NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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October 11, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201
Via email: PainandSUDTreatment@cms.hhs.gov

Re: Development of a CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted Treatment

On behalf of our members, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) regarding the Request for Information (RFI) on the Development of a CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted Treatment. NACDS and our member companies are committed to pursuing policies and other initiatives to aggressively combat prescription opioid misuse, abuse, diversion, and addiction, while continuing to ensure that patients who legitimately require prescription opioids to manage their health conditions have access to these medications. We support the work that CMS is undertaking in accordance with Section 6032 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act") and welcome the opportunity to provide input to CMS on this initiative.

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.

Having attended the September 20 Public Meeting & Webcast on the CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted

Treatment, we note that there were a number of suggestions offered on strategies to prevent opioid addiction and improve access to medication assisted treatment (MAT) services. Notably, leveraging pharmacists in these efforts was among these ideas. NACDS and our members wholeheartedly agree that pharmacists have a critical role to play in curbing prescription opioid misuse and abuse and providing individuals struggling with a Substance Use Disorder (SUD) with convenient options for receiving MAT services. As the face of neighborhood healthcare, pharmacists are trusted healthcare professionals who regularly interact with patients to provide expert advice on proper medication use and deliver a growing number of important healthcare services to the public. Pharmacists have an important role to play in helping to prevent opioid addiction and their extensive education and training makes them uniquely suited to provide care to patients with SUDs.

We understand that the agency is seeking input on patient access, payment, and coverage policies under Medicare and/or Medicaid pertaining to the treatment of chronic care and treatment of SUDs including MAT. With respect to the series of questions that CMS posed regarding these topics, we welcome the opportunity to address the following in our comments:

- Policy solutions to address how certain payment and coverage policies under Medicare and/or Medicaid for the treatment of acute and/or chronic pain may have contributed to the use of opioids;
- Policy solutions to address how payment and coverage policies under Medicare and/or Medicaid may have impeded access to non-opioid treatment of acute and/or chronic pain; and
- Policy solutions to improve coverage and access for SUD treatment options and evidence-based, FDA-approved MAT.

A. Policy solutions to address how certain payment and coverage policies under Medicare and/or Medicaid for the treatment of acute and/or chronic pain may have contributed to the use of opioids.

- *Policy Solution 1: Limit initial opioid prescriptions for the treatment of acute pain – with appropriate exemptions for chronic pain, pain associated with cancer care, hospice or other end-of-life care, and palliative care, as well as prescriptions issued to treat of addiction.*

Unfortunately, certain public and private health plan coverage policies in place over the years may have resulted in an oversupply of opioid prescriptions that contributed to prescription opioid misuse, abuse, and in some patients, the

emergence of addiction. Specifically, covering longer durations of initial opioid prescriptions issued for acute pain episodes may have contributed to these problems.

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.[1] Notably, the average day supply per opioid prescription has increased in recent years, growing from 13.3 to 18.3 days per prescription between 2006 and 2017.[2] 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,[3,4,5] 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.

To address this issue, NACDS supports policies that establish a 7-day supply limit for initial opioid prescriptions issued for acute pain. Informed by the *Guideline for Prescribing Opioids for Chronic Pain* developed by the Centers for Disease Control and Prevention (CDC), this serves to reduce the incidence of misuse, abuse, and overdose of these drugs. We note that CMS has directed Part D plans to implement a hard safety edit limiting the initial dispensing of opioid prescriptions to a supply of

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[1] Centers for Disease Control and Prevention; *CDC Guideline for Prescribing Opioids for Chronic Pain*'; CDC.gov; https://www.cdc.gov/drugoverdose/prescribing/guideline.html

[2] 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

[3] 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.

[4] 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.

[5] 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).

7 days or less, and we support the agency's action in this regard.

To date, 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 laws and policies that are standardized across state lines to promote consistent patient care and implementation. To this end, NACDS 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 Garder (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. We urge CMS both to support this legislation and to continue to urge Medicare Part D Plan sponsors to implement these limits for Medicare Part D covered beneficiaries as well.

- *Policy Solution 2: 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 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.[6]

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[6] 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)

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.[7] While 85% of *all prescriptions* were issued electronically, only 31% *of controlled substance prescriptions* were issued electronically.[8]

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.[9] So far, 25 states have mandated the use of e-prescribing practices.[10] Because of all the tangible benefits of e-prescribing, we encourage CMS to support efforts to extend e-prescribing mandates to all controlled substance prescriptions – not just those covered by Medicare.

B. Policy solutions to address how payment and coverage policies under Medicare and/or Medicaid may have impeded access to non-opioid treatment of acute and/or chronic pain.

- *Policy Solution 3: Improve 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 non-opioid medications and/or through other complementary or

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[7] The Surescripts *2018 National Progress Report* is available here: https://surescripts.com/news-center/national-progress-report-2018/
[8] Ibid.
[9] 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.
[10] 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/

integrated health service interventions, these coverage issues can lead to otherwise unnecessary opioid exposure, potentially leading to 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 require coverage of alternative, non-opioid drug therapies for chronic pain management at the same formulary and cost-sharing tier and require coverage of complementary or integrated health pain management services. We encourage lawmakers and other policymakers to implement policies that will improve access to non-opioid pain management therapies so that clinicians and patients can opt for treatment approaches that are not impeded by coverage challenges.

C. Policy solutions to improve coverage and access for SUD treatment options and evidence-based, FDA-approved MAT.

- *Policy Solution 4: Increase access to SUD treatment by leveraging pharmacists to provide these services.*

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 (and in some states do) provide to further the advancement of SUD treatment and MAT in the Medicaid and Medicare programs.

We strongly encourage CMS to implement policy changes that would utilize community pharmacists in assisting physicians with opioid treatment programs providing MAT for patients diagnosed with SUD. A recent article by Pringle, Aruru,

and Cochran[11] noted that by allowing community pharmacists to be more involved in direct patient care, community pharmacists can help to eliminate gaps and barriers in treatment and increase access to naloxone and other MAT drugs as well as play a critical role in implementing strategies to help reduce population opioid use disorder (OUD) risk. For example, pharmacists can contribute to reducing OUD population prevalence by using Screening, Brief Intervention, and Referral to Treatment (SBIRT) which has been developed, tested, and implemented in numerous healthcare settings to identify persons who are misusing alcohol and other drugs, and has just begun to be used by pharmacists. Through a screening process, pharmacists identify those at risk of OUD and provide brief counseling and motivational interviewing, as well as linkage to care. Allowing community pharmacists to be more involved in direct patient care helps increase provider capacity while also eliminating gaps and barriers in treatment and increasing access to naloxone and other MAT drugs.

Currently, pharmacy-based SBIRT services are being rolled out in Pennsylvania, Virginia, and Ohio. In Virginia, pharmacist-provided SBIRT services are reimbursed by 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. We urge CMS to encourage other states to implement these types of programs in Medicaid so that Medicaid beneficiaries can access this important pharmacist-provided service across the country.

There are several other notable state programs that are actively leveraging community pharmacies and pharmacists to improve access to SUD treatment medications. In Rhode Island, a MAT program is funded by a $1.6 million NIDA grant. Under this initiative, the Rhode Island Hospital is conducting a pilot program[12] 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.

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[11] Pringle JL, Aruru M, Cochran J, Role of pharmacists in the Opioid Use Disorder (OUD) crisis, *Research in Social & Administrative Pharmacy* (2018), doi: https://doi.org/10.1016/j.sapharm.2018.11.005.

[12] https://www.bostonglobe.com/metro/2019/03/12/getting-addiction-care-pharmacy/m1mcceVlLRXX1W9X3WdeOP/story.html

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 to reveal 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.) Unfortunately, in certain states, pharmacist scope of practice limitations prevents the administration of Vivitrol.

Currently, Rhode Island is the only state to adopt a pharmacy-based addiction treatment project of this scope. However, there are other similar and notable pilot programs in Kentucky and Maryland. The Kentucky project allows pharmacists to manage patients with SUD on Vivitrol[13] and the Maryland program offers buprenorphine through a single pharmacy connected to the Health Department.[14]

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.[15] 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.[16] We strongly urge CMS to encourage other states to utilize pharmacists to provide

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[13] https://www.pharmacytoday.org/article/S1042-0991(17)31120-9/fulltext
[14] https://www.bostonglobe.com/metro/2019/03/12/getting-addiction-care-pharmacy/m1mcceVlLRXX1W9X3WdeOP/story.html
[15] https://leg.colorado.gov/bills/hb18-1007
[16] https://www.sos.state.tx.us/texreg/archive/May242019/In%20Addition/In%20Addition.html#99

these types of services to Medicaid beneficiaries. CMS should also consider the successes achieved in the Medicaid program and apply similar policies that would reimburse pharmacies for providing these services to Medicare beneficiaries.

As alluded above, methadone is available only at federally regulated clinics, which severely limits its availability for treating patients that suffer OUD, especially in rural areas where community pharmacies could serve as a viable resource. CMS should pursue policies to expand capacity and access, including allow methadone clinics and other facilities to partner with community pharmacies to monitor and provide continued care after a patient is initially stabilized on methadone in the clinic. Moreover, so that pharmacies can partner in this way, CMS should pursue policies that ensure accurate and fair reimbursement for pharmacies that provide these services in the Medicare and Medicaid programs.

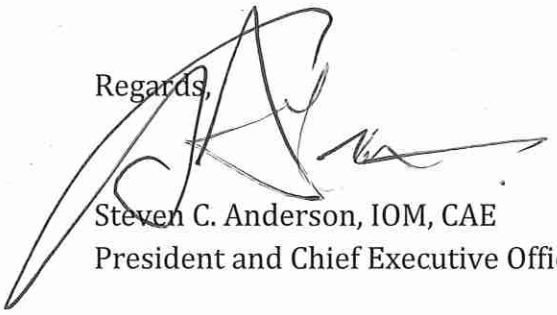
To assist with overcoming the existing statutory and regulatory barriers, we encourage CMS to work with the Substance Abuse and Mental Health Services Administration (SAMHSA) and DEA to address the policies that prevent community pharmacies from offering methadone treatment for OUD. Specifically, individuals prescribed methadone for maintenance and detoxification treatment may only obtain this medication from a narcotic treatment program that has been certified by the Center for Substance Abuse Treatment under SAMSHA. However, SAMSHA does not certify community pharmacies as narcotic treatment programs. Further, a separate DEA registration issued to narcotic treatment programs is required in order to dispense for this purpose. Altogether, these requirements exclude community pharmacies from serving as methadone treatment providers. Given the accessibility of pharmacies in communities across the country, updating these policies to enable pharmacies to provide methadone to treat OUD would serve to improve access to this method of treatment for patients requiring this medication to meet their recovery goals – particularly in communities that otherwise lack access to methadone clinics and individuals in rural communities.

D. Conclusion

NACDS and its members remain steadfast in our commitment to working with policymakers to implement workable solutions to curb the opioid epidemic. To that end, we welcome the opportunity to partner with CMS as the agency moves forward to implement the provisions of the SUPPORT Act that serve this purpose. NACDS thanks you for considering our input regarding the development of a CMS action

plan to prevent opioid addiction and enhance access to MAT, particularly as community pharmacies and pharmacists have such a vital role to play in preventing opioid abuse and increasing patient access to SUD treatment services. 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 Kevin N. Nicholson, R.Ph., J.D., Vice President of Public Policy and Regulatory Affairs, at knicholson@nacds.org or 703-837-4183.

Regards,



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