March 18, 2025

Derek Maltz
Acting Administrator
Drug Enforcement Administration
Attn: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

RE: Special Registrations for Telemedicine and Limited State Telemedicine Registrations (Docket No. DEA-407)

Dear Acting Administrator Maltz,

The National Association of Community Health Centers (NACHC) is the leading national membership organization dedicated to promoting Community Health Centers (CHCs) (also known as Federally Qualified Health Centers or health centers) as the Employer, Provider, and Partner of choice in all communities, as well as the foundation of the primary health care system in America.

Community Health Centers are the best, most innovative, and resilient part of our nation's health system. For nearly sixty years, health centers have provided high-quality, comprehensive, affordable primary and preventive care. In addition to medical services, CHCs provide dental, behavioral health, pharmacy, vision, and other essential health services. Today, health centers serve more than 32.5 million people at over 16,000 locations in urban, rural, suburban, frontier, and island communities, ensuring patients receive the care they need and pay what they can based on a sliding fee scale.

NACHC maintains its role as the national voice for health centers and believes that high-quality primary health care is essential in creating healthy communities and preventing chronic conditions. The collective mission and mandate of NACHC and the 1,496 health centers around the country is to close the primary care gap and provide access to high-quality, cost-effective primary and preventative medical care.

NACHC welcomes the opportunity to comment on the Drug Enforcement Administration's (DEA) proposed Special Registrations for Telemedicine rule. While we appreciate the DEA's forward movement on telemedicine prescribing of controlled substances policy, we are still concerned about language that restricts patient access to telemedicine rather than narrow protections against diversion of controlled substances. At a time of great stress on healthcare systems and a shortage of primary care and behavioral health providers, we are concerned that the proposed changes will only make circumstances harder for our patients and providers. CHC patients face often overwhelming barriers to receiving the care they need. Additional administrative barriers and hurdles will impact patients' ability to access care and negatively impact clinicians' experience. We encourage the DEA to identify ways to make it easier for CHC clinicians to provide the care our patients need, not add additional administrative hurdles for our team members and the

vulnerable people we serve. They have been using telehealth to manage a wide variety of conditions safely and effectively for some time now, regardless of the medications or treatment plans that are deemed to be medically necessary. While we understand the need for protections, we encourage DEA to work to ensure a clear pathway for providers to use telehealth nationwide without unreasonable burdens or restrictions. **NACHC urges the DEA to significantly revise the proposed telemedicine regulation as written and work with Congress to ensure ongoing access to virtual prescribing for patients and providers of certain controlled substances.**

Our comments are broken into the following areas: I. Special Registration; II. Telemedicine Registration Platform; III. Application Process & Costs; IV. Nationwide Prescription Drug Monitoring Program Check; V. Audio-Only Prescriptions; VI. Schedule II Controlled Substance Prescriptions; and VII. State Laws Applicable to Special Registration Participants.

I. Special Registration

NACHC recommends that the DEA create a single Special Registration for Telemedicine to allow for Schedule II prescribing or just Schedule III-V prescribing. In addition, a prescriber could obtain the current form of DEA registration for each state in which they intend to prescribe. The Ryan Haight Act requires that the DEA issue a singular Special Registration for Telemedicine (21 U.S.C.A. § 831(h)). However, the DEA proposes a concept that would see the creation of two Special Registrations for Clinicians, a new federal State Telemedicine Registration for each state in which a prescriber practices telemedicine, and Platform Registration and State Registration numbers for telemedicine platform providers. Such a concept is overly complex, imposing costly and unnecessary burdens on health centers and other stakeholders.

NACHC is concerned about the proposed language specifying that 50% of monthly Schedule II prescriptions must be in-person; this would effectively block nearly all telemedicine offered by providers offering Schedule II prescriptions. Requiring less than 50% of a clinician's Schedule II prescriptions through telemedicine could be seen as overly prescriptive and potentially lead to delays in patient care. If a provider falls below the 50% threshold, it will be disruptive to patient care and lead to discontinuity if that prescriber must then stop prescribing controlled substances to their patient panel until their ratio is back above the threshold. This stipulation could particularly affect providers who rely on telemedicine for hard-to-reach populations, potentially limiting access to necessary medications. Requiring that patients have in-office visits as part of their care creates significant barriers for patients who rely on telehealth services to manage their mental health conditions.

Many health center patients have transportation problems, difficulties securing childcare, or mobility limitations that would make it more difficult to attend an office visit. In a time when access to care is already challenging, the proposed change will make it even more difficult for vulnerable populations to get the treatment they need. One health center in New Jersey raised concerns about the impact this policy would have on patients being treated for Attention-Deficient/Hyperactivity Disorder (ADHD). ADHD is usually well-managed using a telemedicine platform, and the proposed language would severely impact the patients who rely on virtual visits with their doctor to manage their condition. This proposed guardrail does not reflect the real-world use of telehealth nor the challenging realities of documenting this information – which would be

applied to in-person and virtual care. Current safeguards have proven to be effective ways to manage the risks of these medications; this proposal adds a clinically unnecessary level of complexity to an already overwhelmed healthcare system.

Some providers will be unable to fulfill this requirement regardless of the monitoring or scheduling system that is put in place. One health center in Delaware only has two Psychiatric Mental Health Nurse Practitioners on staff to support five offices, one of whom is available via telehealth only because they live outside of the service area of Delaware. If this proposal goes forward, that will result in only one of the health center's psychiatric clinicians being able to prescribe Schedule II controlled substances, thereby limiting the number of patients that health centers can serve. This requirement will also put an additional burden on their psychiatric clinicians and medical clinicians who have in-person availability, all of whom are already busy with caseloads. It will also mean that their patients will need to see multiple providers within their system to manage portions of the same treatment plan. This fragmentation and duplication of care is frustrating for patients and providers and will lead to decreased access, decreased continuity, and missed or delayed refills, which can potentially worsen health outcomes for the most vulnerable patients. These stricter rules will make it harder for health centers to provide care and their patients to access their medication, potentially increasing risks and complicating care management.

Over the last few years, telehealth policies have helped health center patients stay connected to high-quality, affordable care. Almost all (99%) of CHCs utilize telehealth to meet their patients' needs, including delivering comprehensive primary care, mental health services, chronic care management, and nutrition and dietary counseling.[1] Health centers are in medically underserved areas where 1 in 3 of our patients live in poverty and face significant social drivers of health that create barriers to affordable health care services. Health centers have proven highly effective at utilizing telehealth to continue providing primary and preventive care to patients in their communities. In 2023, health centers conducted over 18.2 million virtual visits.[2] Of those visits, 58% were for substance use disorder (SUD). Telehealth has allowed health centers to better bridge the gap in accessing critical SUD services during ongoing healthcare workforce shortages.

The availability of telehealth is particularly popular among health center patients.[3] Results from a 2023 NACHC survey found that almost 90% of patients surveyed agreed that telehealth addressed their needs, was suitable for interaction with their clinician, and that they were generally comfortable and satisfied with care via telehealth. A quarter of the patients surveyed had a visit for behavioral health – 52.55% via audio-only and 65.7% via video (and some were both).[4] This adds to the growing body of research about the strength of telehealth in providing clinically equivalent care[5] on top of the strong patient satisfaction.

A restriction on the state in which care can be offered creates significant harm by reducing access to medical practitioners across state lines – which is regulated by other authorities and is necessary for telehealth to help serve patients in remote areas. Providers licensed in multiple states often

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[1] 2023 UDS Data, HRSA
[2] 2023 UDS Data, HRSA
[3] https://www.hcadvocacy.org/wp-content/uploads/2024/02/NACHC-Telehealth-Policy-Paper-2024.pdf.
[4] NACHC Patient Telehealth Satisfaction Assessment 2023, In review.
[5] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796668

encounter varying telehealth and prescribing regulations, leading to compliance challenges. Harmonizing these laws could reduce confusion and administrative burden, facilitating more efficient and effective patient care. If finalized, this regulation would create direct harm for those patients as they would lose access to the telehealth services they are currently utilizing.

II. Telemedicine Registration Platform

NACHC recommends the DEA revisit the telemedicine registration platform requirements to reduce administrative burden and create guardrails around prescribing practices. We appreciate the DEA's attempt to consider the changing dynamic of the current day practices but remain concerned under this proposal that the DEA fails to take full advantage of the opportunity created by this registration capability. We are wary about over-regulation imposing significant administrative burdens on providers, potentially detracting from patient care. It is crucial that the DEA balance regulatory measures with the practical realities of clinical practice to ensure that providers can focus on delivering quality care. Were the proposal to advance, the telemedicine platform registration should be an opportunity to do two things:

1) *Reduce the administrative burden of the special registration on practitioners operating on a platform.* Because their platform is taking some accountability for the provision of care and all these individuals would have multiple special registrations, it is possible that this platform registration could also simplify compliance for pharmacies and others who interact with the platform.
2) *Allow some narrow guardrails that focus on prescribing practices that the DEA has identified and proven are problematic through its investigations.*

III. Application Process & Costs

NACHC requests the DEA review the application process and special registration costs to ensure minimal financial and administrative burden. Many layers of registration create cost challenges for health centers and do not serve as an effective guardrail against potential bad actors for whom cost is no barrier. Oftentimes, health centers are registered Medicaid providers in neighboring states. Telehealth should be used to increase access to health center services for patients in areas with limited access to Medicaid providers or sliding fee discount arrangements. It costs $888 per state for platform practitioners and $50 per state for clinician practitioners, which could add up for providers needing registration in multiple states.[6] Every dollar is precious to health centers, which provide high amounts of uncompensated care to uninsured patients yearly. In 2023, health centers cared for 5.6 million uninsured individuals, with the total cost of the care gap exceeding $3.16 billion.[7] Health centers operate on razor-thin financial margins and these costs could produce significant barriers to continuing telehealth. Additionally, for practitioners who provide significant portions of care out-of-state, it could disincentivize providers from investing in out-of-state telemedicine care and further exacerbate the mental health workforce shortage.

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[6] https://www.psychiatry.org/psychiatrists/practice/telepsychiatry/blog/dea-special-registration-for-telemedicine#:~:text=Fee%20Structure,per%20state%20for%20clinician%20practitioners.
[7] 2023 UDS Data

IV. Nationwide Prescription Drug Monitoring Program Check

We request that the DEA provide additional details on how it plans to implement this nationwide PDMP program and clarify the agency's capacity to help states and providers fulfill the requirements for implementing this program. While the idea of state-by-state checks is promising, they are not always feasible with today's infrastructure. Adding additional steps to repeatedly verify the patient's identity adds redundant work for providers that detracts from the time available to care for patients. Additionally, actions to implement this capability are beyond the scope of this rulemaking; other federal government agencies and leadership may need to assist states in modernizing PDMP capabilities to enable a seamless 50-state check.

A health center in New York noted that implementing a nationwide PDMP check would increase the administrative workload compared to the current practice of checking only their state PDMP. Currently, information for the PDMP from selected states is available only through logging directly into the PDMP website outside of a health center's EHR, and even then, the state's PDMP usually does not have access to the PDMPs from all other states. The limited search functionality also increases the risk that providers will not match a patient with usage in the system and could miss prescriptions would be found if we had used the more flexible search criteria for the state database.

While monitoring controlled substance prescriptions across the U.S. could enhance patient safety, we are also concerned that this requirement might place additional burdens on providers, potentially diverting time from direct patient care. Creating a requirement that cannot be met, even with a three-year lead time, is a barrier to patient access to care. We request that the DEA not create any additional barriers dependent on actions outside of a health center's control and instead work to facilitate the capability needed for this reporting.

Regarding the provision that would require prescribers issuing telemedicine prescriptions using their special registration to include up to five DEA registration IDs on the prescription, current standards for electronic prescribing have no fields for any of these newly proposed registration numbers and the associated digital certifications. The proposed identification process would create clinically unnecessary steps that would complicate telehealth visits for both patients and providers. The standards also do not support the use of other data elements that may be necessary for the pharmacy provider to identify the eRX associated with a telehealth encounter (prescriber place of service, identification of a platform provider, etc.) If this provision were to move forward, health centers would need additional implementation time to allow for the adoption of electronic prescribing and PDMP transmission standards that support the inclusion of these new data elements.

V. Audio-Only Prescriptions

NACHC requests that the DEA reconsider its proposal to remove audio-only telehealth for important behavioral health appointments. We are concerned that the regulation, if finalized, would disproportionately affect the health center's rural patient population, which already faces higher barriers to accessing health care. For example, patients in remote areas may already be unable to utilize audio-visual telehealth and, under this proposal, would also be unable to request

audio-only telehealth for their mental health treatment. It is essential to consider that requiring an audio-video system after a six-month buprenorphine prescription period could pose challenges for patients lacking access to the necessary technology. Many health center patients have technical limitations that prevent them from using video technology for their visits. Patients with these challenges are often among the most in need of flexible care that meets them where they are.

Requiring an appointment using audio-video technology during a specific window of care creates an unnecessary barrier to essential treatment that will delay the prescription of these lifesaving medications for opioid use disorders (OUD) and is not clinically necessary for safe, effective prescribing of buprenorphine. Allowing audio-only communications can significantly improve accessibility for these patients. It is also worth acknowledging that the Centers for Medicare and Medicaid (CMS) recognizes patients may need to request audio-only telemedicine in certain circumstances and allows patients to request access to audio-only care. Congress has also acted several times to ensure access to audio-only telehealth continues, making its intent for the delivery of telehealth clear.

Many health center patients with medications for opioid use disorders (MOUD) have transportation and scheduling challenges that prevent them from being seen in person at any given time. They also often have unpredictable access to video technology and may not be able to access video during critical times throughout their treatment plan. If these limitations prevent them from receiving a timely refill of their medication, they will be at higher risk for relapse and overdose. Allowing CHC clinicians to assess the patient's needs, individual circumstances, and adherence to care and determine the best level and location of care for each patient allows for the optimal patient-centered, clinically sound approach to using this critical tool for treating OUD.

There is also a double standard in the current regulatory proposal. The DEA allows audio-only in the buprenorphine final rule for the use for treatment of opioid use disorder, but not for other important care. Monitoring this requirement is an additional administrative burden that will fall on CHC clinicians, requiring them to identify and track at the time of each visit the duration of buprenorphine treatment and the type of visits completed previously. This administrative work detracts from their focus on patient care. We are concerned that the DEA's focus on how care is delivered potentially overregulates the provider-patient relationship, which is already governed by state law and other rules, rather than regulating the risk of diversion of controlled substances. We urge the DEA to reconsider the proposal to improve patient trust in their providers and allow health centers to focus on providing high-quality, affordable healthcare for those most in need.

VI. Schedule II Controlled Substance Prescriptions

As mentioned above, we are concerned that the DEA's mention of geographies does not reflect how telemedicine functions in the current health delivery environment. Rather than creating more effective guardrails, the DEA proposes requirements that would harm patients and would also not prevent bad actors from prescribing. Telemedicine has provided unprecedented access in rural areas and communities facing workforce shortages, hospital closures, and a lack of specialty care. According to a 2023 U.S. Government Accountability Office (GAO) report, rural residents must travel 40 miles farther than their urban counterparts to receive

specialty care for opioid and substance use treatment.[8] Health centers are filling the gap where they can. Still, there is no reason that some populations should have less access to care due to overregulation.

We are worried there are almost no providers who can fulfill the 50/50 requirement since it represents a significant documentation and administrative burden on many providers, including those who only provide a small amount of telehealth. NACHC is concerned that, if this rule were finalized, many providers would choose not to undertake this burden in exchange for providing quality healthcare.

NACHC is concerned about the potential negative impacts the in-person medical evaluation requirement to receive subsequent prescriptions may have on health center patients' continued access to necessary controlled medications. As previously mentioned, 1 in 3 health center patients live in poverty and subsequently face significant barriers to affordable health care. Health centers tailor their services to meet the unique needs of their surrounding communities and address barriers by providing high-quality, comprehensive primary health care services. This in-person proposal could negatively impact these individuals and a myriad of other patients that health centers serve, including people who face transportation barriers, parents with young children at home, older adults, patients who started on a controlled prescription during the pandemic and had subsequently become bedridden or homebound and unable to come to the clinic for care, people with disabilities, and people experiencing homelessness.

This proposal will also disproportionately impact health centers and their patients located in rural areas. Nearly 400 health centers operate 5,600 service delivery sites in rural communities, and health centers serve 1 in 5 Americans living in rural communities. Many providers live in major cities and cannot physically travel to these remote sites; therefore, they see their patients via telemedicine. By enforcing in-person requirements, many patients will be unable to continue seeing their providers, especially in regions with less access to care. For instance, one state's Primary Care Association reports that 40% of health centers have their main site in rural areas. The in-person requirement seems an unnecessary burden to make those patients come in for a visit when the current flexibilities provide more benefit than harm. It's critical that health centers are able to maintain their ability to provide care to the most vulnerable patients and use telehealth to meet the patient's needs in the least burdensome way.

NACHC is also concerned about the impact in-person requirements would have amid the healthcare workforce shortage. Telehealth continues to be an effective tool for providing access to care amid increasing clinical workforce shortages. Health centers depend upon over 310,000 clinicians, providers, and staff to deliver affordable and accessible health care. Every health center is different, and the services offered largely depend on the types of providers and staff the health center can retain and recruit. A NACHC survey found that 68% of health centers lost between five and twenty-five percent of their workforce in early 2022, with a majority citing financial opportunities at a large healthcare organization as the main reason for departure.[9] For instance, health centers have reported extreme difficulty in retaining behavioral health staff like psychiatrists and licensed clinical psychologists. Many health centers have tried to fill this gap by utilizing

[8] https://www.gao.gov/blog/why-health-care-harder-access-rural-america.
[9] https://www.nachc.org/wp-content/uploads/2022/03/NACHC-2022-Workforce-Survey-Full-Report-1.pdf.

telepsychiatry providers. Even so, some health centers report a limited supply of psychiatric prescribers, resulting in longer wait times for patients to see prescribers.

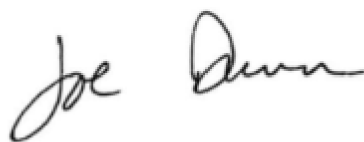
The primary challenge with an in-person mandate – even when not clinically required – is the limitation on access it creates for the millions of Americans seeking treatment for a condition for which there are significant barriers to access. These can include stigma, provider shortages, long distances to see providers and many other barriers. Currently, the average wait time for a physician appointment across the nation is 26 days, with specialty medical appointments having an even longer wait list for in-person appointments. This could result in more patients going without proper assessment and treatment because of the in-person requirement and could likely add to the burden on the hospital systems. Patients may seek treatment in different forms, such as emergency rooms and urgent care centers, where their needs will likely not be met. Telehealth has created meaningful access for these individuals, and we risk losing that progress.

VII. State Laws Applicable to Special Registration Participants

We request the DEA clarify the proposal regarding state laws applicable to special registration participants. During the public health emergency, the DEA waived the requirement that a provider have a registration for each state where they prescribe to patients. As proposed, the DEA would require practices to be "in accordance" with Federal and state law. However, for practices pursuing multiple state registrations it is confusing in the case of conflicting laws. Each state has its own laws regarding telehealth and prescription. Providers licensed in multiple states often encounter varying telehealth and prescribing regulations, leading to compliance challenges. Harmonizing these laws could reduce confusion and administrative burden, facilitating more efficient and effective patient care. We request that the DEA offer additional clarity on this

Thank you for your consideration of these comments. We urge the DEA to maintain these crucial flexibilities when it comes to prescribing via telemedicine to ensure continuity of access for health center patients. If you have any questions, please contact Elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elinderbaum@nachc.org.

Sincerely,



Joe Dunn
Chief Policy Officer