OCHIN

A driving force for health equity

Submitted via regulations.gov and via *regulations.gov*

March 31, 2023

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

Re: Proposed Rule on Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, and Proposed Rule for the Expansion of Induction of Buprenorphine via Telemedicine Encounter

Dear Administrator Milgram,

On behalf of OCHIN, I appreciate the opportunity to provide comments on the *Proposed Rule on Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation* (General Telehealth Prescribing Proposed Rule) and the *Proposed Rule for the Expansion of Induction of Buprenorphine via Telemedicine Encounter* (Buprenorphine Proposed Rule). OCHIN is a national nonprofit health information technology innovation and research network that is comprised of locally controlled community-based providers delivering clinical care at more than 1,300 health care sites with 22,000 providers in 47 states, reaching more than 6 million patients. Our network supports high-quality care for underserved and under-represented groups impacted by health disparities. We understand the intention behind the Drug Enforcement Administration (DEA) decision to propose changes to the in-person requirements for prescribing of controlled substances but urge the Administration to extend all the COVID-19 PHE telehealth evaluation and prescribing flexibilities permanently.

OCHIN: Driving Access to High Quality Care and Improved Outcomes Among Underserved Communities

In addition to supporting the largest network of federally qualified health centers (FQHCs) and other community clinics, OCHIN supports certified community behavioral health clinics (CCBHC), complex specialty mental health organizations, local public health agencies, corrections, school-based mental health and substance use disorders programs, and youth authorities. OCHIN's members serve rural, partially rural, urban, and suburban communities. Nearly 30% of the network's patients are best served in a language other than English, over 40% are Persons of Color and nearly 26% are Hispanic/Latino. In addition, 23% are children, almost 11% are seniors and 2% are veterans. Among the patients who received care via an OCHIN supported EHR platform in 2022, nearly 1 out of 2 are covered by Medicaid, and another quarter were uninsured; nearly 1 out of 2 had two or more chronic conditions; and more than half of our network patients live at or below the federal poverty level. OCHIN has also led efforts to build one of nine PCORnet clinical research networks funded by Patient Centered Outcomes Research Institute (PCORI) and OCHIN's researchers are national leaders in health equity research. The OCHIN led PCORnet network is the nation's largest community health center focused research networks and is the only one that includes data on underinsured and uninsured patients.

Recommendations:

While OCHIN strongly supports the proposed permanent authorization for use of audio-only telehealth when prescribing buprenorphine for opioid use disorder (OUD), we urge the DEA to:

- Establish a special registration process regulation to identify a pathway to waive in-person evaluations prior to the prescribing of controlled substances, especially for buprenorphine, for practitioners who register with the DEA as required by Congress in The Ryan Haight Act of 2008 and reiterated in The SUPPORT For Patients and Communities Act which prescribed a timeline for the process's development by 2019 which has not yet been proposed.[1]
- Extend the COVID-19 PHE flexibilities for the in-person visit requirement for prescribing of Schedule II-V Controlled Substances until, with significant stakeholder input, the Administration develops and proposes the special registration process.
- Extend all telehealth flexibilities for prescribing buprenorphine in the treatment of OUD by relying on the opioid crisis PHE first declared in 2017 during the Trump Administration and renewed every 90-days during the Biden Administration as authorized under The Ryan Haight Act.

At the very minimum, OCHIN strongly urges the DEA to:

- Extend the audio-only option to Schedule III-V Controlled Substances given OCHIN data underscoring how important this telehealth modality is for safety-net patient populations, particularly those in rural communities and facing housing and transportation insecurity.
- Remove the 30-day prescription limitation when clinically indicated for Schedule III-V Controlled Substances and there has not been an in-person or qualifying referral. This is particularly critical for buprenorphine where lack of access after initial treatment is associated with a substantially heighted risk of overdose and death. Further, there is a paucity of evidence that buprenorphine is driving overdose and death[2] —to the contrary, lack of access is driving overdose and death.
- Remove proposed requirement that a qualifying referring practitioner must be DEA-registered. The DEA registered prescribing practitioner already provides documentation that establishes an audit trail for Agency's oversight needs.
- Authorize referral to an entire medical group or organization instead of a specific clinician. This is particularly important in the context of FQHCs and community health centers. In addition, we urge the DEA to clarify that exceptions to in-person requirements can be made when providers are participating in team-based care delivery. Specifically, if a patient is being treated by a care team, they may be seen in-person by one practitioner on the care team and not need to be seen in-person by all other practitioners on the care team.
- Retain existing DEA documentation requirements without imposing additional ones for telehealth visits. Both Medicare and many Medicaid programs require telehealth billing modifiers for telehealth that can be used by the DEA when conducting audits. The additional (and duplicative) documentation requirements create another disincentive for clinicians who are hesitant to treat patients in need of

[1] We do not agree that the current proposed rules fulfill this obligation. The statute specifically directs the Agency to develop a special registration process separately from the other circumstances specified by regulation.

[2] Multiple studies have confirmed that the combination of buprenorphine/naloxone has a lower risk of overdose as compared to methadone. *Treating Opioid Dependence with Buprenorphine in the Safety Net: Critical Learning from Clinical Data*, The Journal of Behavioral Health Services & Research, 2017. Funding: ADVANCE (PCORI, 2014 – 2024). (2017). Buprenorphine was involved in a very limited number of overdose deaths (2.2%) and that did not increase during the flexibilities provided during the COVID-19 PHE. *Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic*, JAMA Network Open, (Jan. 20, 2023)

controlled substance treatment, particularly patients with OUD, because they are experiencing historically high rates of burn-out exacerbated by documentation requirements for various federal and state programs and commercial health insurers.

OCHIN Analysis: Telehealth Utilization and Access Barriers Underscore Need to Maintain COVID-19 PHE Telehealth Flexibilities

As detailed in the enclosed Appendix, OCHIN quality improvement analysts and researchers have documented the significant role that telehealth, particularly audio-only services and treatment, play in driving access to services and treatment for patients in rural and underserved communities. OCHIN also conducted an in-depth analysis of telehealth utilization among California network members (given the number of OCHIN members in the State and rural/urban and demographic diversity). This analysis documented that patients facing housing and transportation insecurity, for example, were relatively more likely to use telehealth, particularly audio-only, to access services and treatment when compared to other patients.

In addition, even prior to the COVID-19 PHE, patients in the OCHIN network faced significant barriers to in-person specialty care services and treatment including for specialties that prescribe Schedule II-V medication as part of a treatment regimen. Across the OCHIN network, average wait time to see a specialist has increased from 2019 (50 days) to 2022 (56 days). Further, average wait times vary by specialist type and different demographic groups are disparately impacted. For example, in 2022, the average wait time to see a psychologist or psychiatrist was 48 days in the OCHIN network and Hispanic patients had a longer average wait time of 52 days.

Based on data-driven retrospective analysis of OCHIN network data, OCHIN forecasts that the proposed reduction in COVID-19 telehealth flexibilities will substantially constrict access to *medically necessary* treatment and place another unprecedented strain on the safety net. If DEA does not extend existing COVID-19 PHE flexibilities, there will be a clear and direct rise in morbidity and mortality, particularly for individuals with OUD in need of buprenorphine treatment and patients in underserved and rural communities.

A Deadly Storm: Interplay of National Trends, Clinical Practice Needs, and Proposed Limits on Telehealth

Changes to any of the COVID-19 PHE flexibilities would come at a time when there is a convergence of the behavioral and mental health crises (particularly among youth), the opioid/fentanyl epidemic where access to buprenorphine treatment is critical, and the widely anticipated constriction in access to care among the most underserved due to the unprecedented volume of Medicaid revalidations of eligibility underway.[3] Any limitations on the COVID-19 telehealth flexibilities will deepen these public health crises, particularly among rural and other underserved communities. In addition, as OCHIN works with federal

[3] We appreciate the DEA's goal of reducing disruption to established patient care which prompted the proposed 180-day grace period before applying proposed restrictions to patients established via telehealth during the COVID-19 PHE for Schedule III-V Controlled Substances. However, many patients may lose coverage for a period of time due to the Medicaid re-validation process and all network members are already reporting significant strain due to staff turnover and shortages caused during the COVID-19 PHE. This will create another layer of crisis as already established patients must be scheduled within 180 days including those in rural areas, and many of the patients in the OCHIN network experience housing and transportation insecurity and instability. In addition, all new patients will have to be prioritized to be seen within the initial 30 days further straining safety net providers' capacity to deliver care for those with established care plans. This will disincentivize the treatment of new patients with OUD who require buprenorphine treatment given the additional proposed DEA documentation requirements and inability to schedule appointments.

and state legislators and policymakers to increase access to specialty care where persistent shortages continue to plague the most underserved communities, limiting prescribing for *medically necessary* schedule III-V Controlled Substances to an initial 30-day limit when there is not an in-person evaluation or qualifying referral severely limits use of this modality of care to bridge access. We anticipate that limiting telehealth will accelerate structural inequality for the most underserved and at-risk populations served in the OCHIN network.[4]

We urge the DEA to consider the Association of American Medical Colleges (AAMC) and American Association of Colleges of Nursing assessments of existing and projected shortages that have been worsening with no foreseeable end to the shortages in sight.[5] To be clear, average wait times have increased even when COVID-19 PHE telehealth flexibilities have been in place because other factors are driving persistent shortages. Without the option of telehealth, the impact of these shortages would be worse. Specifically, the number of clinicians exiting clinical practice is on the rise without a commensurate increase in clinicians to replace them. Further, the need for certain clinicians and specialists continues to rise relatively more rapidly as (1) the Baby Boom ages and attendant age-related conditions increase, (2) the disease burden due to chronic conditions increases, and (3) three unprecedented public health emergencies (COVID-19, opioids epidemic, and the mental health crisis) have converged. The assertion that there is no longer a shortage of prescribers of buprenorphine does not comport with reality for patients in the safety net—there remains a substantial mismatch between where prescribers are located and who they serve versus the needs of the most medically and socially complex. Similar mismatches are pervasive in underserved and rural communities between prescribers of other Schedule II-V Controlled Substances and where patients are located.

Finally, the 30-day limitation for buprenorphine to treat opioid use disorder is not supported by clinical practice and will exacerbate the mounting casualties of overdose and death. We are also concerned that school-based health clinics and youth authorities that are providing *medically necessary* Schedule II prescriptions via telehealth will have patients who have will have their established care disrupted worsening their health outcomes and adversely impacting them long-term. The proposed changes that reduce the COVID-19 flexibilities represent federal regulation of clinical practice that undermine the ability of clinicians to exercise their judgement to tailor treatment to patients based on specific context and medical needs.

Telehealth has become a vital modality for delivering health care. Limiting use of this modality will drive worse outcomes and harm patients. Please contact me at stollj@ochin.org if we can provide any additional information to help inform the rule making process to ensure patients can receive the care they need.

Sincerely,

Jennifer Stoll

[4] The proposed rule directly conflicts with various Executive Orders (EO) including the EO on Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government issued on the Biden Administration's first day in office.

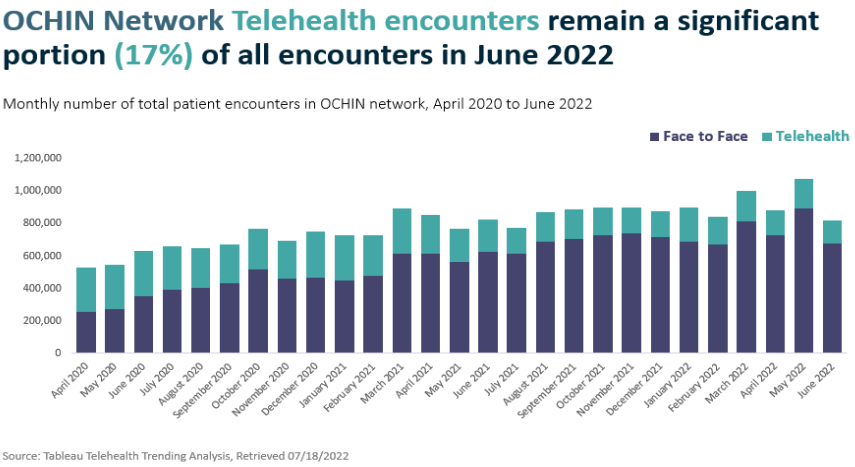
[5] See, for example, *A growing psychiatrist shortage and an enormous demand for mental health services*, *AAMC News*, August 9, 2022; *Nursing Shortage*, American Association of Colleges of Nursing, accessed March 31, 2023.

Executive Vice President
External Affairs

APPENDIX

OCHIN Data on Telehealth Utilization Among Patients Facing Structural Barriers to Access

During the COVID-19 PHE, an unprecedented amount of data was generated on the use of telehealth for the delivery of healthcare services and treatment. In the OCHIN network, telehealth utilization increased dramatically once the PHE was declared and has progressively decreased, though utilization rates still exceed pre-COVID-19 pandemic levels.



State and federal telehealth flexibilities during the COVID-19 PHE have improved access to health care services for historically underserved communities, including Hispanic patients, individuals accessing care in a language other than English, and individuals who face housing insecurity and transportation barriers.

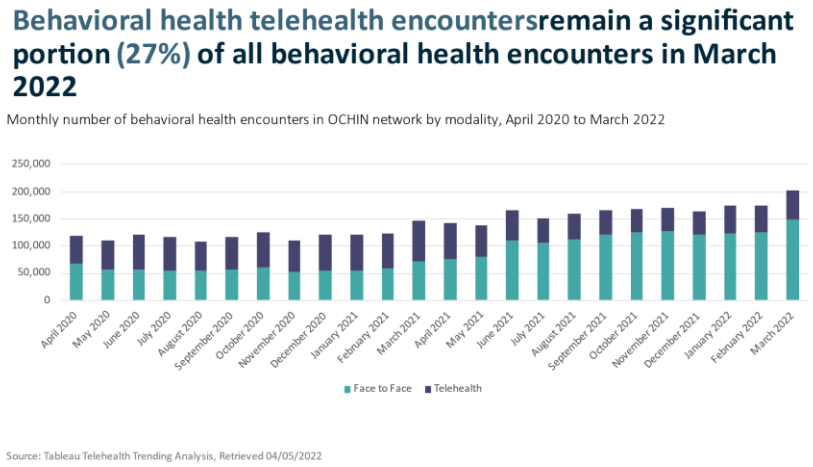
As part of our in-depth analysis of utilization in California, OCHIN analysts found that in 2020:

- 37% of OCHIN's members' patient encounters were conducted using telehealth, the majority in primary care services.
- 45% of encounters were delivered in a language other than English, with 3 out of 4 of such encounters served in Spanish.
- Patients who stated they needed housing and transportation support were 14% and 17% more likely to use telehealth, respectively.

OCHIN analysts also found that about 26% of the patients served by OCHIN members used audio-only telehealth. Among the patients served:

- 36% of audio-only encounters were for patients best served in language other than English.
- 51% of audio-only encounters were by Hispanic patients.
- Patients who were experiencing housing insecurity were 10% more likely to have an audio-only visit compared to people without housing insecurity.
- Patients who were experiencing transportation needs were almost three times as likely to have an audio-only visit compared to people with transportation.

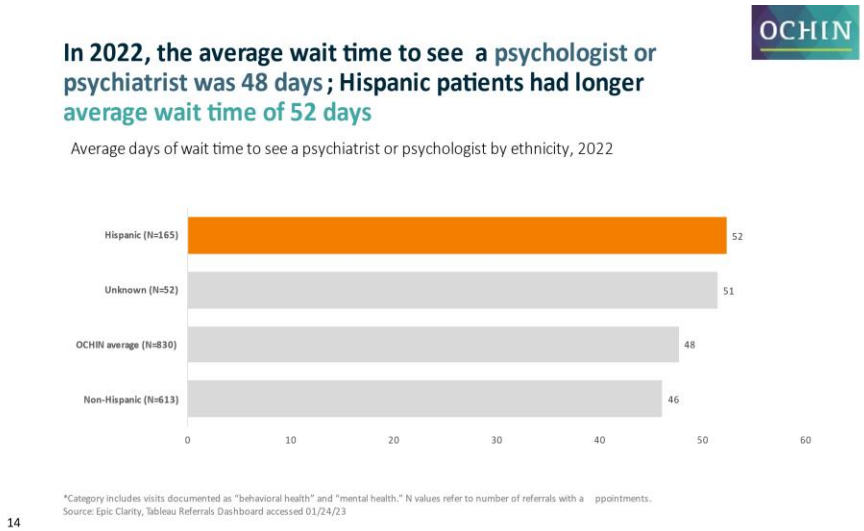
In the OCHIN network behavioral health encounters are conducted via telehealth at higher rates than other types of patient encounters, with 27% of all behavioral health visits taking place via telehealth. In March 2022, more than one in four behavioral health patient encounters was conducted via telehealth.



The implications for buprenorphine are even more pronounced. Telehealth expansion during the COVID-19 PHE helped reduce the risk of overdosing for Medicare beneficiaries struggling with opioid use, according to a study from the CDC, CMS, and the National Institute on Drug Abuse. The report also suggest that opioid users were more likely to stick with treatment longer due to telehealth options. Studies indicate that the further a patient must travel, the less likely they are to seek treatment.[6] Before the COVID-19 flexibilities, in 2018, only 11.1% of people who needed treatment for substance use received it.[7]

Persistent Primary Care and Specialty Shortages Already Limit Access to Medically Necessary Treatment

Across the nation there has been an increase of behavioral health cases and a lack of providers, as half of the counties in the U.S. do not have a psychiatrist or an addiction medicine specialist. New data from George Washington University shows that the shortages also have disproportionately affected low-income consumers, as nearly 1 of 4 behavioral health providers did not see any Medicaid beneficiaries in 2020. Some services, like psychiatric care for children, are simply not available in many areas of the nation. In testimony before the Oregon House



[6] *Distance traveled to outpatient drug treatment and client retention*, 25 J. Substance Abuse Treatment 279 (2003); *The influence of distance on utilization of outpatient mental health aftercare following inpatient substance abuse treatment*, 28 Addictive Behaviors 1183 (2003).

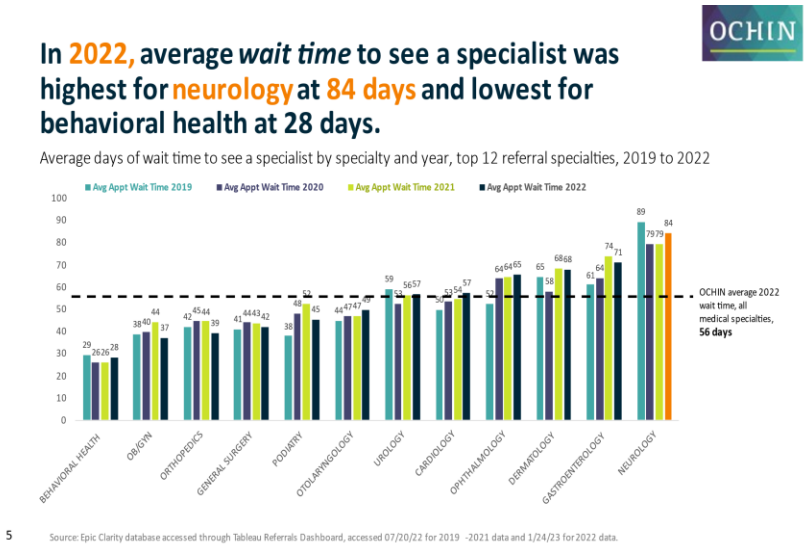
[7] *Drug and Opioid-Involved Overdose Deaths—United States, 2017-2018*. MMWR Morb Mortal Wkly Rep (2020).

Committee on Behavioral Health and Health Care, a pediatric emergency medicine specialist, described how lack of services for families in rural Oregon who have a child struggling with thoughts of self-harm. Children can be transported hundreds of miles away, by ambulance, to be evaluated at a pediatric emergency department in the Portland metro area. Almost 90% of large rural counties do not have an opioid treatment programs and that 72% do not have a buprenorphine provider. Because of the DEA COVID-19 telehealth flexibilities the number of patients receiving buprenorphine for opioid use disorder increase significantly while also improving retention and reducing the likelihood of overdoses.

The infrastructure and provider network to provide access to specialty services needed to address high incidence and high disease burden conditions such as behavioral health, diabetes, chronic heart disease, and other chronic health conditions do not exist locally for community health clinics in rural and underserved communities.

The lack of access to specialty care is not limited to behavioral and mental health specialists. In fact, in the OCHIN network, patients that require medically necessary prescriptions for Controlled Substances provided by other specialists faced even longer average wait times. OCHIN network data reflects local, regional, and national trends of limited access and delayed referrals to specialists, which are drivers of health disparities. In a 2019 analysis, OCHIN found time to appointment was 44 days on average across patients served in the network. Referrals that took longer than 2 months to schedule were 40% less likely to be completed. In 2020, average wait time for all specialty referrals increased to 52 days, and in 2021, the average wait time was even longer—56 days.

Further, wait times greatly vary based on which specialty care is needed. The reduction in telehelath prescribing of Controlled Substances when medically necessary will substantially reduce access to specialist who will not be able to treat patients via telehealth. Telehealth will be only option for many patients requiring certain specialty services and the DEA proposed rule will drive further structural barriers to access for rural and underserved communities.



Finally, the shortages are not limited to specialty care either. The Health Resources and Services Administration (HRSA), data dashboards as of February 2023 indicate 160 million people currently reside in a Mental Health Professional Shortage Area (HPSA) and there are 8,039 fewer practitioners than are needed. Currently, 99 million people reside in a Primary Care Shortage Area and there are 17,097 primary care practitioners that are needed.

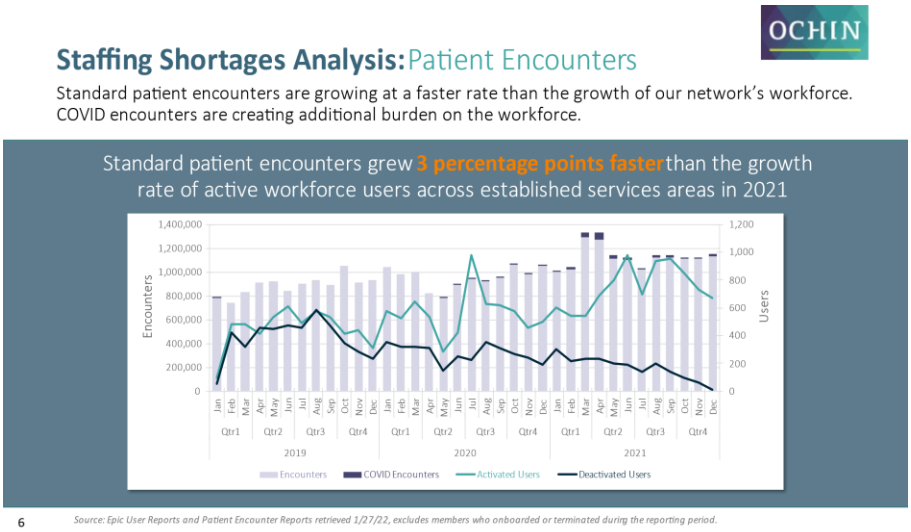
The foregoing clinician shortages are even more pronounced for school-based health clinics, corrections, and youth authorities. In the case of the latter two, the proposed 30-day rule would preclude the initiation of treatment in many correctional facilities for OUD despite the significant need as there are not

enough eligible prescribers available to conduct the in-person evaluation within 30-days and an indeterminate amount of time when an in-person evaluation could be conducted.

While HHS agencies are working judiciously to expand access, this proposed rule would limit essential modalities to improve access. For example, SAMSHA has called for grantees able to deliver care and services via modalities that are most appropriate and effective for serving children and adolescents in the rural service area. If telehealth is used, grantees must clearly demonstrate that use of telehealth will still lead to improved delivery of behavioral health services within the target rural service area. The DEA's proposed changes could significantly undermine efforts to support school-based health clinics by limiting the use of telehealth even though there may clinicians o.

Staffing Shortages and Impact of Increased Documentation Requirements

In addition to clinician shortages that have been well-documented, community health clinics are facing unprecedented operational and support staffing shortages that increase the administrative burdens faced by clinicians at a time of increased patient need.



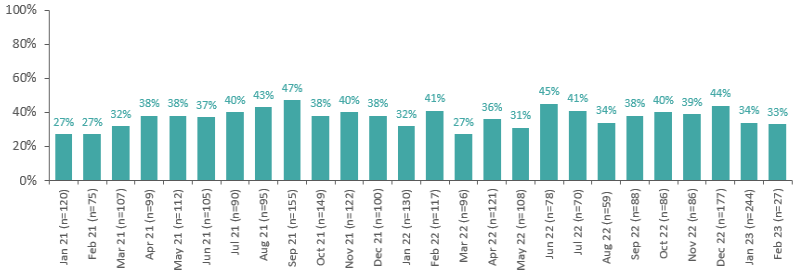
The proposed addition telehealth specific documentation requirements are duplicative as there are already existing DEA documentation requirements and Medicare and state Medicaid telehealth billing requirements related to telehealth. These are the types of redundant government paperwork requirements that are consuming limited staff time and driving clinician burn-out without a clinical or administrative benefit since the necessary information to maintain DEA audit trails is already collected.

Clinicians in the OCHIN network continue to report high rates of feeling burn-out. Chief among the cited reasons for burn-out include: (1) after hours workload (referred to a pajama time completing

documentation and administrative tasks) (37%); (2) too much time spent on bureaucratic tasks (33%); and lack of capacity in my clinic to address patient needs (30%); and (4) no personal control over my workload (e.g., working too many hours) (33%). The duplicative DEA documentation requirements will only serve to further exacerbate this burden.

This is fueling an early exodus from the nursing and physician profession further exacerbating long-standing and projected shortages.

In February 2023, 33% of providers surveyed reported feelings of burnout



1 Source: OCHIN Clinical User Satisfaction Survey, March 2023

The Telehealth Limitation on Medication Is Not Supported by Clinical Evidence and Practice

For OUD treatment using buprenorphine, the evidence base simply does not support the restrictions on the use of telehealth. Researchers from the Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services, and the National Institutes of Health found that between September 2019 and February 2021, patients receiving treatment for OUD through telehealth had 33 percent lower adjusted odds of a fatal overdose than those receiving no medication treatment, compared with a 38 percent lower risk of a fatal overdose among patients being treated in-person and 59 percent among those in certified opioid treatment programs.[8] A study of two primary care programs providing buprenorphine treatment for OUD utilizing telehealth found that the removal of the in-person requirement greatly reduced health disparities.[9]

OCHIN understands that the DEA means to control diversion by imposing a 30-day supply limitation upon the supply of a prescribed controlled substance. However, there will be some conditions that require less than 30 days-supply for treatment, while other conditions, such as some behavioral health treatments, where 30 days could pose a barrier to continuity of care and lead to increase morbidity and mortality. The DEA should identify and investigate markers of overprescribing and prescribing practices that objectively lead to increased diversion in close partnership with the U.S. Department of Health and Human Services and clinical advisors to identify practices not supported by the clinical evidence. This can be used for education first and to identify abhorrent practices.

It is crucial that we work to mitigate the risks of rural and underserved patients being unable to secure an in-person visit within 30 days through no fault of their own, due to social drivers of health and the

[8] *Association of Receipt of Opioid Use Disorder–Related Telehealth Services and Medications for Opioid Use Disorder With Fatal Drug Overdoses Among Medicare Beneficiaries Before and During the COVID-19 Pandemic*, JAMA Psychiatry March 29, 2023.

[9] *Telemedicine increases access to buprenorphine initiation during the COVID-19 pandemic*, JSAT (May 2021).

ongoing health care workforce shortages. For example, patients in rural settings face travel and access challenges, often times traveling in excess of 50 miles each way to receive a refill of the medication, taking an entire day away from other responsibilities such as work or childcare. 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. Without telehealth access, longer duration prescriptions are critical to ensuring continuity of treatment.

Telehealth Utilization and Access to Address Increasing Incidence and Severity of All Hazards Conditions

Finally, telehealth is needed to meet the increasing number of public health emergencies and environmental disasters that displace patients and render their normal care system inaccessible, situations which are particularly apt for the use of audio-only telehealth. In an emergency such as a flood or wildfire, patients will be separated from their primary provider while also experiencing heightened levels of psychological distress, a combination of circumstances that can lead to regression in substance use disorder care or degradation of mental health, outcomes they may be avoided with access to audio-only telehealth. Including telehealth as an ongoing modality to deliver care provides patients access to necessary care when they need it most and in circumstances when their ability to be served by a provider is extremely limited. Ensuring audio-only telehealth prescribing is accessible and a permitted method of prescribing Controlled Substance will help keep patients treated during times most likely to result in complications from chronic illnesses treated by controlled medication.