needs of their patients in providing care. On the other hand, community pharmacists are also required to be evaluators of the legitimate medical use of controlled substances.

Pharmacies fully understand that controlled substances are subject to abuse by a minority of individuals who improperly obtain controlled substance prescriptions from physicians and other prescribers. Pharmacies strive to treat medical conditions and ease patients' pain while simultaneously guarding against the abuse of controlled substances. The key is to guard against abuse without impeding our primary goal of assisting patients who need pharmacy services.

#### C. Law Enforcement Initiatives

NACDS and our member pharmacies support the mission and activities of numerous federal and state agencies and law enforcement bodies. NACDS interacts routinely with other state and federal officials to devise strategies to protect Americans from the dangers of prescription drug diversion and abuse. NACDS and our members vigorously support the mission of DEA. We seek to work with DEA on a routine basis. NACDS and our members frequently dialogue with DEA officials about efforts to stem prescription drug diversion, both at DEA headquarters and throughout the nation at numerous DEA field offices. We support the work of the National Association of State Controlled Substance Authorities (NASCSA) as their members develop, implement, and maintain PDMPs. We support the mission and objectives of the National Association of Boards of Pharmacy (NABP) regarding opioids, and have worked with them on a number of initiatives over the years, the most recent being the development of a consensus document to alert prescribers and pharmacists about potential "red flags" in the prescribing and dispensing of controlled substances.

#### D. Promoting Access to Naloxone

Improving community access to naloxone is a critical public health measure to curbing opioid deaths. Pharmacists and pharmacies are primed to work with other healthcare providers to increase access to naloxone for overdose prevention purposes. Pharmacists are recognized medication experts who are well-situated in local communities to improve access to naloxone. In fact, research has shown that nearly all Americans (91%) live within five miles of a community retail pharmacy, making community pharmacists the most readily accessible healthcare provider for many individuals.

In recent years, chain pharmacy has worked with policymakers and other stakeholders to update state laws to allow pharmacists to provide naloxone without patient-specific prescriptions. Modernizing state laws in this manner eliminates administrative barriers to pharmacist-provided naloxone, and ultimately improves access to this overdose prevention tool. A number of states provide improved pharmacy access, but more efforts are needed.

#### E. Target Illegitimate Drug Sellers

NACDS believes that an important strategy to stop drug diversion and abuse is addressing the problem of illegitimate internet drug sellers. These illicit online drug sellers have websites that target U.S. consumers with ads to sell drugs often without any prescription required. They operate in clear violation of U.S. state and federal laws and regulations that protect public health and safety. They sell drugs to consumers without the

safety precautions of a legitimate prescriber-patient relationship, a legitimate pharmacist-patient relationship, a valid prescription, or a licensed U.S. pharmacy. NACDS, through its position on the Board of the Alliance for Safe Online Pharmacies (ASOP Global), has worked closely with policymakers to offer solutions to combat these illegitimate websites, which threaten patient health and safety. We support enhancing efforts to enforce existing laws and regulations against these bad actors.

Moreover, we support targeting illegal internet drug sellers by having entities such as domain name registrars that issue websites, financial entities that handle payment transactions, internet service providers that show the illegitimate websites on the internet, and common carriers that provide the mailing services stop illicit transactions at their point of interaction with these bad actors.

NACDS also supports efforts to stop the flow of synthetic opioids coming into the United States. Synthetic fentanyl and other synthetic opioids are now the leading cause of overdose deaths nationwide. In 2016 alone, 20,000 people died due to synthetic opioids according to provisional CDC information. With synthetic opioid deaths on the rise, NACDS supports the efforts of the federal government to enact legislation and garner resources to stop illegal synthetic opioids from entering the United States.

## F. Shutting Down Rogue Pain Clinics

According to DEA, practitioners in rogue pain clinics are responsible for the prescribing and dispensing of millions of dosage units of oxycodone, a schedule II narcotic. NACDS supports the efforts of states that have enacted legislation to shut down these rogue clinics, such as restricting a physician's ability to dispense oxycodone from a pain clinic.

## III. Education Strategies Needed to Reduce Opioid Misuse and Abuse

Most opioid pain medications are not prescribed by pain specialists, but by primary care physicians, internists, dentists, and orthopedic surgeons. Surveys of these prescribers reveal significant gaps in education and training on pain management and safe prescribing. For these reasons, NACDS supports prescriber education initiatives at the federal and state level on appropriate pain treatment practices, as well as prevention, identification, and treatment of opioid addiction. We support the ongoing work at FDA to develop further prescriber education tools through its Risk Evaluation and Mitigation Strategies (REMS) for opioids.

NACDS also supports education efforts targeted at the general public on safe and appropriate use of controlled substances. While there are some educational tools for patients taking controlled substance prescriptions, patient education could be enhanced

through the development of a streamlined patient education tool that combines the information that patients currently receive in various formats into one document that clearly and concisely conveys key information about the medication. Such a document would ensure that patients are not oversaturated with information from confusing, lengthy documents, which may contribute to patient oversight of critical information and ultimately lead to misuse and abuse of medications. To facilitate this goal, we encourage FDA to move forward with developing and adopting a standardized single patient medication information document (i.e., the "one document solution") to help ensure that patients who are prescribed controlled substances better understand appropriate use of these medications.

NACDS has developed web-based training programs to help pharmacists and other pharmacy personnel learn how to combat diversion and abuse of controlled substances. NACDS is also continuing to collaborate with partners to develop educational programs and provide learning opportunities on opioid abuse issues for the pharmacy community. We have worked with entities including the American Public Health Association and DEA to foster awareness and encourage participation in learning sessions that are tailored to the education needs of the pharmacy community. In fact, DEA has expressed appreciation for NACDS' proactive outreach to the chain pharmacy industry to cultivate awareness of the sessions that DEA hosts for pharmacists that cover prescription drug abuse issues.

## IV. Promote Access to Treatment for Individuals with Substance Abuse Disorders

In addition to the strategies outlined above for preventing the misuse and abuse of opioids, it is imperative that policymakers concurrently work to remove barriers to treatment for individuals with substance use disorders (SUD). Without access to treatment, the cycle of abuse will only continue for the many individuals struggling with addiction. To this end, NACDS is supportive of requiring health insurance companies and other payors to provide coverage for SUD Treatment Programs for opioids, heroin, cocaine, and other drugs that are abused. Moreover, we are supportive of funding for robust community opioid abuse/treatment and prevention programs that serve neighborhoods on the front lines of this national epidemic.

#### V. Conclusion

NACDS commends you for the important work that you are pursuing to address the opioid abuse problems plaguing the country. We look forward to supporting your work in this area through the various policies and activities that we have outlined above.

Sincere

Steven 🗘 Anderson, IOM, CAE

President and Chief Executive Officer

National Association of Chain Drug Stores

cc: The Honorable Eric D. Hargan, Acting Secretary and Deputy Secretary of Health and Human Services

The Honorable Seema Verma, Administrator, Centers for Medicare and Medicaid Services

The Honorable Scott Gottlieb, M.D., Commissioner, Food and Drug Administration The Honorable Robert W. Patterson, Acting Administrator, Drug Enforcement Administration

The Honorable Richard Baum, Acting Director, Office of National Drug Control Policy

The Honorable Chris Christie, Chair, President's Commission on Combatting Drug Addiction and the Opioid Crisis

Members of the United States Senate

Members of the United States House of Representatives