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President & Chief Executive Officer

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The Honorable Chris Christie  
Chair  
President's Commission on Combating Drug Addiction and the Opioid Crisis  
White House Office of National Drug Control Policy  
750 17th Street, N.W.  
Washington, DC 20006

Dear Governor Christie:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to provide input to the President's Commission on Combating Drug Addiction and the Opioid Crisis ("Commission") as the Commission studies the scope and effectiveness of the federal response to drug addiction and the opioid crisis and develops recommendations to the President for improving that response.

NACDS represents traditional drug stores and 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 and over 60 international members representing 21 countries. Please visit [nacds.org](http://nacds.org).

The ongoing opioid abuse problem concerns both legal and illicit substances; that is, prescription opioids as well as heroin and illegal fentanyl analogs. NACDS and the chain pharmacy industry are committed to partnering with law enforcement agencies, policymakers, and others to work on viable strategies to prevent prescription drug diversion and abuse, including prescription opioids. 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.<sup>1</sup> Chain pharmacies engage daily in activities with the goal of preventing drug diversion and abuse. 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. We believe that holistic approaches must be implemented at the federal level. We are pleased that we are helping to solve the opioid abuse problem.

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<sup>1</sup> Source: *Xponent*, QuintilesIMS, Danbury, CT, 2017.

Pharmacists take their role in helping to ensure safe use of medications very seriously—but they cannot do it alone. We support a collaborative approach to curb prescription drug abuse and preserve patient access to their medically-necessary pain medications. We believe that there are a variety of ways to help curb prescription drug diversion, and chain pharmacies actively work on many initiatives to reduce this problem.

## **I. Introduction**

### **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 neighborhood 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 and efforts 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 prescription drug monitoring programs (PDMP). We support the mission and objectives of the National Association of Boards of Pharmacy (NABP), 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.

## **II. Opportunities to Enhance Existing Strategies to Curb Opioid Abuse**

### **A. Patient and Provider Education**

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. NACDS also supports education efforts targeted at the general public.

*Prescriber Education:* NACDS supports efforts to enhance education and training for prescribers prior to issuing a prescription for certain classes of controlled substances. This includes support for prescriber education initiatives at both the federal and state level aimed at appropriate pain treatment and preventing, identifying, and treating opioid addiction, among other issues. Already, FDA has implemented prescriber education tools under the REMS programs for extended release and long-acting opioid products and for transmucosal immediate-release fentanyl (TIRF) products. We have encouraged collaboration among FDA, the

Institute of Medicine (IOM), and other agencies and stakeholders to identify further opportunities and develop prescriber education tools for other controlled substances. Additionally, we have encouraged collaboration among ONDCP and state boards of medicine to ensure enhanced training for prescribers on the legitimate use of controlled substances.

*Patient Education:* Prevention is essential to addressing prescription drug abuse. To this end, patient education on safe and appropriate use of controlled substances is an important prevention strategy. While there are some educational tools for patients taking controlled substances prescriptions (for example, the patient education component of the extended release and long acting opioid REMS), patient education could be enhanced through streamlining and improving the written information that patients receive with their prescriptions. Currently, patients receive numerous written materials with their prescriptions, including medication guides, patient package inserts, and other consumer medication information. Patients would benefit from receiving this information in one streamlined document, designed and written in a manner that recognizes patients' information needs, which clearly and concisely conveys critical information about the prescription. Such a document would ensure that patients are not oversaturated with information from confusing, lengthy documents that may contribute to patient oversight of critical information and ultimately lead to misuse and abuse of medications. Notably, FDA previously held public hearings to gather information to assist the agency with the development and adoption of a standardized single patient medication information document (i.e., the "one document solution"). We have encouraged FDA to expedite implementation of the one-document solution, as doing so could help to ensure that patients who are prescribed controlled substances better understand appropriate use of these medications.

#### **B. Controlled Substance Prescription Drug Monitoring Programs**

NACDS and chain pharmacies support controlled substance prescription drug monitoring programs (PDMP) to help combat prescription drug diversion. Currently, 49 states have implemented a PDMP. Recognizing the role these programs have in helping to prevent drug abuse and diversion, chain pharmacies actively support them. Pharmacies submit information on the controlled substances they dispense monthly, weekly, and daily, depending on the particular state's program requirements. This includes details on the patient, prescribed drug dosage and quantity, and the prescriber. The information is available to healthcare providers to access as appropriate when making treatment decisions. The data may also be used by states to conduct confidential reviews to determine any patterns of potential abuse or diversion.

Unfortunately, there is great variability among state PDMPs. Among the 49 states and the District of Columbia that have these programs, there exist no nationwide standards for the data that these programs collect, maintain, or provide; nor are

there any nationwide standards for who may access the data among health care providers such as prescribers and pharmacists, health plans and Medicaid, or law enforcement officials; and there is no nationwide interconnectivity among the programs, which hinders regional surveillance of patients at risk and potential criminals. NACDS supports initiatives to establish a robust, national database with timely, reliable information and a standard set of requirements.

These monitoring programs offer many benefits to aid in curbing prescription drug diversion and abuse at the prescriber, pharmacy, and patient levels. These programs encourage appropriate intervention to determine if a person may have a drug addiction so that treatment may be facilitated.

### **C. Role of Electronic Prescribing**

NACDS supports efforts to accelerate the deployment of electronic prescribing of controlled substances, including working with federal and state regulators and stakeholders to mandate prescribers to issue all controlled substance prescriptions electronically.

Since electronic prescribing offers new dimensions of safety and security for controlled substance prescriptions, NACDS is supporting draft federal legislation that would require prescriptions for controlled substances in the Medicare Part D program to be issued electronically. In addition, NACDS recently developed model state legislative language to pursue mandatory electronic prescribing for all prescriptions. NACDS has developed a three-part strategy to achieve the goal of mandatory electronic prescribing nationwide: (1) work with stakeholder groups at the national level to foster support for e-prescribing. This would include other pharmacy associations and prescriber associations; (2) develop a strategy for engaging stakeholders at the individual state level; and (3) develop model legislation for use in the states.

We urge that the Administration finalize the DEA interim final rule (IFR) that allows for the electronic prescribing of controlled substances. The current limitations in the IFR serve as barriers to more widespread adoption of electronic prescribing technologies. Finally, we urge CMS to move to the latest version of the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard so that prescribers and pharmacies may take full advantage of current electronic prescribing technologies.

### **D. Limiting Initial Fills of Controlled Substance Prescriptions**

Several states have enacted laws or rules to establish limits on the maximum day supply that prescribers can authorize on initial prescriptions for certain controlled substances. A growing number of states are considering legislation that would enact similar limits.

Notably, there is variation across states with respect to the scope of these policies, especially concerning the pending legislative proposals. Although most of the prescription limits apply to opioids, a few states' policies apply limits to all controlled substance prescriptions. Additionally, some state policies differ with respect to the duration of the initial prescription. Furthermore, while many states exempt prescriptions written for the treatment of certain medical conditions, not all states make such considerations.

NACDS advocates for standardized policies that ease implementation challenges so that patient care is not adversely impacted. We believe that the Commission could serve as a forum to assist states with implementing standardized policies.

#### **E. Promoting Access to Naloxone**

Pharmacists and pharmacies are primed to work in conjunction 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. As such, there are a number of ways to leverage the accessibility of pharmacists to improve access to naloxone.

A number of states have employed various approaches to make it easier for pharmacists to provide naloxone to patients such as laws that establish authority for pharmacists to "furnish" naloxone without a prescription; allowing pharmacists to exercise prescriptive authority and dispense naloxone in accordance with a written statewide protocol; and employing the use of standing orders and/or collaborative practice agreements between prescribing practitioners and pharmacists. Chain pharmacy supports state laws and policies such as these that eliminate administrative barriers to pharmacist-provided naloxone by authorizing pharmacists to provide naloxone without patient-specific prescriptions.

Additionally, we support liability protections for all healthcare providers, including pharmacists, who prescribe and dispense naloxone in good faith. Such protections can help to eliminate the fears of healthcare providers who may otherwise be wary of providing naloxone because of liability concerns. Alleviating these concerns ultimately serves to improve access to naloxone for overdose prevention purposes. Chain pharmacy supports adoption of laws and policies that serve this purpose.

Finally, we support laws that establish Good Samaritan liability protections for healthcare providers and others who furnish naloxone in emergency situations. This will ensure that any healthcare provider or other individual who administers naloxone in an emergency is not held liable for aiding an individual in distress.

We encourage the Commission to work with stakeholders to improve access to naloxone, and to support federal legislation that provides the liability protections outlined above.

**F. Take-back and Disposal of Consumers' Unused Medications**

NACDS supports the safe and effective disposal of unwanted consumer medications, including controlled substances, to stem the abuse of such drugs and to better protect the environment. Most people who abuse prescription opioids get them for free from a friend or relative,<sup>2</sup> so it is important for consumers to be able to safely dispose unused medications. However, those who are at highest risk of overdose (using prescription opioids nonmedically 200 or more days a year) get them in ways that are different from those who use them less frequently.<sup>3</sup> These people get opioids using their own prescriptions (27 percent), from friends or relatives for free (26 percent), buying from friends or relatives (23 percent), or buying from a drug dealer (15 percent).<sup>4</sup> Those at highest risk of overdose are about four times more likely than the average user to buy the drugs from a dealer or other stranger.<sup>5</sup>

We believe that policymakers who have decided to tackle the drug disposal issue should ensure that pharmacies are able to create programs that best serve the needs of their patients, as well as workable solutions for their store locations. Overall, patients should have a wide variety of options for how they can dispose of their unused medications. With more options, we can expect to have higher patient participation in prescription drug disposal programs.

When policymakers consider proposals for drug disposal, we ask that they consider retail pharmacies' support for broad 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: take-back kiosks in pharmacies, mail-back envelopes made available for sale or for free by pharmacies, community drug take-back events hosted at pharmacies, in-home disposal products, funding of take-back kiosks at law enforcement locations, and vouchers to patients to obtain mail-back envelopes from pharmacies.

Retail pharmacies support consumer education programs on drug disposal developed and funded by the government and/or pharmaceutical manufacturers. When policymakers consider drug disposal programs, we support the efforts of the federal government, state governments, and/or pharmaceutical manufacturer stewardship organizations to develop and provide drug disposal educational materials for consumers. Ideally, such materials would focus on the dangers of

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<sup>2</sup> <https://www.cdc.gov/drugoverdose/data/prescribing.html>; accessed June 2017.

<sup>3</sup> Ibid.

<sup>4</sup> Ibid.

<sup>5</sup> Ibid.

misuse and the potential for addiction to prescription controlled substances, treatment resources available, and the proper way to dispose of unused prescription controlled substances. We believe that these educational materials should be posted on government websites and be made available to pharmacies, with each pharmacy determining the best method for making those materials available to its patient population in a written and/or electronic format. Finally, any legislative package adopting the policy proposals outlined above should also include a preemption provision.

NACDS encourages the Commission to work with DEA to promote continued periodic take-back events hosted by DEA. We also encourage the Commission to pursue patient education programs as outlined above.

#### **G. Collaborative Legislative Solutions**

NACDS and our members are focusing our energies on real, workable solutions that will address the problem of prescription drug abuse while also ensuring that legitimate patients are able to receive their prescription pain medications. In line with this goal, we supported the recently enacted "Ensuring Patient Access and Effective Drug Enforcement Act" (P.L. 114-145). This legislation requires HHS to submit a report to Congress that identifies obstacles to legitimate patient access to controlled substances and outlines how collaboration among federal and state agencies and industry can benefit patients and prevent diversion and abuse of controlled substances. The Act requires that HHS develop this report acting through the FDA Commissioner, SAMHSA Administrator, AHRQ Director, and CDC Director, in coordination with the DEA Administrator, and in consultation with the Secretary of Defense and the Secretary of Veterans Affairs. The report must be submitted to Congress no later than one year after the date of enactment. HHS has not met the one-year deadline for submitting this report to Congress.

This legislation also facilitates open dialogue on issues related to prescription drug diversion and abuse by directing key federal agencies to consult with patient groups; pharmacies; drug manufacturers; common or contract carriers and warehousemen; hospitals, physicians, and other healthcare providers; state attorneys general; federal, state, local, and tribal law enforcement agencies; health insurance providers and entities that provide pharmacy benefit management services on behalf of a health insurance provider; and wholesale drug distributors.

We look forward to working with the Trump Administration to continue to implement this legislation to develop multi-stakeholder approaches to address prescription drug diversion and abuse.



### **III. Additional Matters for Consideration**

#### **A. Target Illegitimate Internet 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 valid prescription, or a licensed U.S. pharmacy.

We support targeting illegal internet drug sellers by enabling 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, to stop illicit transactions at their point of interaction with these bad actors. NACDS serves on the Board of Directors of the Alliance for Safe Online Pharmacies (ASOP) to support their work to shut down illegal internet drug sellers.

#### **B. Shutting Down Rogue Pain Clinics**

As the number of domestic-based rogue internet pharmacies has declined, there has been an increase in the number of rogue pain clinics. According to DEA, the practitioners in these clinics are responsible for the 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 the restriction of physicians' ability to dispense oxycodone from pain clinics.

### **IV. Conclusion**

NACDS thanks you for the opportunity to comment as you work through these critical issues. We look forward to continued collaboration with the Trump Administration in the coming years.

Sincerely,



Steven C. Anderson, IOM, CAE  
President and Chief Executive Officer