March 29, 2023

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

RE: Expansion of Induction of Buprenorphine via Telemedicine Encounter (RIN 1117-AB78/Docket No. DEA-948)

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 provider 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 and 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 patients; nearly 70% of health center patients live under 100 percent of the Federal Poverty Level (FPL) 91% live under 200 percent FPL. Additionally, 79 percent of health center patients are uninsured or publicly insured.¹ Health centers and these needs are growing increasingly complex. From 2013 to 2017, the percentage of health center patients diagnosed with substance use disorder grew 73% so ready access to medications like buprenorphine via telehealth has been a lifeline for health center patients. NACHC strongly urges the DEA to review proposals that may impede a patient’s ability to maintain access to buprenorphine which is crucial to treatment opioid use disorder (OUD).

NACHC welcomes the opportunity to comment on this proposed rule and discuss the anticipated implications of these proposed changes on health center patients who use buprenorphine. Our comments will focus on the positive telehealth has brought in caring for health center patients and the anticipated burden the in-person requirement placed on health center patients using buprenorphine.

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 2019.² 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. Patients utilized telehealth for a variety of services, including 31% of visits addressed substance use disorder (SUD). Telehealth has allowed health centers to better bridge the gap in accessing critical SUD 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.

NACHC is concerned about the potential negative impact the in-person medical evaluation requirement may have on patients’ ability to receive subsequent buprenorphine prescriptions and their ability to maintain continued access to this necessary controlled medication. We understand the DEA’s intention to curb inappropriate use of buprenorphine, but we are concerned the in-person medical examination visit requirement to get subsequent prescription refills will have negative repercussions on our patient population. Health center patients, especially those who are uninsured, experience higher social drivers of health that can impact accessing appropriate and timely care. Patients’ abilities to afford time off from work to see providers in person, access to transportation to/from said appointments, find childcare to attend appointments all serve as potential barriers to meeting the in-person requirement.

The DEA’s current proposal 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 bedridden 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 the in-person requirement and NACHC is concerned about the negative health implications of this proposal.

Recent research shows that the flexibilities to prescribe buprenorphine via telehealth as a result of the pandemic did not lead to substantial medication diversion or misuse. NACHC is concerned about the implications of this proposed rule, which could decrease access to buprenorphine for many patients and thus decrease the number of patients utilizing Medications for Opioid Use Disorder (MOUD). This could lead to an increase in overdose deaths. Furthermore, there are many areas across the country that lack, or have very limited, Medication Assisted Treatment (MAT)

4 NACHC Patient Telehealth Satisfaction Assessment 2023, In review.
5 https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796668
6 https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/
7 https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689
services offered; most recent data show that 40% of counties lack buprenorphine prescribers.\(^8\) This makes an in-person appointment an even longer journey for patients to bear and coordinate.

**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.\(^9\)

These workforce shortages 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 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 for patients. By enforcing in person requirements, many patients will not be able to continue seeing their providers, especially in regions with less access to MOUD care.

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.\(^10\) This could result in more patients going without proper assessment and treatment for MOUD 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. While this could be burdensome on the health care system, this could also be financially devastating for uninsured patients to pay for these health care services out of pocket. Not being able to access buprenorphine can result in negative health outcomes for patients trying to recover from OUD; they are more likely to relapse when they cannot access buprenorphine. Discontinuation of MOUD within 30 days is already common, occurring between a third and two-thirds of cases, depending on the population and specific medication used.\(^11\)\(^12\) NACHC urges the DEA to review the proposal and weigh the potential negative effects it can have on these vulnerable patients.

Finally, NACHC requests that the DEA clarify certain situations within the final rule that are not addressed in this proposed rule, as outlined below:

- Situations in which a patient receives a short (such as 3 to 7 days) initial prescription via telemedicine for buprenorphine, is then lost to follow up, and subsequently re-engages more than 30 days after the initial prescription and requests another short refill of buprenorphine via telemedicine.

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\(^{8}\) [https://oig.hhs.gov/oei/reports/oei-12-17-00240.pdf](https://oig.hhs.gov/oei/reports/oei-12-17-00240.pdf)


\(^{12}\) [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5750108/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5750108/)
Clarify when the "30 day limit" is reset. For instance, if a patient receives a 30-day supply of buprenorphine without an in-person visit, is lost to follow up, and then re-engages 12, 24, or 36 months later, can there be a new 30-day telemedicine period of prescribing prior to an in-person evaluation.

Clarify whether the "30-day supply" can be given via multiple separate prescriptions of buprenorphine, and if these separate prescriptions can span a time course longer than 30 days so long as the cumulative duration of the prescriptions does not exceed 30 days.

Whether the 30-day limit applies to situations in which a patient was initially evaluated in-person by another DEA practitioner at another clinical site (outpatient clinic, hospital or emergency room) for the patient's OUD and is prescribed buprenorphine, and the patient subsequently transitioned buprenorphine care to a different clinical site, but via telemedicine. There was no formal referral between the two clinical sites, but rather the patient initiated the transition in care.

Thank you for your consideration of these comments. We appreciate the DEA’s intention to craft rules specific to buprenorphine, and understand the DEA is seeking to strike a balance in flexibility. NACHC strongly recommends the DEA take into consideration unique barriers health center patients face for an in-person visit to get subsequent refills of this life-saving treatment. If you have any questions, please contact Vacheria Keys, Director of Policy and Regulatory Affairs, at vkeys@nachc.org.

Sincerely,

Joe Dunn
Senior Vice President, Public Policy and Research
National Association of Community Health Centers