

November 5, 2019

Melisa Byrd
Medicaid Director
District of Columbia Department of Health Care Finance
One Judiciary Square 441 4th Street, N.W.
Washington, DC 20001

Re: **SUPPORT Act Section 1003 Demonstration Project to Increase Substance Use
Provider Capacity**

Dear Ms. Byrd:

On behalf our members, the National Association of Chain Drug Stores (NACDS) is writing to provide information to assist with efforts to increase provider capacity for substance use disorder treatment and recovery programs in the Medicaid population and to highlight to the state the value of pharmacist-provided substance use disorder treatment services that serve this purpose and help in the fight against the opioid epidemic.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 157,000 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 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

I. Introduction

NACDS' member companies serve Americans' healthcare needs 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 goal. NACDS members support the efforts of the District of Columbia Department of Health Care Finance (DHCF) to increase provider capacity to provide substance use disorder (SUD) treatment and recovery services to Medicaid beneficiaries.

With the number of individuals suffering from SUD steadily increasing, there is a growing need for additional provider capacity to administer SUD treatment and recovery services to patients. According to the 2018 National Survey on Drug Use and Health conducted by the Substance Abuse and Mental Health Services Administration, 20.3 million individuals aged 12 years and older in the United States struggled with a SUD in the past year¹. More specifically, not only is there an increasing need for providers that are knowledgeable, skilled, and capable of providing SUD and medication assisted treatment (MAT) but also for those that are skilled and trained to

¹ https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHffrBriefingSlides2018_w-final-cover.pdf

identify and provide early-detection and whole-person treatment services. NACDS and its members are committed to serving the healthcare needs of patients who legitimately require prescription opioids and other controlled substance medications to manage their health conditions while also working to aggressively combat the misuse, abuse, and diversion of controlled substances. Every day, pharmacists face a moment of truth when presented with an opioid prescription, making decisions as a provider of patient care and as part of the solution to the opioid-abuse epidemic. As the state works with CMS to increase provider capacity to provide SUD and MAT services and programs in the Medicaid program, we encourage the state to leverage pharmacists in providing these important services given the value yielded by pharmacists among the providers of these services.

II. Community Pharmacists Should be Utilized in Assisting Physicians with Opioid Treatment Programs that Provide MAT for Patients Diagnosed with SUD

As DHCF continues its demonstration planning efforts to assess treatment needs and recruit and train providers to offer treatment or recovery services for SUD, it is important to keep in mind the value of pharmacists and the services they provide in SUD and MAT programs. Allowing community pharmacists to be more involved in direct patient care serves to increase provider capacity while also eliminating gaps and barriers in treatment and increasing access to naloxone and other MAT drugs. Pharmacists also offer a critical role in implementing strategies to help reduce population SUD risk. For example, pharmacists can contribute to helping states reduce SUD population prevalence by using Screening, Brief Intervention, and Referral to Treatment (SBIRT), which has been developed, tested, and implemented in numerous healthcare settings to help identify persons who are misusing alcohol and other drugs. SBIRT is an evidence-based practice used to identify, reduce, and prevent problematic use, abuse, and dependence on alcohol and other substances of abuse and includes a referral to treatment for those in need.

Currently, pharmacy based SBIRT services are being rolled out in Pennsylvania, Virginia, and Ohio. In Virginia, pharmacist provided SBIRT services are reimbursed by Virginia Medicaid. While the expansion of pharmacist provided SBIRT under Medicaid in Virginia is a positive step, further expansion in other states would improve access to SUD care. When state and federal legislative barriers are removed, pharmacists can offer an even greater role in care of patients with SUD. Through a universal screening process, pharmacists could identify those at risk of SUD and provide brief counseling and motivational interviewing, as well as linkage to care.

In addition to these vital services, pharmacists are also trained and equipped to help in the battle against opioid abuse. Examples of ways pharmacists could help include:

- Providing essential screenings and immunizations related to Hepatitis B, Hepatitis C, HIV, Tuberculosis (TB), and depression to improve the population health of communities. For example, one community pharmacy partnered with a state health department to provide HIV screening in their pharmacies; the state health department gains access points to their at-risk population through the reach of pharmacies and in-turn reimburses the pharmacies per screening provided. Data from this partnership shows that pharmacy can provide these services at a lower cost than the health

department, and patients find the pharmacies to be less stigmatizing locations than other places to receive screenings and these services.

- Increased use of pharmacogenomic testing to determine the right pain medication and dosing. By performing pharmacogenetic testing, personalized medicine allows patients to be prescribed with the right drug to be administered for adequate pain control – to avoid experiencing dose-dependent side effects or lack of drug efficacy. Pain medication may alleviate pain for one patient while proving no relief for another. Pharmacogenetic testing can help alleviate this problem.

In fact, there are some notable pilot programs that are actively leveraging retail pharmacies and pharmacists to improve access to SUD treatment medications. A Rhode Island MAT program is funded by a \$1.6 million NIDA grant. The Rhode Island Hospital is conducting a pilot program² involving six pharmacies working with 125 patients to manage their MAT. In the pilot, patients receive their initial MAT prescription from a physician at CODAC, a large addiction-treatment program with seven locations in Rhode Island. After the physician determines a patient is stable on their medication, a pharmacist working under a collaborative practice agreement takes over the patient's care.

Visiting the pharmacy once or twice a week, patients meet in a private room with their pharmacist. The pharmacist places a swab under the patient's tongue for several minutes, which will be sent to a lab for analysis, which reveals whether that patient has taken the full dose of their prescribed medication or used any illicit substances. With that information, pharmacists counsel patients about recovery goals, struggles, and successes. They also employ motivational interviewing, a counseling technique that helps patients overcome ambivalence and make behavioral changes.

Most patients enrolled in the pilot are expected to take buprenorphine, but patients also have the option of Vivitrol, a once-a-month injection of naltrexone which blocks the effects of opioids. (Methadone is not available as it can only be obtained at federally regulated clinics.) In certain states, pharmacist scope of practice limitations prevents the administration of Vivitrol, a long-acting injectable.

Currently, Rhode Island is the only state to adopt a pharmacy-based addiction treatment project of this scope. However, there are other similar/notable pilot programs in Kentucky and Maryland. The Kentucky project allows pharmacists to manage patients with SUD on Vivitrol³ and the Maryland program offers buprenorphine through a single pharmacy connected to the Health Department.⁴

In addition to the piloting distribution of SUD treatment medications that are seen in Rhode Island, Kentucky, and Maryland, retail pharmacies and pharmacists play a critical role in helping to prevent drug abuse and diversion as seen in other programs. Both Virginia and

² <https://www.bostonglobe.com/metro/2019/03/12/getting-addiction-care-pharmacy/m1mcceVILRXX1W9X3WdeOP/story.html>

³ [https://www.pharmacytoday.org/article/S1042-0991\(17\)31120-9/fulltext](https://www.pharmacytoday.org/article/S1042-0991(17)31120-9/fulltext)

⁴ <https://www.bostonglobe.com/metro/2019/03/12/getting-addiction-care-pharmacy/m1mcceVILRXX1W9X3WdeOP/story.html>

Colorado have adopted programs that are intended to enhance SUD treatment options for patients at the pharmacy level.

Other programs are utilizing community pharmacies and pharmacists to play a critical role in providing treatment services to patients with SUDs. Recently, Colorado and Texas have pursued program changes that enhance SUD treatment options for patients at the pharmacy level. In Colorado, legislation was enacted in 2018 that permits pharmacists acting under a collaborative practice agreement to administer injectable MAT for SUDs and receive an enhanced dispensing fee for the administration under the Colorado medical assistance program.⁵ Similarly in Texas, the state submitted a State Plan Amendment in recent months that will expand the pharmacy benefit to reimburse pharmacists for administering Vivitrol to beneficiaries covered under Medicaid fee-for-service and Medicaid managed care.⁶ We strongly urge DHCF to utilize pharmacists to provide these types of services to Medicaid beneficiaries.

III. Ensuring Patient Access and Effective Drug Enforcement

As DHCF seeks approval of a demonstration project under Section 1003 of the SUPPORT Act, it is important to recognize the need for concurrent initiatives that will decrease the number of opioid prescriptions that go unused. NACDS would like to share policy initiatives that chain pharmacies have adopted to help curb prescription opioid abuse and misuse that also serve this purpose. 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 are needed to achieve this goal. Although the rate of fatal drug overdose has decreased by 5% for the first time since 1990, significant work still remains.⁷ Accordingly, NACDS continues to support key policies that serve an important role in curbing the abuse, misuse, and diversion of prescription opioids and other controlled substance medications while maintaining patient access to needed medications. We believe that sharing these policies with DHCF will provide insight into the pharmacy community's commitment to being part of the solution in the opioid epidemic and demonstrate the willingness of community pharmacies to treat individuals with SUD.

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 is informed by 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 drugs.

A clinical evidence review performed by the CDC revealed that a greater amount of early opioid exposure is associated with a greater risk for long-term use and addiction.⁸ Notably, the average

⁵ <https://leg.colorado.gov/bills/hb18-1007>

⁶ <https://www.sos.state.tx.us/texreg/archive/May242019/In%20Addition/In%20Addition.html#99>

⁷ <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

⁸ Centers for Disease Control and Prevention; *CDC Guideline for Prescribing Opioids for Chronic Pain*; CDC.gov; <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>

day supply per opioid prescription has increased in recent years, growing from 13.3 to 18.3 days per prescription between 2006 and 2017.⁹ Moreover, various studies have found that the majority of patients who were prescribed opioids did not use their full prescription and had large quantities of unused opioids,^{10,11,12} which unfortunately creates opportunities for diversion, misuse, and abuse of these unused medications. Considering these trends, the risk of early exposure to higher amounts of opioids, and the high rate of patients not needing the full quantity of opioids initially prescribed, it is imperative that policies be implemented to promote careful prescribing practices for prescription opioids.

More than 30 states have adopted laws or other policies limiting the maximum day supply that can be authorized on an initial opioid prescription for acute pain. Chain pharmacy encourages the enactment of legislation that is standardized across state lines to promote consistent patient care and implementation. We encourage lawmakers in the District of Columbia to implement a similar policy by enacting laws to curb overprescribing. NACDS also is pleased to support the *John S. McCain Opioid Addiction Prevention Act* (H.R. 1614/S. 247), introduced in the Senate by Senators Kirsten Gillibrand (D-NY) and Cory Gardner (R-CO) and in the House by Representatives John Katko (R-NY) and Rep. Thomas Suozzi (D-NY). This important legislation would establish a 7-day supply limit for initial opioid prescriptions written for acute pain, while preserving access to needed medications for patients with non-acute pain who require prescription opioids—those with chronic pain or pain associated with cancer care, hospice or other end-of-life care, or palliative (disease-related) care—and for patients receiving an opioid prescription that is used for the treatment of addiction.

B. Pursue Policy Changes to Encourage Utilization of Electronic Prescribing

Chain pharmacy strongly supports policies that promote the use of electronic prescribing (e-prescribing) to transmit prescription information between prescribers and pharmacists. Use of this technology substantially improves safety and security in the prescribing process. For controlled substances in particular, e-prescribing adds new dimensions of safety and security. Electronic controlled substance prescriptions cannot be altered, cannot be copied, and are electronically trackable. Furthermore, the federal Drug Enforcement Administration (DEA) rules for electronic controlled substances prescriptions establish strict security measures, such as two-factor authentication, which reduces the likelihood of fraudulent prescribing. Notably, the

⁹ Centers for Disease Control and Prevention; *2018 Annual Surveillance Report of Drug-Related Risks and Outcomes*; United States, 2018; <https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf>

¹⁰ One study that surveyed U.S. adults who had received opioids found that approximately 60 percent of patients who were no longer using the medication had unused opioids. A. Kennedy-Hendricks et al.; "Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults"; *JAMA Internal Medicine*; vol. 176, no. 7 (2016): p. 1027-1029.

¹¹ Two studies reported that over one-half of patients did not use all of the opioids prescribed to them after surgery; these studies found that patients reported leaving 15 to 20 pills unused, representing 54 percent to 72 percent of the opioids they were prescribed. M. V. Hill et al.; "Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures," *Annals of Surgery*; vol. 265, no. 4 (2017): p. 709-714 and B. C. Maughan et al.; "Unused Opioid Analgesics and Drug Disposal Following Outpatient Dental Surgery: A Randomized Control Trial"; *Drug and Alcohol Dependence*; vol. 168 (2016): p. 328-334.

¹² One study on patient opioid use after a cesarean section and thoracic surgery found that most patients, 83 percent and 71 percent respectively, used less than half of the total opioids they were prescribed. K. Bartels et al.; "Opioid Use and Storage Patterns by Patients after Hospital Discharge following Surgery," *PLOS ONE*; vol. 11, no. 1 (2016).

state of New York saw a 70% reduction in the rate of lost or stolen prescription forms after implementing its state mandatory e-prescribing law.¹³

Although there continues to be significant growth in the adoption and utilization of e-prescribing, considerable opportunity remains for additional uptake in the adoption of e-prescribing of controlled substances. According to the most recent data available, 1.91 billion prescriptions were issued electronically in the United States in 2018, of which 115 million were for controlled substances.¹⁴ While 85% of *all prescriptions* were issued electronically, only 31% of *controlled substance prescriptions* were issued electronically.¹⁵

To enhance healthcare providers' utilization of this technology, chain pharmacy urges the adoption of laws and policies requiring electronic prescriptions given the numerous benefits that e-prescribing technologies have for patients, providers, and for the healthcare system. NACDS supported historic action in 2018 when the President signed the bipartisan *Every Prescription Conveyed Securely Act* into law, requiring controlled substances prescriptions covered under Medicare Part D to be electronically transmitted starting in 2021.¹⁶ So far, 25 states have mandated the use of e-prescribing practices.¹⁷ Because of all the tangible benefits of e-prescribing, we urge policymakers in the District of Columbia to adopt laws and policies requiring electronic prescriptions where practical, and to extend e-prescribing mandates to all controlled substance prescriptions – not just those covered by Medicare.

C. Beneficial Enhancements to State Prescription Drug Monitoring Programs

Over the years, states have established PDMPs as a tool to provide critical information to prescribers and dispensers. PDMPs provide healthcare providers with useful information about patients'-controlled substance prescription histories that can alert clinicians to individuals who may be diverting controlled substance prescriptions or who are at risk of a substance use disorder and require intervention.

While PDMPs exist across the country, there are significant differences among the different state programs that have resulted in disparate data and access requirements. These challenges are compounded by the lack of interconnectivity and complete data sets among many PDMPs, impeding their optimal use. To better address this, NACDS supports the creation of a nationwide PDMP database, which is especially important to enhance existing health IT solutions in the marketplace, designed to ensure safe and effective opioid use, and improve patient care.

¹³ 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)

¹⁴ The Surescripts 2018 National Progress Report is available here: <https://surescripts.com/news-center/national-progress-report-2018/>

¹⁵ Ibid.

¹⁶ The *Support for Patients and Communities Act* (H.R. 6) was enacted to include the *Every Prescription Conveyed Securely Act*, legislation requiring Schedule II through V controlled substances prescriptions covered under Medicare Part D to be electronically transmitted starting in 2021.

¹⁷ Laws Requiring the E-Prescribing of Opioids Have Gained Momentum, but Prescriber Adoption is Playing Catch Up, Jan. 2, 2019. Available here: <https://surescripts.com/news-center/intelligence-in-action/opioids/laws-requiring-the-e-prescribing-of-opioids-have-gained-momentum-but-prescriber-adoption-is-playing-catch-up/>

Experts have pointed toward eight best practices for increasing provider utilization of PDMPs.^{18,19} Evidence suggests that physicians do not use PDMPs consistently, or at all, due to a lack of data timeliness to show real-time prescribing data in their workflow and lack of health IT integration with electronic health records (EHRs). NACDS supports ongoing health IT initiatives that equip providers with real-time data within EHRs. Improvement of health IT integration to combat the opioid crisis also requires use of electronic controlled substance prescriptions.

The variability in PDMP use, design, state information technology infrastructure (including interoperability between PDMP and electronic health record platforms and interoperability between PDMPs across state lines,) and data accessibility must be addressed to optimize PDMP use and promote consistent patient care. Given the present functionality and interoperability challenges, NACDS is calling on stakeholders to work together to develop and implement a nationwide PDMP database to harmonize and maximize state PDMPs. Such a system should be built in tandem with efforts that require e-prescribing for controlled substances to provide timely, in-workflow analyses of real time data with actionable point of care guidance for prescribers and dispensers. Working in tandem with e-prescribing technology would help ensure that prescribers receive immediate, in-workflow information at the point-of-prescribing, thus eliminating the need to access another system or database. Moreover, this would help ensure that any federal or state opioid prescribing limits are followed.

A nationwide PDMP database could pull information from several data sources, including clinical data extracted from insurers, PBMs, and state PDMPs. Under this concept, eligible health IT entities would access the national database to enhance current commercial health IT solutions, which are designed to curb prescription drug abuse. Such a concept would effectively resolve system challenges while fostering competition and avoiding anti-competitive industry tactics, including regulatory arbitrage. Providing access to a national database will also create a fair and level playing field in the health IT section and provide the means to make a meaningful difference at the point of patient care.

Additionally, controlled substances prescribing information could be included within EHRs. NACDS would support a nationwide database operationalized through existing technology enhanced through competition and innovations, provided that the database includes the following principles:

- The most effective use of PDMP data is in ensuring appropriateness of controlled substance use when the prescriber is issuing a prescription for a patient. To that end, prescribers should have real-time, actionable data at the point of care to better inform their prescribing decisions. We recommend that a national database be utilized by pharmacies as a secondary safeguard, in addition to the prescriber's review. In exercise of their professional judgment, pharmacists can take necessary actions to investigate and attempt to resolve any concerns identified as a result of a query, as part of the process of determining whether to fill controlled substance prescriptions.
- Data is accessible to prescribers, dispensers, and supporting staff (e.g. automatic and free registration into PDMPs).

¹⁸ Pew Charitable Trusts, Dec. 2016.

¹⁹ Duke Margolis Center for Health Policy, Feb. 15, 2018.

- Compile data exclusively on controlled substances; stay focused on main mission.
- Sufficiently protect proprietary data rights of participating stakeholders.
- Establish a national database, adhering to the principles of competition and deregulation with respect to accessing said data to create or enhance commercial health IT solutions aimed at curbing prescription drug abuse.

NACDS strongly supports the development of a nationwide PDMP database. We propose that the database be housed within the Office of the National Coordinator for Health Information Technology (ONC) at HHS. It could be built upon existing state PDMP data and/or pull data from other sources – we are open to the most reasonable approach that harmonizes existing gaps and inconsistencies. We support building and accessing this national database in a manner that fosters competition and innovation in the Health IT solution space; and thus, does not rely on single marketplace solution. We look forward to working with key stakeholders to discuss the development and implementation of a nationwide PDMP database.

Concurrent with this initiative, in the near term, NACDS supports more immediate PDMP program changes to foster the goal of a nationwide database that would require prescriber utilization and ensure appropriate access for authorized users. These include establishing a daily reporting requirement across all programs so that the information in the database is timely, standardizing the data that is reported so that there is consistent information across different states' PDMP databases, enabling interstate access to PDMP information across state lines, and standardizing different state PDMP use requirements for prescribers to optimize prescribing practices. Altogether, these changes will serve to improve the timeliness and quality of data and encourage broader PDMP use by healthcare providers.

D. Providing Workable Disposal Options to Safely and Appropriately Discard of Unused Opioid Prescriptions.

To reduce opportunities for the diversion, misuse and abuse of opioid prescriptions that ultimately go unused, patients need options to responsibly dispose of any unused medications in their possession. NACDS supports state and federal policies to provide consumers with workable disposal options to safely and appropriately discard unused opioid prescriptions. We support DEA's drug take back days and work with the agency to help ensure success in removing unwanted controlled substances from consumers' homes.

The Food and Drug Administration (FDA) has called upon manufacturers to establish programs for the return or destruction of unused opioids.²⁰ Chain pharmacy fully supports FDA's goals in this regard. Manufacturer-funded drug disposal solutions are consistent with the concept of product stewardship, which underlies other manufacturer-funded efforts to remove or dispose of old, unused, or unsafe products (e.g., electronics). An example of manufacturer-funded disposal, which we support, is mail-back envelopes made available to pharmacies for disposal. A program of manufacturer-funded mail-back envelopes for unused opioid drugs also recognizes that the entire drug supply chain has a role in drug disposal. Under such a scenario, pharmacies

²⁰ "FDA Asks E&C for New Authority on Opioid Evaluation, Seizure; Suggests Requirements on Manufacturers;" *Inside Health Policy*; <https://insidehealthpolicy.com/daily-news/fda-asks-ec-new-authority-opioid-evaluation-seizure-suggests-requirements-manufacturers>, accessed February 9, 2018; Referencing FDA policy document provided to the House Energy and Commerce Committee.

would provide manufacturer-funded mail-back envelopes to patients upon request when those patients fill opioid prescriptions. Combating prescription drug abuse requires collaboration. Retail pharmacies seek collaborative efforts, including working with manufacturers, as well as local, state, and federal law enforcement officials, to help patients safely and effectively dispose of their unwanted drugs.

In addition, NACDS supports other flexible solutions that provide consumers with drug disposal options to maximize the effectiveness of drug disposal, including broad drug disposal programs that allow pharmacies to voluntarily facilitate at least one of the several DEA authorized options for drug disposal. In addition to mail-back envelopes made available to pharmacies by manufacturers, these options include, but are not limited to: take-back kiosks in 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. When policymakers consider proposals for drug disposal, it is imperative that such proposals consider the full complement of available community resources and allow pharmacies to accommodate their patients' needs through this variety of disposal options. We urge DHCF to consider supporting a policy of meeting patients' needs through a variety of drug disposal options.

E. Improved Coverage for Pain-Management Treatment Options to Improve Access to Non-Opioid Therapeutic Alternatives

All too often, chronic pain patients are prescribed an opioid due to health plan coverage limitations where alternative therapies are not preferred, are less affordable, or are not covered services. For patients whose pain may be better managed on nonopioid medicines and/or through other complementary or integrated health service interventions, these coverage issues can lead to otherwise unnecessary opioid exposure, potentially leading to the misuse, abuse or diversion. It is imperative that we work to reverse the dynamic through which chronic pain patients are prescribed an opioid when alternative therapies (pharmacologic and/or other complementary or integrated health services) are not preferred, are less affordable, or are not covered.

NACDS supports enactment of federal and state policies that requires coverage of alternative, non-opioid drug therapies for chronic pain management at the same formulary and cost-sharing tier and requires coverage of complementary or integrated health pain management services. We encourage lawmakers and other policymakers to implement policies that will improve access to nonopioid pain management therapies so that clinicians and patients can opt for treatment approaches that are not impeded by coverage challenges.

In addition to the above policies that chain pharmacies have adopted, currently, NACDS members are involved in numerous activities to help patients with SUD. These activities include educating patients on safe opioid use, the importance of proper and safe storage and disposal of opioid products, alternatives to opioids, and dangers of mixing opioids with other medications like benzodiazepines; providing increased access to naloxone as well as naloxone administration; needle exchange programs; and engagement in opioid awareness, management, and prevention programs. While these services cover a wide range of areas, there are still many

more services that pharmacists can provide to further the advancement of SUD and MAT in the Medicaid program.

IV. Overcoming Barriers to Increasing Provider Capacity to SUD Treatment and Recovery Services and Programs:

A. Introduction

Although pharmacists are skilled, knowledgeable, and readily available to provide SUD treatment and recovery services, there are multiple barriers that prohibit pharmacies/pharmacists from providing these services to Medicaid beneficiaries. While the Medicaid program covers services used to treat SUD, state laws and regulations not only affect the distribution of these drugs and services to Medicaid beneficiaries, but also, they impose barriers for providers to be a point of service for impacted Medicaid beneficiaries. There are also federal regulations that determine which providers can offer SUD treatment to Medicaid patients, which also limits provider capacity. Removing such barriers to pharmacists' and pharmacies' providing MAT services would further improve access to SUD treatment and improve care related to substance abuse, particularly so with increasing provider capacity for methadone services as pharmacists and pharmacies are able to provide access to this particular treatment option under federal laws and regulations. We therefore urge DHCF to work with its federal partners to eliminate this barrier to treatment for patients requiring this medication to meet their recovery goals.

B. NACDS Recommendations

For the District of Columbia demonstration to be successful, we believe that DHCF should address all barriers that are prohibiting provider willingness to provide these services. We strongly encourage DHCF to consider current research being done by the U.S. Government Accountability Office (GAO), who is also working to increase access to these services within the Medicaid population.

As required by Section 1011 of the SUPPORT Act, GAO is conducting a study to identify barriers to providing medication used in the treatment of SUD under certain Medicaid distribution models as well as options for state Medicaid programs to remove or reduce such barriers. This study is also focusing on patient access and models of distribution of SUD treatment medications like buprenorphine, naltrexone, and buprenorphine-naloxone combinations. While the study is focusing on the purchasing, storage, ordering, prescribing, dispensing, and administration of SUD treatment medications by providers, it is also analyzing provider willingness to provide or prescribe substance use disorder treatment medications to Medicaid beneficiaries. In our discussions with GAO, NACDS flagged several state and federal barriers that hinder patient access to SUD and MAT services and programs, and we urge DHCF to also take these barriers into consideration as it works to increase provider capacity to provide these services.

1. State Barriers

As you are aware, under the Medicaid program, prescription drug coverage is an optional benefit; states are not required to cover prescription drugs for Medicaid

beneficiaries. Similarly, SUD services are also optional under the Medicaid statute, and states may opt not to cover these for a variety of reasons, thus potentially limiting pharmacists'/pharmacies' ability to provide these services. In its June 2018 report to Congress, the Medicaid and CHIP Payment Access Commission (MACPAC)²¹ reported that although these are optional services, nearly all state Medicaid programs offer some form of SUD and MAT services, which includes outpatient and residential treatments with varying degrees of intensity. However, most do not cover all the levels of care, leading to gaps in care across states. Currently, all state and the District of Columbia Medicaid programs cover buprenorphine and 48 states and the District of Columbia cover naltrexone.

2. *Federal Barriers*

There are also federal restrictions that limit the magnitude in which pharmacists and other providers can provide SUD services to Medicaid beneficiaries. The US Drug Enforcement Agency (DEA) regulations for prescribing and dispensing medications that treat SUD impact the extent to which providers and offer treatment options for patients. For example, specifically for pharmacies, buprenorphine may be dispensed in retail pharmacy settings, but there are specific requirements that are in place when buprenorphine is dispensed in a retail setting which requires pharmacies to take steps to ensure that the prescriber had the appropriate waiver to issue the prescription. Specifically, to prescribe these products for maintenance therapy, a qualified prescriber must request a waiver from the Center for Substance Abuse Treatment, which will then notify DEA of all waiver requests.²²

In special circumstances, physicians and other medical personal may administer buprenorphine to patients with opioid dependencies without a buprenorphine waiver. For example, there are no federal limits on a physician or other authorized hospital staff maintaining or detoxifying a person with buprenorphine as an incidental adjunct to medical or surgical conditions other than opioid dependency.

For those patients that are being treated with naltrexone, which can be used to treat both opioid use disorders and alcohol use disorders, there are fewer restrictions. Naltrexone can be dispensed in retail pharmacies and can be prescribed or furnished by any health care provider who is licensed or otherwise authorized under state law to prescribe or furnish medications.

NACDS believes that it is imperative for DHCF to partner with providers and policymakers to remove the barriers and increase provider capacity so that patients can have unhindered access to SUD and MAT services. Without access to treatment, the cycle of abuse will only continue for the many individuals struggling with addiction. As such, NACDS offers to DHCF the same suggestions for consideration that were provided to the GAO to assist with efforts to increase the number of available providers, removing barriers, and increasing patient access to SUD and MAT services in the Medicaid population:

²¹ <https://www.macpac.gov/wp-content/uploads/2018/06/June-2018-Report-to-Congress-on-Medicaid-and-CHIP.pdf>

²² These practitioners are referred to as DATA waived practitioners. Drug Addiction Treatment Act of 2000 (DATA 2000)

1. *Development and Adoption of Standardized Federal/State Requirements:* Since there are varying state and federal regulations that limit the type of provider and setting in which SUD services can be obtained, there is limited possibility that the capacity of providers will increase equally across state Medicaid programs. There is an ongoing need for standardized federal requirements that can be applied across all states and across all Medicaid delivery models. Current federal requirements set the parameters and framework for states to follow but give states the very broad authority to operate loosely within those parameters. As a result, there are multiple variations of state SUD and MAT programs that ultimately cause delays in patient access and treatment. To eliminate these variations and gaps in care, as well as increase the number of trained and available providers where patients can receive SUD and MAT services, ***we recommend the development of standardized federal requirements that are mandatory for state adoption and participation in demonstration programs. Standardized federal requirements would remove the differences in treatment options and coverage, remove restrictions on which providers can administer these services, which will result in ensuring that there is an adequate number of providers for SUD treatment services in all settings, including community pharmacies, within the Medicaid program.***

Restrictive SUD and MAT programs with limited providers and access settings are not appropriate for the Medicaid program. Medicaid beneficiaries are less mobile than the general population as they rely on public transportation and cannot travel to providers that are not conveniently located. Therefore, restricting which providers and settings where these services and treatment can be obtained results in restricted patient ability to access their healthcare providers, thus reducing the likelihood of successful treatment and completion of SUD and MAT programs and regimens. To ensure that patients have access to the provider of their choice, at a minimum, the standardized federal standards should require states to follow the same accessibility standards as required for other Medicaid covered services.

2. *Recognizing Pharmacists as Providers Can Increase Provider Capacity in SUD and MAT Programs:* In light of the state and federal barriers that contribute to limited provider capacity, we would like to highlight that community pharmacist are uniquely trained, capable, and fully understand the importance of timely and accurate SUD and MAT treatment and services, and are readily available to assist in efforts to combat the opioid epidemic and to address opioid priority areas. However, failure and lack of Federal recognition of pharmacists as providers serves as a major obstacle that is preventing pharmacists from fully functioning as a provider of services for patients diagnosed with SUD.

According to the Association of American Medical Colleges, by 2030, there will be a shortage of more than 120,000 doctors. Pharmacists are uniquely positioned to help address this anticipated shortage by playing a greater role in the delivery of healthcare services in collaboration with other health care team

providers. Retail community pharmacies offer an important role in the care of patients with SUD. Face-to-face interactions among pharmacists and patients have made pharmacists keenly aware of the challenges and complexities associated with this epidemic. ***In addition to suggesting removal of limiting requirements, and the development of additional standardized federal and state requirements, we strongly recommend the development and adoption of policies that allow pharmacists to serve a greater role in the delivery of healthcare services, along with exploration of working in collaboration with other providers.*** Recognition of pharmacists as providers will improve patient access and health and it will help the District of Columbia to ensure that the proper resources are available to states to adopt and implement SUD and MAT services and programs within the Medicaid program.

Community pharmacists are among the advanced healthcare professionals with doctorate-level education and years of clinical training. Drawing upon their education, training, and accessibility, community pharmacists can be better utilized in the battle against the opioid crisis by helping in identifying and treating those with opioid addiction. This includes providing services such as opioid antagonist counseling or opioid risk factor intervention services.

Community pharmacies are easily accessible and provide greater convenience than other options for Medicaid patients that require these services. Community pharmacies are conveniently located as 91.7% of Americans live within 5 miles of a community retail pharmacy, making community pharmacies a more readily available option for SUD and MAT treatment services than many other treatment locations.

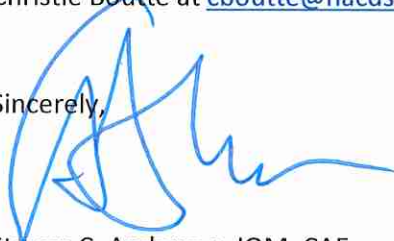
Recognizing pharmacists as providers will increase the number of provider options and access to care points where patients can obtain services from their provider of choice. Providing patients with more options and more convenient options will help maintain continuity of care. Despite the training, knowledge, and reliability of pharmacists, pharmacists are not being utilized at the top of their profession. The lack of recognition of pharmacists as providers limits patient access to services, which can jeopardize their health and result in increased future health care costs.

V. Collaboration in the Fight Against the Opioid Epidemic

Community pharmacies have a long-standing and ongoing commitment to working as part of the solution to opioid abuse. NACDS welcomes the opportunity to further partner with DHCF in the implementation of other sections of the SUPPORT Act that would help increase provider capacity, decrease barriers to access, and minimize the number of Medicaid beneficiaries at risk for SUD. As well trained, highly trusted, and readily available providers, community pharmacists are ready to partner in initiatives that are a part of the solution to the opioid-abuse epidemic.

NACDS thanks you for considering our input on this Request for Information. We welcome the opportunity to work with policymakers to advance any and all the policy initiatives that we have outlined in these comments. If you have any questions, please do not hesitate to contact Christie Boutte at cboutte@nacds.org or 703-549-3001.

Sincerely,



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