United States Senate Committee on the Judiciary

"Tackling the Opioid Crisis: A Whole-of-Government Approach"

Written Testimony of:

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Chairman Graham, Ranking Member Feinstein, and Members of the Committee:

Thank you for conducting this hearing that aims to address stakeholder viewpoints on current actions and future solutions to combat the opioid crisis. My name is Ronna Hauser, and I am the Vice President of Policy and Government Affairs Operations at the National Community Pharmacists Association (NCPA). NCPA represents America's community pharmacists, including nearly 22,000 independent community pharmacies. Our members provide a crucial part of the public's access to healthcare. Almost half of all community pharmacies provide long-term care healthcare services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care settings.[1] Community pharmacies employ more than 200,000 individuals and provide pharmacy services to millions of patients every day. NCPA's members are small business owners who are among America's most accessible healthcare providers. We appreciate being asked to testify today at this hearing from the community pharmacist perspective. NCPA is committed to working collaboratively with Members of Congress, the Administration, and other stakeholders in furthering

[1] *2019 NCPA Digest* (2019).

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viable solutions to prevent drug abuse and diversion.

Independent community pharmacies play a critical role in ensuring patients have immediate access to medications.[2] Our members have extensive knowledge and experience in caring for patients with chronic pain as well as those in their communities with substance use disorders.

NCPA members participate in numerous initiatives to appropriately dispense and dispose of controlled substances and to identify possible overutilization. Examples include:

- Evaluating prescriptions to attempt to detect forgeries or alterations.
- Adopting electronic prescribing, which has helped eliminate forgery efforts.
- Taking part in Dispose My Meds™, which has more than 2,100 participating sites across the country.
- Utilizing Allied Against Opioid Abuse's Pharmacist Toolkit, which aids pharmacists in conversations with patients and caregivers regarding opioid prescriptions.
- Advocating for greater pharmacist access to naloxone, which has resulted in increased access across the country, and in turn, saved lives.

These initiatives are having a positive impact. For example, prescriptions for opioids are down 28 percent between 2012 and 2017. Deaths from prescription opioids and drugs of abuse also declined 5

[2] *Opioid Epidemic: Community Pharmacists' Recommendations*, NCPA, *available at* http://www.ncpa.co/pdf/hhs-opioid-roundtable-pharm-recommendations.pdf.

percent in 2018, despite increases in deaths from illicit opioids such as heroin, fentanyl analogs, and cocaine.[3]

NCPA supports continued dialogue between supply chain partners and with agency partners to provide clarity on the purchasing, dispensing, and disposing of controlled substances

NCPA members work collaboratively with supply chain partners including manufacturers, wholesalers, technology vendors and others to tackle the opioid crisis. Allied Against Opioid Abuse (AAOA), which launched in early 2018, is a coalition of partners from the healthcare supply chain and public health communities and serves as a national education and awareness initiative. The aim of this collaboration is to see that patients and their families can access crucial information and educational resources about the rights, risks, and responsibilities related to prescription opioids. As part of its work, AAOA collaborated with its pharmacy partners, including NCPA and individual state pharmacy associations, to develop a suite of resources specific to the pharmacy community[4] to help pharmacists engage with and educate patients and prescribers about safe use, storage, and disposal of prescription opioids.

The AAOA Pharmacy Toolkit assets include a Pharmacy Display; Patient Handout; Patient Engagement Guide; Tips for Talking with Patients and Caregivers; Provider Engagement Guide; and a Safe Storage and Disposal Training Deck, among other items.[5] The toolkit's Prescriber Engagement

[3] R. Matt Gladden et al., *Changes in Opioid-Involved Overdose Deaths by Opioid Type and Presence of Benzodiazepines, Cocaine, and Methamphetamine — 25 States, July–December 2017 to January–June 2018,* Centers for Disease Control and Prevention (Aug. 30, 2019), *available at* https://www.cdc.gov/mmwr/volumes/68/wr/mm6834a2.htm
[4] Pharmacy Toolkit, Allied Against Opioid Abuse, *available at* https://againstopioidabuse.org/pharmacytoolkit/.
[5] *Id*.

Guide[6] can help guide conversations between pharmacists and other providers, containing tips for how and when to engage with prescribers to prevent misuse and abuse while working to ensure patient access to effective pain management. For example, an NCPA member in Planada, California has found the toolkit helpful in facilitating these sometimes-difficult conversations.[7] She passes out the Rights, Risks, and Responsibilities resource as part of her routine in counseling every patient with a new opioid prescription and making them comfortable before leaving the pharmacy, saying, "The resource helps me stay on track and cover all the points I need to review in a short amount of time." As many pharmacists also do, she monitors trends and alerts prescribers when rates of opioid prescriptions are higher than their peers, and she also uses the Prescriber Engagement Guide to facilitate further education about alternative therapies and set up the pharmacist as an ally in treating patients.

NCPA also supports enhancing integration and data-sharing, an effort that community pharmacists have long supported as it will allow pharmacists to accurately and efficiently identify at-risk patients. NCPA recommends increased interoperability of robust electronic databases, such as prescription drug monitoring programs (PDMPs), to track all prescriptions for controlled substances to identify improper prescribing and dispensing behavior as well as individuals at high risk of overutilization. Interoperability with certified EHR technology (CEHRT) applications will improve prescriber access to a patient's prescription opioid history at the point of prescribing.

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[6] Prescriber Engagement Guide, Allied Against Opioid Abuse, *available at* https://againstopioidabuse.org/resource/prescriber-engagement-guide/.

[7] Pharmacists in Action: Educating Patients About Prescription Opioids, Allied Against Opioid Abuse, *available at* https://againstopioidabuse.org/pharmacists-in-action-educating-patients-about-prescription-opioids/.

NCPA continues to work with agency partners, including the DEA, to facilitate open dialogue about the challenges facing pharmacies when purchasing, dispensing, and disposing of controlled substances. However, NCPA highlights that the DEA can still provide clarity to pharmacies handling controlled substances by updating documents that are intended to assist pharmacies in navigating the DEA's expectations. For example, NCPA and several pharmacy stakeholders have requested that the DEA release an updated version of the DEA's Pharmacist's Manual, which has not been updated since 2010.[8] Updating the Pharmacist's Manual is important because there have been several changes to the law since 2010 regarding the purchasing, dispensing, and disposing of pharmaceutical product.

Notably, Congress passed the Drug Supply Chain Security Act (DSCSA), which preempted state and federal laws regarding when a pharmacy could sell to another pharmacy without being registered as a wholesale distributor. NCPA members have noted that the "Five Percent Rule" in the DEA's Pharmacist's Manual conflicts with provisions in the DSCSA regarding when a pharmacy should be registered as a wholesale distributor. The conflicting language has created confusion among pharmacies and inconsistent application across several states. At the very least, NCPA requests the DEA update and release the Pharmacist's Manual to address this inconsistency for pharmacies.

NCPA stresses the importance of healthcare provider education

NCPA is active in educating our members regarding opioid use, abuse, and dispensing. We have an online series of opioid education for pharmacists and are actively publishing resources on our

[8] DEA, Pharmacist's Manual, *available at* https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf.

website to offer even more beneficial materials to aid pharmacists in understanding various issues surrounding the crisis.[9] For example, we offer resources on background, the pharmacist's role, prevention, naloxone, treatment, as well as legislative updates to ensure our members are up to date on the practical and policy implications of this nationwide crisis. This area of our website offers links to various HHS tools and includes webinars we have hosted on opioid issues. In addition, NCPA supports increased education of all prescribers in relation to pain management. The pharmacist's role is to work collaboratively with prescribers and provide continuity of education and monitoring.

NCPA supports advancing the role of the pharmacist in Medication-Assisted Treatment

Advancing the pharmacist's role in Medication-Assisted Treatment (MAT) for opioid use disorder (OUD) can help improve access and outcomes while reducing the risk of relapse. In fact, pharmacists are already partnering with physicians to provide MAT. Currently, 48 states and the District of Columbia allow pharmacists to enter into collaborative practice agreements with physicians and other prescribers to provide advanced care to patients, including MAT. When such relationships form, pharmacists have taken the lead in developing treatment plans, communicating with patients, improving adherence, monitoring patients, identifying treatment options and performing tasks to alleviate the physician's burden.

Pharmacies providing MAT are even aiding city governments by partnering with local rehabilitation centers, physicians, and drug courts. For example, Alps Specialty Pharmacy in Missouri provides several services for patients receiving MAT including the following: (1) streamlining access to

[9] *Walking Through Opioid Management*, NCPA, *available at* https://www.ncpanet.org/innovation-center/opioid-resources

Vivitrol, a long-acting injectable therapy, through insurance and financial support resources; (2) adherence support (timely refill/appointment reminders to ensure the injection is given on time); and (3) monthly Clinical Pharmacist Assessments to evaluate efficacy, safety, and adherence. A pharmacist at Alps manages 20-50 patients a month at any given time and offers these services to streamline patient access to treatment as well as help coordinate patient management.

Although this program has shown to be successful for patients in Missouri, some insurance companies mandate that Vivitrol be reimbursed under a "medical benefit," which limits pharmacists to assisting with billing/filling and forces prescriber offices to "buy and bill." Further, some insurance companies mandate that Vivitrol be filled through a specific mail-order pharmacy. This requirement prevents pharmacies from assisting with patient management. NCPA suggests that plans be required to include opioid antagonist medications, such as Vivitrol, under a medical or pharmacy benefit.

Pharmacists have both the knowledge and experience to provide MAT; however, treatment is limited due to current regulatory barriers as stated above. Patients should be able to choose to seek these services from their community pharmacists. In addition, pharmacists are unable to obtain a Drug Addiction Treatment Act (DATA) waiver. To this end, NCPA supports expanding practitioner eligibility for DATA waivers to include pharmacists. We encourage the Committee to consider ways in which community pharmacists can be utilized in expanding these MAT services.

NCPA asks Congress to consider recognizing pharmacists as providers for OUD services

Negative reimbursement pressure from insurers and pharmacy benefit managers (PBMs) and the inability of pharmacists to enroll in Medicare Part B as providers limits the positive impact

pharmacists can provide to help combat the opioid crisis. Pharmacists are key players in counseling treatment for OUD and provide many opioid abuse services, such as management and counseling treatment. In fact, efforts through the Patient Access to Pharmacists' Care Coalition (PAPCC) have focused on pharmacists having a greater role in the healthcare system as providers, particularly for substance use treatment. This includes allowing pharmacists to furnish these treatment services under Medicare Part B. These services would include opioid antagonist counseling and interventions to reduce the risk of overdose and death.

Due to independent pharmacists' expertise in medication management and frequent interaction with their patients, they are equipped to educate patients about their use of controlled substances. Further, they can alert patients to possible health consequences and motivate and support them as they take steps to change their behavior. Patients currently choose to seek medication-related services from their community pharmacist for many reasons, as they have established relationships with their community pharmacists. Allowing the patient to seek these services from their pharmacist increases medication adherence. Therefore, we ask that Congress work with CMS to formally recognize pharmacists as providers to furnish these opioid abuse reduction services under Medicare Part B and establish pharmacist-specific codes as necessary to augment existing codes under the physician fee schedule.[10]

NCPA supports qualifying OUD for CCM services

Congress and HHS should consider including OUD as a qualifying chronic condition under

[10] 42 U.S.C. 1395w-4.

chronic care management (CCM). CCM services are performed by a physician or a non-physician practitioner and their clinical staff every calendar month for Medicare beneficiaries who have multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; and place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.[11] These services range from creating a comprehensive care plan based on a physical, mental, psychosocial, and functional assessment of the patient to managing a patient's care transition between various healthcare providers and settings.

According to the CDC, in order to confirm a diagnosis of OUD, the patient is observed within a 12-month period for associated symptoms and can experience a risk of overdose and death when suffering from the disorder.[12] Further, the American Psychiatric Association (APA) considers OUD a "chronic lifelong disorder, with serious potential consequences including disability, relapses, and death."[13] Under the CCM process, a pharmacist can provide the CCM service under the supervision of a qualified health practitioner, such as a physician, physician's assistant, or nurse practitioner.

NCPA supports broader coverage of SBIRT

NCPA urges Congress to promote the expansion of pharmacies' ability to identify individuals with substance use disorders. Specifically, health plans participating in federal programs should

[11] *Chronic Care Management Services*, MLN Booklet, Centers for Medicare & Medicaid Services (July 2019), *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf.

[12] *Module 5: Assessing and Addressing Opioid Use Disorder (OUD)*, Centers for Disease Control and Prevention, *available at* https://www.cdc.gov/drugoverdose/training/oud/accessible/index.html.

[13] *Opioid Use Disorder*, American Psychiatric Association, *available at* https://www.psychiatry.org/patients-families/addiction/opioid-use-disorder/opioid-use-disorder.

reimburse pharmacists for Screening, Brief Intervention and Referral to Treatment (SBIRT) activities. For example, Virginia Medicaid's Addiction Recovery Treatment Services (ARTS) is a transformative benefit being offered for Medicaid patients. The benefit includes coverage for SBIRT provided by pharmacies. The purpose of SBIRT is to identify individuals who may have alcohol and/or other substance use problems. Following screening, a brief intervention is provided to educate individuals about their use, alert them to possible consequences and, if needed, begin to motivate them to take steps to change their behavior. However, the Virginia Medicaid SBIRT program is not being utilized to its potential due to billing barriers that are preventing pharmacists from being able to offer these services at their pharmacies. Even though pharmacists in Virginia can deliver SBIRT and bill for it under Medicaid, pharmacies are blocked from billing because there is not a current pathway to enroll pharmacists as providers in the Medicaid system. Health plans should allow pharmacist participation in SBIRT activities if the state allows coverage for such services provided to Medicaid patients, as in Virginia.

NCPA recommends expanding access to naloxone

In addition, NCPA supports increased access to harm reduction through a variety of avenues, including the expansion of access to naloxone by allowing dispensing under a standing physician's order (prewritten medical order) and developing nonprescription naloxone. NCPA advocates for pharmacists to participate in wider distribution of naloxone under pathways approved by state regulatory boards. Currently, 48 states and the District of Columbia allow pharmacists to dispense naloxone without a physician's prescription. However, costs associated with these programs act as a

deterrent for pharmacies' larger participation in the pathways. For example, device training and overdose response counseling that pharmacists provide when dispensing naloxone are not covered. Further, in some states, pharmacists must enter into collaborative practice agreements to provide naloxone, while some states require patient screening and counseling even though such services are not always eligible for reimbursement. NCPA believes pharmacists should be able to directly prescribe naloxone to their patients, the least restrictive means to increasing access to naloxone.

Congress should explore the role of community health workers in managing patients with SUDs

Community health workers (CHW) are recognized public health professionals in almost all 50 states. They serve as liaisons between health and community services. Many pharmacy team members already adhere to various CHW practices and principles, including the role they play in conducting home visits and identifying social determinants of health to evaluate patients for SUDs. NCPA members are part of CPESN USA®, a national network of clinically integrated pharmacies which coordinates patient care with physicians, care managers, and other patient care teams to provide medication optimization activities and enhanced services for high-risk patients. NCPA member pharmacies in these networks work directly with payers to add enhanced services into contracts and lower costs of care.[14] Two CPESN USA pharmacies in Missouri were featured in an article in the Standard Democrat through their use of CHWs.[15] NCPA believes Congress should increase opportunities to utilize the relationship between pharmacists and CHWs to further identify

[14] CPESN, *available at* https://www.cpesn.com.
[15] *Local Pharmacies are Including Community Health Workers in Staff*, The Standard Democrat (May 17, 2019), a*vailable at* https://standard-democrat.com/story/2609607.html.

and treat patients with SUDs.

NCPA suggests additional, workable disposal options to prevent diversion

NCPA believes there is an increased opportunity for collaboration between the DEA and community pharmacists with any expansion of DEA Take-Back Days. NCPA suggests that Congress explore workable disposal options to help address the availability of unused opioids that end up being misused. Congress should work with other federal agencies to further this effort, such as the DEA and the FDA. In fact, the White House Office of National Drug Control Policy (ONDCP) released its *National Drug Control Strategy* earlier this year and included a recommendation to expand the DEA's twice-yearly drug Take-Back Day by allowing more registered collectors and disposal sites to support prevention efforts.[16]

NCPA operates a prescription disposal program, Dispose My Meds™, a program where, at cost to the pharmacy, community pharmacists can help their patients safely dispose of unused and expired medications. NCPA believes there is an increased opportunity for collaboration between Congress, federal healthcare agencies such as DEA and ONDCP, and community pharmacists to expand workable disposal options to better address opioid abuse, misuse, and diversion.

NCPA members assisting with implementation of CARA

On July 22, 2016, former President Obama signed into law the Comprehensive Addiction and Recovery Act (CARA), a multi-faceted effort to address the opioid epidemic afflicting the United

[16] ONDCP, *National Drug Control Strategy* (Jan. 2019), *available at* https://www.whitehouse.gov/wp-content/uploads/2019/01/NDCS-Final.pdf.

States. CARA gives Prescription Drug Plan (PDP) sponsors the authority to establish a drug management program for at-risk beneficiaries ("lock-in" program). For frequently abused drugs, the sponsor may limit an at-risk beneficiary's coverage to one or more prescribers and one or more pharmacies. NCPA supports the Act's requirement that pharmacists work with CMS to construct the new Medicare Part D lock-in program and applauds Congress for exempting long-term care patients from these lock-in provisions.

Further, NCPA appreciates CARA's requirement that the Attorney General, in coordination with the DEA Administrator, the HHS Secretary, and the ONDCP Director, must coordinate with covered entities, including but not limited to retail pharmacies, hospital pharmacies, long-term care facilities, manufacturers, and distributors to expand or make available disposal sites for unwanted prescription medications. As stated above, NCPA operates a prescription drug disposal program to further this effort in increasing the prevalence of disposal sites for unused medications.

Pharmacists are successfully implementing provisions from the SUPPORT Act

On October 24, 2018, President Trump signed into law H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act that contained several changes to law to combat the opioid crisis. First, the Act requires e-prescribing for controlled substances in Medicare Part D starting January 1, 2021. NCPA members are prepared for this requirement, and have observed that the rate of e-prescribing for controlled substances has risen drastically in the last several years. According to Surescripts, 31 percent of all controlled substances prescribed were sent electronically in 2018, compared to 21 percent in 2017

and 11 percent in 2016.[17] In addition, 57 percent of prescribers and 94 percent of pharmacies were utilizing e-prescribing in 2014, rising to 73 percent of prescribers and 99 percent of pharmacies in 2018.[18] NCPA supported an exemption for this requirement for long-term care patients, which is essential in protecting long-term care patients' access to medically necessary pain medications. NCPA also supported the inclusion of language in the SUPPORT Act that would ensure PBMs cannot use e-prescribing to steer patients to specific pharmacies.

The Act further requires HHS and DEA to put out guidelines on when pharmacists can refuse to fill opioids, an essential provision to allow pharmacists discretion when they are faced with situations in which dispensing an opioid may not be appropriate. In addition, beginning no later than January 1, 2021, the Medicare program must provide for electronic prior authorization requests from prescribing healthcare professionals to Part D plan sponsors or Medicare Advantage plans for covered Part D drugs and a response to the healthcare professional. This requirement will lead to more efficient prescribing and dispensing by enabling the exchange of data within practitioners' workflow to support better patient care.

NCPA supports the SUPPORT Act's requirement that starting in January 2021, at-risk beneficiaries for drug abuse in the Part D program shall be included in the list of targeted beneficiaries eligible for medication therapy management (MTM) services, which will further improve treatment plans for those beneficiaries. Lastly, the Act creates enhanced Automation of Reports and

[17] *National Progress Report*, Surescripts (2018), *available at* https://surescripts.com/news-center/national-progress-report-2018/
[18] *Id*.

Consolidated Order System (ARCOS) transparency by providing drug manufacturers and distributors with anonymized information through ARCOS to help identify, report, and stop suspicious orders of opioids and reduce diversion rates, which NCPA supports.

NCPA supports supply chain reports to the ARCOS database

According to the DEA, ARCOS, is "an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level – hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions."

As Congress and the DEA continue to strengthen usage of ARCOS data, NCPA is supportive of measures that would require supply chain entities, including pharmacies, to report the sale of controlled substances to such database, subject to important exclusions that ensure patient access to needed medications. For example, pharmacy-to-pharmacy sales should be excluded from ARCOS reporting if such sale were for a "specific patient need" as defined under the DSCSA. Under the "specific patient need" exclusion, pharmacies may sell to another pharmacy without passing DSCSA-compliant tracing data to the purchasing pharmacy. The "specific patient need" exclusion was created to ensure that pharmacy-to-pharmacy transactions for a specific patient are facilitated in a manner that ensures patients have timely access to their medications. NCPA supports the extension of this exclusion to ARCOS reporting of controlled substances.

Conclusion

NCPA urges the Committee to consider expanding and utilizing the pharmacist's role when

determining new policies to help combat the opioid crisis. NCPA is committed to continue assisting the Committee and other industry stakeholders in developing such viable solutions.