NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

September 6, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted via regulations.gov

Re: Docket No. CMS-1770-P; Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule, Among Other Policies

Dear Administrator Brooks-LaSure:

The National Association of Chain Drug Stores (NACDS) thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the proposed Calendar Year (CY) 2023 payment policies under the Physician Fee Schedule (PFS) and Other Changes to Part B Policies, as well as other related policies in the CMS proposal.

I. Section III. H. Medicare Part B Payment for Preventive Vaccine Administration Services

NACDS greatly appreciates CMS' continued focus on ensuring Part B vaccine administration rates are appropriately established and better reflect the costs of providing preventive services to Medicare beneficiaries. We remain supportive of CMS' approach—implemented in CY2022—to establish a uniform payment rate of $30 for the administration of an influenza, pneumococcal or hepatitis B (HBV) vaccine and a payment rate of $40 for administration of the COVID-19 vaccine.

Pharmacists play an increasingly important role in providing preventive immunizations for Medicare beneficiaries both in the administration of routinely recommended vaccines but also in the response to the COVID-19 pandemic. As mass immunizers, pharmacies may administer the influenza and pneumococcal pneumonia vaccines under the respective HCPCS codes, G0008 and G0009, and directly bill Medicare for vaccine administration. When applicable, pharmacies may also bill for the HBV immunization utilizing HCPCS codes G0010. Pharmacies must manage vaccine ordering and inventory, storage, ancillary supplies, and indirect overhead costs associated with reporting and other administrative tasks specific to immunizations such as billing. Further, providers administering vaccines, including pharmacists, also must effectively

plan for an influx of patient visits solely for immunization during certain times of year, such as back to school and flu seasons.

Additionally, throughout the ongoing COVID-19 pandemic, pharmacies have established themselves as essential partners in vaccination – they administered 2 of every 3 COVID-19 shots in this country, or more than 262 million doses of vaccine. The role of pharmacists and their staff including pharmacy technicians, particularly as immunizers, will remain essential to building better health, through the pandemic recovery and beyond. For example, pharmacists and pharmacy technicians will continue to play an essential role in identifying future outbreaks and providing booster vaccinations. Especially as our nation shifts to COVID-19 becoming endemic and to a returned focus on routine care services, pharmacies will be critical to ensuring access and care across diverse communities.

Maintaining access to immunizations is critical to the health of Medicare beneficiaries. The COVID-19 pandemic has further highlighted the importance of access to and uptake of immunizations. As described in the proposed regulation, prior to the actions taken by CMS for CY2022, immunization administration payment rates for Part B vaccines had fallen so low that they did not adequately cover the costs of providing these services for healthcare providers, including pharmacies, who play an increasing role in immunizing Medicare beneficiaries.

We therefore strongly support CMS' establishment of appropriate uniform Part B preventive vaccine administration rates for influenza, pneumococcal and HBV. However, COVID-19 vaccine administration rates may need to be higher even beyond the public health emergency (PHE), which we discuss more fully below. **Further, we urge CMS to continue to consider long-term approaches to accurately reflect the costs of administration and updating these costs as needed as described below.**

A. Use of the Geographic Adjustment Factor (GAF)

NACDS agrees with CMS' proposal to continue to adjust vaccine administration rates to reflect cost differences for different geographic localities. While CMS has historically adjusted vaccine administration rates for geography using the geographic practice cost indices (GPCI), continued use of these to adjust by geography would maintain reliance on a crosswalk to fee schedule rates unnecessarily.

As CMS notes in the proposed rule, continuing to adjust payment rates using the PFS GPCIs to reflect cost differences for each geographic areas would require a crosswalk to the resource value units (RVUs) established under the PFS for a CPT code that describes a similar service and is reflective of the mix of the components of the RVU (work, practice expense and malpractice).

NACDS supports CMS' proposal to use the GAF—in place of the GPCI— to adjust the payment to reflect the costs of administering preventive vaccines in each of the PFS fee schedule areas.

B. Annual Updates to the Administration Payment Rates Using the MEI

CMS proposes to update vaccine administration payment rates for Part B preventative vaccine administration using the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The MEI is a fixed weight input price index that reflects the physicians' own time and the physicians' practice expenses, with an adjustment for the change in economy wide, private nonfarm business total factor productivity. CMS proposes to rebase and update the MEI for CY2023 and forecasts the increase in the MEI for CY 2023 to be 3.8 percent.

While NACDS believes that cost reporting would be the best approach to updating the vaccine administration payment rates to ensure they cover costs, we recognize that this may not be possible annually. However, we encourage CMS to consider opportunities to adjust payment rates based on actual costs at least every few years. CMS should take into account the differences that drive cost of administration, including the following:

- Frozen versus refrigerated storage
- Pre-filled syringe vial versus multi-dose vial
- Reconstitution versus ready-to-administer
- Pre-administration requirements (i.e., requirements to query a state registry prior to recommendation, which requires additional labor and technology requirements)
- State registry reporting and gaps in data—not all providers report into registries so patient records, especially for adults, may be incomplete
- Technology/interoperability to support data submission to several different outlets (i.e., different state/county immunization registries), monitor storage conditions, order, ship and track, and for quality assurance programs
- Costs associated with patient outreach (i.e., telephonic, SMS, email, mailed letters, etc.) for series, seasonal, or gap in care therapies; as well as implementing scheduling and reminder systems
- Staffing/labor costs
- Onsite infrastructure for patient triage
- Continuous clinical vaccine training
- Patient screening and evaluation
- Patient counseling about safety and efficacy
- Additional costs when administered off-site

C. Unique Costs Associated with Administering the COVID 19 Vaccine Likely to Extend Beyond PHE

In the proposed rule, CMS states that while they acknowledge that the current costs for administering the COVID-19 vaccine may be higher and necessitate a higher administration rate during the PHE, that effective January 1 of the year following the year in which the PHE ends, the $40 payment rate for administration of the COVID–19 vaccines will be adjusted to align with

the payment rate for the administration of other Part B preventive vaccines. NACDS strongly urges CMS to reconsider this proposal as the operational costs associated with administration of the COVID-19 vaccine remain higher than for other Part B preventive vaccines and this will not change immediately following the end of the PHE.

While pharmacy vaccine administration costs for the other, existing Part B preventive vaccines are similar, COVID-19 vaccine administration does involve additional, operational costs that will continue regardless of the PHE. During the pandemic, the already labor intensive activities around vaccine administration have been further compounded as each encounter involves incremental time, labor, and resources due to heightened levels of screening, counseling, engineering controls, cleaning and sanitizing, reporting, etc. Further, there are unique storage requirements for COVID-19 vaccines compared to the other Part B preventive vaccines. The pandemic has created additional demands on pharmacies and required increased caution in delivering even routine immunizations, leading to the need for additional resources and investment to support administration, including to support ongoing patient education to reduce vaccine hesitancy and promote uptake.

Given the continued likelihood of variants emerging and the potential of new vaccines or boosters to address them, it seems COVID-19 immunizations may not stabilize into a routine, predictable cost and schedule for a few years regardless of the PHE.

Therefore, we recommend CMS maintain the current payment rate of $40 for COVID-19 vaccinations, rather than aligning with that of the other Part B payment rates, for the upcoming plan year and reassess the following year whether there continue to be additional costs associated with administering COVID-19 vaccines following the PHE.

D. <u>In-Home Additional Payment for Administration of COVID–19 Vaccines</u>

Currently, CMS permits an additional payment for in-home administration of vaccines with a national rate of approximately $35 for the COVID–19 vaccine if administered in the home under specified circumstances (under HCPCS code M0201). This payment is in addition to the administration payment rate for the COVID-19 vaccine. CMS proposes to continue this additional payment for CY2023 and the payment rate will be updated using the MEI and will be adjusted geographically using the GAF.

Reaching homebound beneficiaries greatly expands access for this population to essential preventive care services. Older homebound adults may be particularly vulnerable to adverse outcomes associated with COVID-19 as well as influenza and pneumonia. NACDS believes the add-on payment supports access to preventive services in a convenient location for these beneficiaries. However, there continue to be additional costs in providing this service. CMS should consider the following expenses as they evaluate this policy moving forward:

- Costs for travel (e.g., mileage)
- Costs for travel time (e.g., additional payroll)
- Security (e.g., additional personnel to ensure vaccine administrator safety)

- Cold storage costs
- Physical layout of the site
- Handling and preparation of vaccine and supplies (e.g., these factors are standard in a pharmacy's controlled environment)
- Clinical condition of the patients (e.g., greater diversity of clinical conditions resulting in increased task times devoted to patient eligibility screening, patient consults and adverse event monitoring)
- Enhanced cleaning and sanitization procedures.

NACDS supports CMS' proposal to continue the add-on payment for CY2023. We also urge CMS to consider making this additional payment permanent and consider applying it when other preventive immunizations are also provided in-home or at the same time as COVID-19. Doing so will help support public health access to some of Medicare's most vulnerable beneficiaries.

As stated, CMS currently limits the conditions under which the in-home payment rate applies including requirements that the patient has difficulty leaving the home, the patient may be difficult to reach because of disability or socio-economic barriers, the sole purpose of the visit is to administer the COVID-19 vaccine, and requirements on what is considered "a home". **The restrictions are too limiting, as there is great value for pharmacies to conduct on-site clinics at multi-living unit arrangements, nursing home facilities, and assisted living facilities. Pharmacists/pharmacies that conduct these offerings should also be eligible for reimbursement for the time and travel to conduct these services for the Medicare population. With these current policy restrictions, CMS is discouraging beneficiary vaccination opportunities.**

E. Clarification on Policies for COVID– 19 Vaccine and Monoclonal Antibody Products

NACDS supports CMS' proposal to continue to pay for COVID–19 monoclonal antibody products under the Medicare Part B vaccine benefit through the end of the calendar year in which the Emergency Use Authorization declaration is terminated. We also support maintaining the payment rate for administering a COVID–19 monoclonal antibody product used for treatment or for post-exposure prophylaxis of COVID–19 in a healthcare setting, including pharmacies, as well as the payment rates for administering a COVID–19 monoclonal antibody product in the home as described on the CMS COVID–19 Monoclonal Toolkit.

II. Section III. G. 2. Shared Savings Program Participation

A. Increasing Participation in Accountable Care Models in Underserved Communities by Providing an Option for Advance Investment Payments to Certain ACOs

In the proposed rule, CMS proposes to make advanced shared savings payments (advance investment payments (AIP)) to low revenue ACOs that are inexperienced with Medicare ACO initiatives with performance-based risk, that are new to the Medicare Shared Savings Program

(MSSP) and that serve underserved populations. The goal of the payments is to support expanded participation in MSSP among ACOs in underserved regions, support the social needs of Medicare enrollees and, as a result, improve health equity outcomes. CMS outlines that ACOs would need to use these advance investment payments to improve health care provider infrastructure, increase staffing, or provide accountable care for underserved beneficiaries, which may include addressing social needs. CMS notes that AIPs are intended to "provide the means to build the ACO's population health management capabilities, including the provision of accountable care for underserved beneficiaries."

In the proposed rule, CMS provides examples of how AIPs may be used to increase staffing, including "hiring behavioral health clinicians and case managers to integrate behavioral health treatment into the primary care setting; hiring oral health providers to integrate dental services into the primary care setting; or encouraging partnerships with healthcare systems and local, community-based organizations". Pharmacies and pharmacists serve as a critical access point to a variety of care interventions and other clinical needs for patients—especially within underserved communities—as demonstrated by the key role pharmacies have played in the pandemic response. **To this end, NACDS recommends CMS clarify that ACOs applying for AIPs could use funds to invest in partnerships with other community-based providers, including community pharmacies, to expand the reach of community-based services as well as support patient access to more care settings where they may be screened for and connected with services to meet health and SDoH needs.**

Pharmacists can more meaningfully be integrated into value-based and total costs of care models and AIPs may be one way to support their integration into team-based accountable care, especially in underserved communities. Given that 90 percent of Americans live within 5 miles of a pharmacy and pharmacists are viewed as one of most trusted providers, partnerships between ACOs and pharmacies/pharmacists can strengthen access to care and delivery of patient-centered care. Research continues to demonstrate the positive impacts of pharmacists on patient health outcomes and healthcare cost savings, in alignment with existing quality measures across CMS programs, including MSSP. NACDS' white paper, Accelerating the Center for Medicare and Medicaid Innovation's Mission, Integrating Community Pharmacy Care into Value-Based Programs Amid COVID-19 Pandemic Recovery & Beyond, outlines in greater detail the value of integrating pharmacy care into value-based payment models.

III. MIPS Quality Measures - New Quality Measures Proposed for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years

A. Adult Immunization Status (AIS) measure

CMS proposes to add the AIS measure to MIPS noting it supports the comprehensive evaluation of compliance with recommended adult immunizations (influenza, Tdap/Td, herpes zoster, and pneumococcal vaccines) that improve quality care and prevent disease for the general population. If adopted, the measure would replace the current individual MIPS measures—

Q110: Preventive Care and Screening: Influenza Immunization and Q111: Pneumococcal Vaccination Status for Older Adults.

NACDS strongly supports CMS' inclusion of this measure in MIPS. We agree with CMS' assessment that this preventive measure offers a "comprehensive evaluation for compliance with recommended adult immunizations." Including the AIS measure in MIPS will support increased adult immunization rates by encouraging physicians to emphasize all recommended immunizations.

Increased adult immunizations in Medicare has the potential to reduce health care costs by decreasing the prevalence of vaccine preventable diseases, many of which are associated with hospitalizations and use of other health care services. For example, testing of an adult immunization composite measure in the Indian Health Service health care delivery system demonstrated the composite measure's capacity to "improve system performance and increase vaccination coverage."[1] Use of this measure will support improved immunization uptake and information collection across the healthcare team and care settings. To improve population health, communication and integration of data are critical, especially including pharmacies in the case of immunizations and all other pharmacy-provided clinical services.

As CMS continues to implement strategies to advance vaccination coverage through quality measurement, NACDS also suggests CMS explore the opportunity to directly incentivize pharmacies for vaccination coverage of their populations. Community pharmacies have proven their value to advance vaccination rates by providing high quality, comprehensive vaccine care at convenient locations and within expanded hours. However, pharmacies are not directly incentivized to advance healthcare quality through standardized measurement for vaccines and other clinical services. Such incentives would drive better vaccination rates for Medicare beneficiaries. For example, neither the Part B nor D programs directly pay pharmacies for their performance on health quality metrics, and existing measures used in Part D are not pharmacy-specific because they were designed at the plan level. Also, vaccination measures do not exist within the Part D program. NACDS encourages CMS to consider opportunities to align incentives for pharmacies to truly advance vaccine uptake, and healthcare quality overall, as a part of the broader strategy to improve care for Medicare and Medicaid beneficiaries. Specifically, NACDS suggests CMS explore a pharmacy quality incentive program with standardized health quality metrics, similar to the quality programs designed for other suppliers of care, which could be tested through CMMI.

IV. Leverage pharmacies to expand access to behavioral healthcare services and fill gaps in care.

We note that CMS has proposed numerous substantive policy changes to expand coverage and improve access to care for patients with behavioral healthcare needs. Through these proposed

[1] "Moving More Electrons To Optimize New Adult Composite Immunization Measures, " Health Affairs Blog, September 20, 2019.D0!: 10.1377/hblog20190919.68890

policy changes, CMS has rightly prioritized connecting patients in need of mental health and substance use disorder (SUD) treatment services with that care; doing so is critically important given the current shortage of mental health and substance abuse treatment providers impacting access to care in communities across the country. Leveraging the full breadth of qualified providers and delivering care in new and innovative ways is essential to ensuring sufficient treatment capacity to meet patients' needs.

While the CMS proposed policy changes would enhance coverage and access to mental health and substance abuse treatment delivered by various practitioners and in broader care settings, CMS has omitted policy changes that that would additionally utilize pharmacies in this regard. **Considering the accessibility, qualifications, and proven record of pharmacists in delivering a growing number of clinical services that can support patients' behavioral healthcare needs as delineated below, we encourage CMS to further leverage pharmacies by implementing policy changes in support of this.**

A. Access to behavioral health services at pharmacies helps to make care more accessible for patients in underserved communities – including those in racial and ethnic minority groups who are disproportionately impacted by inequitable access to healthcare services.

Pharmacists are qualified and well-suited to partner with clinicians and other behavioral health services professionals to provide an array of services in support of patients' recovery and related wraparound services. As the most accessible healthcare provider to most Americans, leveraging this access is an essential yet underutilized way of extending clinicians' reach in providing destigmatizing care to patients with behavioral healthcare needs – especially in communities hardest hit by the mental health and substance abuse treatment provider shortages and for individuals from racial and ethnic minority groups that experience access barriers to healthcare services. Notably, longstanding inequities and social determinants of health faced by Black, Indigenous, and People of Color (BIPOC) including uneven healthcare access, lack of insurance coverage, poverty, and crowded living conditions can exacerbate access to treatment services for these individuals.[2] The pandemic response has shown that pharmacies serve as a critical access point for the provision of healthcare services for this otherwise underserved population of patients, as more than 40% of individuals vaccinated at pharmacies were from racial and ethnic minority groups. [3] Further, pharmacies provide more than 20,000 COVID-19 testing sites nationwide, and 70% of such sites are in areas with moderate to severe social vulnerability.[4] Utilizing pharmacists to support the provision of

[2] https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-question-and-answers/

[3] GAO, Federal Efforts to Provide Vaccines to Racial and Ethnic Groups, available at https://www.gao.gov/assets/gao-22-105079.pdf

[4] White House, FACT SHEET: Biden Administration Announces Historic $10 Billion Investment to Expand Access to COVID-19 Vaccines and Build Vaccine Confidence in Hardest-Hit and Highest-Risk Communities, available at https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/25/fact-sheet-biden-administration-

behavioral healthcare services can similarly improve access to care for patients in racial and ethnic minority groups.

Working together, pharmacists and other practitioners can help provide needed access to treatment services such as medications for opioid use disorder (MOUD)/medication assisted treatment (MAT) and patient support. In fact, new access points to behavioral health support in communities are much needed, especially considering that an estimated 1.4 million Americans have suffered from opioid use disorder (OUD) in the past year[5], yet a mere 11% of adults with substance use disorders (SUDs) are receiving treatment.[6] Promisingly, a recent study examined the distribution of community pharmacies across a state relative to the location of substance abuse treatment centers and opioid-related overdoses to explore the potential for community pharmacies to play a greater role in opioid abuse prevention and treatment.[7] The study found that community pharmacies were more prevalent than substance abuse treatment centers—especially in rural counties—which could make them an important partner in enhancing access to MOUD/MAT and prevention efforts in underserved areas.[8]

To improve access to behavioral health services for patients in underserved communities – including for BIPOC patients who are disproportionately impacted by inequitable access to care - CMS should implement policy changes that leverage pharmacies to augment the delivery points for these needed healthcare services.

B. A growing body of evidence supports leveraging pharmacists in the provision of medications for opioid use disorder/medication assisted treatment.

Pharmacists have an important role to play working with physicians and other healthcare providers to identify and connect patients in need of treatment for OUDs to that care. Pharmacies are increasingly helping to bridge access gaps for treatment and have directly helped battle opioid abuse for years. In fact, evidence shows that pharmacist involvement in

announces-historic-10-billion-investment-to-expand-access-to-covid-19-vaccines-and-build-vaccine-confidence-in-hardest-hit-and-highest-risk-communities/

[5] Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration (2020), available at: https://www.samhsa.gov/data/sites/default/files/reports/rpt29393/2019NSDUHFFRPDFWHTML/2019NSDUHFFR1PDFW090120.pdf

[6] Substance Abuse and Mental Health Services Administration (SAMHSA). (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52).

[7] Look, K., Kile, M., Morgan, K. et al. (2018). Community Pharmacies as Access Points for Addiction Treatment. Research in Social and Administrative Pharmacy, S1551-7411(18)30217-1. https://www.ncbi.nlm.nih.gov/pubmed/29909934

[8] Ibid.

OUD care helps improve access and outcomes, while reducing the risk of relapse.[9,10] Pharmacists' accessibility and clinical expertise makes them uniquely suited to provide care to patients with SUDs. Access to treatment and support are critical to help individuals struggling to overcome this burden.

Especially at the point of dispensing, pharmacies and pharmacists are uniquely positioned to offer Screening, Brief Intervention, and Referral to Treatment (SBIRT) services to at-risk patients. A recent study[11] noted that by allowing community pharmacists to be more involved in direct patient care, community pharmacists can help eliminate gaps and barriers in treatment and increase access to naloxone and MOUD/MAT, as well as play a critical role in implementing strategies to help reduce population OUD risk. For example, pharmacists can contribute to reducing OUD prevalence by using SBIRT to identify persons who are misusing alcohol, opioids, and other substances. Through a screening process, pharmacists identify those at risk and provide brief counseling and motivational interviewing, as well as linkage to care when needed.

Evidence indicates that risk for opioid medication misuse can be identified in rural and urban community pharmacies—and consumers are generally open to screenings and discussions with pharmacists about potentially problematic usage.[12] Given the strong ties of community pharmacies in neighborhoods across the country, work is underway to implement collaborative, community-based SBIRT models where patients are first screened in the comfort and convenience of their local, familiar, community pharmacy and then receive intervention and linkage to care from the pharmacists they know and trust. Pharmacist-provided SBIRT services also increase provider capacity while eliminating gaps and barriers to SUD screening and treatment. This model can increase access to screening and education, as well as help to eliminate gaps in linking patients to treatment through local coordination. Pharmacist-provided SBIRT services have been developed in Pennsylvania, Virginia, and Ohio. Notably within Virginia, the state Medicaid program now expressly supports coverage for pharmacist provided SBIRT.

Once patients are identified as having an OUD or other SUD, pharmacists can offer a critical role in providing convenient options for receiving MOUD/MAT services. Providing patients with access these services at pharmacies can also help to destigmatize treatment and in doing so, improve patient compliance with prescribed therapies. When pharmacists partner with physicians and other healthcare professionals to provide MOUD/MAT, they streamline and improve care. Pharmacists' responsibilities for MOUD/MAT and other SUD treatment can

[9] DiPaula, B.A. & Menachery, E. (Mar/Apr 2015). Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients, Journal of the American Pharmacists Association, 55(2), 187-192, available at: https://www.ncbi.nlm.nih.gov/pubmed/25749264

[10] Raisch, W. (2002). Opioid Dependence Treatment, Including Buprenorphine/Naloxone, *Pharmacology & Pharmacy,* 36(2), 312-321.

[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] Cochran, G., Rubinstein, H., Bacci, J. et al. (2016). Screening Community Pharmacy Patients for Risk of Prescription Opioid Misuse. Journal of Addiction Medicine, 9(5) 411-416. https://www.ncbi.nlm.nih.gov/pubmed/26291546

include administration of injectables, directly observed therapy, treatment plan development, patient communication, care coordination, adherence monitoring and improvement activities, among others. Moreover, pharmacies offer an array wraparound services (where permitted in different states) that can be especially beneficial to at-risk patient groups such as the provision of services for take-home naloxone, prescribing of PEP & PrEP therapies, prescribing of hormonal contraceptives, immunization services (including for hepatitis B, HPV and others), tobacco cessation services, needle exchange and access to various other basic healthcare services.) A patient may not be easily able to attend routine appointments with a traditional medical provider due to circumstances such as work or family commitments, or more recently, the capacity limitations brought on by the pandemic. However, the extended hours of many pharmacies provide additional opportunities for individuals to receive needed interventions and support - especially for patients who cannot take time off during typical work hours and who would greatly benefit from access to care in the evenings and weekends.

Currently, notable state programs are actively leveraging community pharmacies and pharmacists to improve access to different SUD treatment medications. In certain states, such as Ohio, pharmacists can administer naltrexone as part of a MAT or MOUD plan for patients. There are other notable pilot programs in Kentucky and Maryland. The Kentucky project allows pharmacists to manage patients on naltrexone[13] and the Maryland program offers buprenorphine through a single pharmacy connected to the Health Department.[14] Further, in Kentucky, the Board of Pharmacy has authorized pharmacists to execute clinical protocols and initiate the dispensing of medications for several conditions, including OUD pursuant to recommendations by the American Society of Addiction Medicine.[15]

In Rhode Island, a MOUD/MAT program is funded by a $1.6 million NIDA grant. Through this initiative, Rhode Island Hospital is conducting a pilot program[16] involving six pharmacies working with 125 patients to manage their MOUD/MAT. In the pilot, patients receive their initial MOUD/MAT prescription from a physician. 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, which will be sent to a lab for analysis to inform whether that patient has taken the full dose of their prescribed medication or used any illicit substances. With this information, pharmacists counsel patients about recovery goals, challenges, 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 a once-a-month injection of naltrexone.

[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] Kentucky Board of Pharmacy. Board Approved Protocols. https://pharmacy.ky.gov/Pages/Board-Approved-Protocols.aspx
[16] https://www.bostonglobe.com/metro/2019/03/12/getting-addiction-care-pharmacy/m1mcceVlLRXX1W9X3WdeOP/story.html

Leveraging all qualified health professionals, including pharmacists, to address this public health issue is imperative. Implementing more pharmacy-based MOUD support programs, similar to what was stood up in the Rhode Island example, would allow more clinicians to expand access to essential treatment services for their patients in need. Many of these programs build on the existing relationships that pharmacists have with their patients. Community pharmacies are an untapped resource that can offer screenings, referrals, and educational counseling and improve access to these needed SUD services. With pharmacists as additional pain management and SUD providers, more patients may receive timely and effective interventions and treatments.

NACDS urges CMS to pursue policy changes that will leverage pharmacists in the provision of medications for OUD/MAT – similar to the growing number of state programs that do the same.

V. Continued delay of the enforcement timeline for electronic prescribing requirements under Sec. 2003 of the SUPPORT Act is unwarranted.

When Congress originally enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act") in 2018, lawmakers established that the electronic prescribing of controlled substances (EPCS) requirements created under Sec. 2003 would apply beginning on January 1, 2021. Four years after enactment of this important law, we are dismayed to see CMS propose delayed enforcement of the requirement for a third time. Timely enforcement of the federal EPCS mandate is essential to supporting the nation's ongoing fight against drug abuse and diversion, especially now when these problems have been exacerbated by the COVID-19 public health emergency.

We remain concerned that without the promise of imminent enforcement, some prescribers who could otherwise make the necessary system updates may delay doing so because the deadline is no longer looming. In past rulemaking, CMS has acknowledged that use of electronic prescribing varies between states and is associated (in part) with differences in regulations. However, "[s]ubstantial adoption of EPCS has occurred in the […] states that require it."[17] The different state experiences continue to illustrate how enforced mandates serve as a necessary catalyst for encouraging prescribers to use this technology. For example, both Iowa and New York have laws establishing EPCS requirements that are substantially similar to the requirements of Sec. 2003, and both of those states enforce their laws with fines. In those two states, the rate of EPCS prescriber enablement is 79.6% and 85% respectively – which is notably higher than the national average.[18] Thus, enforcement of laws for EPCS clearly encourages compliance, while the continued enforcement delay of the of the Medicare Part D EPCS requirements undermines the requirements of the program.

[17] Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies 85 Fed. Reg. 50,260 (August 17, 2020).
[18] https://surescripts.com/enhance-prescribing/e-prescribing/e-prescribing-for-controlled-substances (Data sourced June 2022)

We note that CMS's planned enforcement action for non-compliant prescribers for the first year of enforcement would be a non-compliance letter, and that there would be no immediate fines or actions against non-compliant prescribers. This initial enforcement action would serve as a prompt for noncompliant prescribers to finally come into compliance with the EPCS requirements that took effect back in 2021 without imposing any other penalties. Furthermore, for prescribers who are unable to conduct EPCS due to circumstances beyond the prescriber's control (e.g. in times of disaster or because of other extraordinary circumstances), the temporary waiver process outlined both in federal law and the implementing rules exists to accommodate and temporarily except prescribers in these situations. For these reasons, further enforcement delay is simply unjustified. **NACDS urges CMS to begin enforcement of the EPCS requirements established under Sect. 2003 of the SUPPORT Act no later than January 1, 2023 - as CMS had indicated it would do last year.**

Conclusion

In conclusion, NACDS thanks CMS for this opportunity to submit comments, and for your consideration of our recommendations. If we can provide any additional information, please contact Sara Roszak, Senior Vice President of Health and Wellness Strategy and Policy at sroszak@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

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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 155,000 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.