

March 28, 2023

Administrator, Anne Milgram Drug Enforcement Administration 8701 Morrisette Drive Springfield, VA 22152

RE: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In- Person Medical Evaluation (RIN 1117-AB40/Docket No. DEA-407)

Dear Administrator Milgram,

The National Association of Community Health Centers (NACHC) is the national membership organization for federally qualified health centers (also known as FQHCs or health centers). Health centers are federally-funded or federally-supported nonprofit, community-directed primary care clinics that serve as the health home for over 30 million people, including 1 in 5 Medicaid beneficiaries and over 3 million elderly patients. It is the collective mission and mandate of over 1,400 health centers around the country to provide access to high-quality, cost-effective primary and preventative medical care as well as dental, behavioral health, and pharmacy services. Health centers also provide other "enabling" or support services that facilitate access to care to individuals and families located in medically underserved areas, regardless of insurance status or ability to pay.

Health centers serve some of the nation's most vulnerable people; nearly 70% of health center patients live under 100 percent of the Federal Poverty Level (FPL) and 91% live under 200 percent FPL. Additionally, 79 percent of health center patients are uninsured or publicly insured. Health center patients have always had complex care needs, and these needs are growing increasingly complex. From 2013 to 2017, the percentage of health center patients diagnosed with substance use disorder grew 73% and patients diagnosed with depression grew 39%. Access to medications to help treat conditions like these via telehealth has been a lifeline for health center patients. NACHC strongly urges the DEA to review proposals that may negatively impede a patient's ability to not only receive but maintain access to medications crucial to their health regimen.

NACHC welcomes the opportunity to comment on this proposed rule and will focus our comments on areas most important to FQHC patients and providers. Our comments are broken into three sections: I. Telehealth Increases Patient Access to Health Care Services, including Crucial Medications; II. Specific Feedback on the Proposed Rule; and III. Other Recommendations.

I. Telehealth Increases Patient Access to Health Care Services, including Crucial Medications

¹ https://www.nachc.org/wp-content/uploads/2022/03/Chartbook-Final-2022-Version-2.pdf

² https://www.nachc.org/wp-content/uploads/2022/03/Chartbook-Final-2022-Version-2.pdf

Over the last three years, telehealth has helped health center patients stay connected to high quality, affordable care despite the COVID-19 pandemic. In 2020, 98% of health centers nationwide offered telehealth services compared to just 43% in 2019.³ Health centers are located 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 the most vulnerable and underserved communities. In 2021, health centers conducted over 26 million virtual visits.⁴ Patients utilized telehealth for a variety of services; 54% of visits were for mental health and 31% of visits addressed substance use disorder, for instance. Telehealth has allowed health centers to better bridge the gap in accessing critical behavioral health services amid a global pandemic and ongoing healthcare workforce shortages.

The availability of telehealth is also popular among health center patients. Preliminary results from a new NACHC survey show 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). This adds to the growing body of research about the strength of telehealth in providing clinically equivalent care besides eliciting strong satisfaction from patients.

We appreciate the flexibilities provided by the DEA during the COVID-19 pandemic⁷, which ensured that both adults and children could continue accessing medically necessary controlled substances via telemedicine by waiving the requirement that the patient have a prior in-person visit, regardless of their location, during the PHE. As telehealth continues to gain more popularity and becomes embedded in the delivery of health care, it is imperative that new regulations consider the positive impact telehealth has on increasing access for patients, while also balancing protections when prescribing controlled substances.

II. Specific Feedback on the Proposed Rule

Requirement for an In-Person Medical Evaluation for Subsequent Prescriptions for Controlled Medications

NACHC is concerned about the potential negative impact the in-person medical evaluation requirement may have on patients' ability to receive subsequent prescriptions and their ability to maintain continued access to necessary controlled medications. Health centers tailor their services to meet the unique needs of their surrounding communities and address barriers to culturally competent and comprehensive primary health care services. NACHC urges the agency to consider how this proposal can limit access to respectable and affordable care for patients experiencing legal and social challenges. Reacting quickly to the onset of the public health emergency (PHE), the DEA created flexibilities allowing DEA-registered practitioners to prescribe controlled substances via to adults and children, regardless of their location, without the

2

³ https://bphc.hrsa.gov/sites/default/files/bphc/data-reporting/uds-2021-data-trends-speakers.pdf

⁴ https://bphc.hrsa.gov/sites/default/files/bphc/data-reporting/uds-2021-data-trends-speakers.pdf

⁵ NACHC Patient Telehealth Satisfaction Assessment 2023, In review.

⁶ https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796668

⁷ https://www.deadiversion.usdoj.gov/coronavirus.html

requirement of an in-person exam. This flexibility avoided interruptions in patient care regimens, and the positive impact of these flexibilities have been recognized. For example, the Office of National Drug Control Policy has recommended that the DEA permanently allow qualified practitioners to prescribe controlled substances to patients via telemedicine without first conducting an in-person evaluation. The DEA's current proposal, however, could affect and impact myriad of patients that health centers serve: 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 bed ridden or homebound and unable to come to the clinic for care, people with disabilities, and people experiencing homelessness. All of these patients can face significant obstacles to meeting that in-person requirement and NACHC is concerned about the negative health implications of this proposal.

Additionally, health centers that specialize in serving LGBTQ patients often report that individuals from outside of their service area seek services from the health center via telehealth because, in their community, there is a lack of access to affordable services that take into account the unique clinical needs of the LGBTQ population. This in-person requirement could create disruptions in care for patients that *choose* a certain health center based on the services available, which may not be located in close proximity to them. A study from the LGBTQIA+ Primary Care Alliance found that 9 out of 11 health centers noted significant demand for healthcare from out-of-state patients. Due to increasing stigma against the LGBTQ community in certain states across the country, it may be difficult for a patient to find an in-person provider in close proximity who can best serve their needs for an in-person exam. Schedule III-V controlled substances include testosterone as a Schedule III drug¹⁰, which is used for gender-affirming care. Telehealth helps these patients access critical medications without the unnecessary burden of arranging travel, requesting time off from work, arranging childcare, and other logistical barriers.

NACHC is also concerned about the impact an in-person requirement would have amid the health care workforce shortage. Telehealth continues to be an effective tool for providing access to care amid increasing clinical workforce shortages. Health centers depend upon over 220,000 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 recent 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 health care organization as the main reason for departure. 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 telepsychiatry providers for psychiatrist needs. Even so, some health centers report a limited supply of psychiatric prescribers, resulting in longer wait times for patients to see prescribers.

This proposal will also disproportionately impact the workforce for health centers and their patients located in rural areas. Nearly 400 health centers operate 5,600 service delivery sites located in rural communities, and health centers serve 1 in 5 Americans living in rural

⁸ https://www.deadiversion.usdoj.gov/coronavirus.html

⁹ https://www.whitehouse.gov/wp-content/uploads/2022/06/Telehealth-and-Substance-Use-Disorder-Services-in-the-Era-of-COVID-19-FINAL.pdf, pg 19

¹⁰ https://www.dea.gov/drug-information/drug-scheduling

¹¹ The National Association of Community Health Centers. (2022, March). Current State of the Health Center Workforce. Pandemic Challenges and Policy Solutions to Strengthen the Workforce of the Future. https://www.nachc.org/current-state-of-the-health-center-workforce/

communities. Many providers live in major cities and are unable to physically travel to these remote sites, and therefore, see their patients via telemedicine. Rural providers use telehealth to form partnerships with providers in urban or larger cities to expand their network to reach more patients. By enforcing in person requirements, many patients will not be able to continue seeing their providers, especially in regions with less access to care. For instance, one state Primary Care Association reports that 40% of their health centers have their main site located in rural areas. 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.

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. ¹² These wait times 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.

NACHC recommends if the DEA plans to move forward with the qualified telemedicine referral, to allow for referrals to an entire medical provider group or organization instead of a specific clinician. Requiring a specific clinician-to-clinician referral, as required by the language in the proposed rule, will be operationally challenging for health centers. There are myriad reasons why a clinician-to-clinician referral could fail to meet the patient's needs. For example, the telehealth provider could no longer work with the health center or could lack the time or bandwidth to accept a referral. We recommend the DEA modify its proposal to allow for referrals to a general medical entity, group or practice that may consist of many providers. This will increase the likelihood of a clinician being able to see the patient and decrease any barriers.

Limiting Prescriptions for a Controlled Medication Issued to a Patient to a 30-Day Supply

NACHC wants to ensure that health center patients are able to continue to receive crucial medications while balancing attempts to control diversion. The proposed rule restricts a patient receiving telehealth to a 30-day supply of a controlled substance. We understand the DEA means to control diversion by imposing a 30-day supply limitation. However, there will be some conditions that require less than 30 days-supply for treatment, while other conditions, such as some mental health treatments, where 30 days could pose a barrier to continuity of care. We want to mitigate the risks of health center patients being unable to secure an in-person visit within 30 days through no fault of their own, due to social drivers of health or the ongoing health care workforce shortages, for example. In many situations, such as mental health or substance use disorder treatment, losing access to treatment could be detrimental to the patients' health, or even produce more harm than the original condition being treated. When possible, we recommend that the DEA balance deferring to practitioner's judgment when prescribing certain medications using specific guidelines in place, while also being in accordance with best practices and applicable state and local regulations. In addition, NACHC believes that review of the Prescription Drug Monitoring Database, as mentioned in the proposed rule, will identify those patients or providers that are engaged in non-compliant prescribing activities, as it does currently and as it did prior to the PHE.

_

¹² https://www.merritthawkins.com/trends-and-insights/article/surveys/2022-physician-wait-times-survey

III. Other Recommendations

The Special Registration to Engage in the Practice of Telemedicine

NACHC is concerned that this rule does not create a process for providers to prescribe controlled substances via telemedicine and urges DEA to include a detailed process in the final rule. Despite multiple Congressional directives and years of requests^{13 14 15}, this Notice of Proposed Rulemaking does not outline a registration process allowing the consistent prescribing of controlled substances via special registration for telemedicine.

The Controlled Substance Act already includes seven exceptions for a practitioner to prescribe a controlled substance via telemedicine, which includes special registration for telemedicine, under the practice of telemedicine authority recognized by the CSA. The CSA specifically requires practitioners to fulfill certain requirements to qualify for a special registration:

- 1. The practitioner must demonstrate a legitimate need for special registration.
- 2. The practitioner must be registered to deliver, distribute, dispense, or prescribe via telemedicine a controlled substance in the state where the patient is located.
- 3. The practitioner must maintain compliance with federal and state laws when delivering, distributing, dispensing, and prescribing a controlled substance.

NACHC urges the DEA to move forward with the development of a special telemedicine registration to ensure access to medically necessary services via telemedicine. This registration process can be an opportunity for certain health center providers to subject themselves to a higher level of scrutiny by DEA and receive greater flexibility to prescribe without in-person referral requirements, time limits on prescribing, and the ability to prescribe a wider range of substances in return.

Omission of Schedule II Controlled Medications

Beginning March 16, 2020, the DEA allowed DEA-registered practitioners across the United States to prescribe all Schedule II-V controlled substances to patients even if no in-person medical evaluation had been conducted, provided certain conditions were met. The COVID-19 PHE has demonstrated almost three years of evidence for the prescription of Schedule II controlled medications via telemedicine.

We understand the DEA's concerns around Schedule II substances such as Adderall and Ritalin but urge the DEA to work with CMS and explore options to allow certain health care providers, particularly School-Based Health Centers, to prescribe Schedule II prescriptions via telemedicine. One primary care association reported that many of their state's school-based health centers have seen increased medication adherence given the telemedicine flexibilities granted by the PHE. The provider is able to discuss the treatment plan with both the child and their

5

¹³ The <u>Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act</u>, October 24, 2018. Required promulgation of final regulations related to a Special Registration for Telemedicine.

¹⁴ Senator Warner (D-VA) sent DEA a <u>letter</u> requesting a continuity of care plan for patients being prescribed controlled substances via telemedicine after the end of the PHE.

¹⁵ Fiscal Year (FY) 2023 Omnibus Appropriations bill

^{16 21} U.S.C. §802(54).

parent who attend the appointment virtually. Furthermore, prior to the pandemic, providers were unable to meet with patients during extended breaks such as summer or winter break, increasing the chances for medication adherence to decrease. With telemedicine appointments, the provider is able to prescribe the medication easily, which can be filled and picked up at a local pharmacy convenient to their patient. Research shows that treatment of a condition such as ADHD with a controlled substance does not increase the risk of developing a substance use disorder and that proper treatment of a mental health condition can potentially lower the likelihood of a future substance use disorder. School-Based Health Centers continue to play a crucial role by improving student access to care, especially primary and behavioral health services, to try and decrease absenteeism and improve overall student outcomes. Being able to have flexibilities in prescribing certain Schedule II drugs via telemedicine, with certain guardrails in place, can enhance medication adherence and overall child wellbeing.

Align In-Person Requirement with CMS Regulations

NACHC appreciates the DEA's proposal to continue access for patients that have an ongoing telehealth relationship for 180 days after the end of the public health emergency. However, NACHC recommends that the timeline coordinate with the overall telehealth rules put forth by the Centers for Medicare and Medicaid Services (CMS), specifically maintaining existing telehealth flexibilities until 12/31/2024. For example, if a Medicare beneficiary needs a controlled substance prescription, the in-person visit requirement that is currently paused through CMS will cover the in-person visit requirement per this proposed rule after 12/31/24. This modification would further evidence DEA's intent to better align with CMS on telemedicine, such as the proposal in this proposed rule to modify the definition of "practice of telemedicine" to coincide with CMS' regulations around telemedicine.¹⁹

Thank you for your consideration of these comments. We urge the DEA to maintain these crucial flexibilities when it comes to telemedicine prescribing to ensure continuity of access for heath center patients. If you have any questions, please contact Vacheria Keys, Director of Policy and Regulatory Affairs, at wkeys@nachc.org.

Sincerely,

Joe Dunn

Senior Vice President, Public Policy and Research

National Association of Community Health Centers

¹⁷ https://www.uclahealth.org/news/are-children-who-take-ritalin-for-adhd-at-greater-risk-of-future-drug-abuse

¹⁸ https://mhealthintelligence.com/news/school-health-centers-get-5m-to-expand-telehealth-access-to-care

¹⁹ https://www.govinfo.gov/content/pkg/FR-2023-03-01/pdf/2023-04248.pdf, pg 12878.