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Scott A. Brinks
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Submitted electronically via www.regulations.gov

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

Dear Mr. Brinks:

On behalf of AHIP,[1] thank you for the opportunity to provide input on the proposed rule on Expansion of Induction of Buprenorphine via Telemedicine Encounter, published in the *Federal Register* on March 1, 2023.

AHIP and our members strongly support the use of medications for opioid use disorder (MOUD) as a valuable tool in helping patients manage opioid use disorder (OUD) and the ability of telemedicine to bring this treatment to patients who might not otherwise be able to access it. The Substance Abuse and Mental Health Services Administration (SAMHSA) has indicated there are no significant differences between telemedicine and in-person buprenorphine for continued substance use treatment, retention in treatment, or engagement in services.

We offer our strong support for permanently expanding access to buprenorphine via telemedicine for patients with opioid use disorder and substance use disorder OUD/SUD. We are concerned that some aspects of the proposed rule would undermine this important access.

We support access to treatment in a manner that is consistent with clinical evidence on the benefits and risks of MOUD treatment and documented research, like the research cited by SAMHSA, on the effectiveness and risks of various approaches to provide this treatment.

[1] AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to making health care better and coverage more affordable and accessible for everyone. We believe that when people get covered and get and stay healthy, we all do better. The best way to do that is to expand on the market-based solutions and public-private partnerships that are proven successes.

While the country has made progress in addressing challenges associated with the opioid epidemic through more responsible prescribing, helping people connect with evidence-based treatments and recovery support, and cracking down on illicit prescribing and distribution - there is more to do to improve affordable patient access to quality care for the patients who need it.

Improving the health and well-being of those who suffer from OUD/SUD continues to be a key objective for health insurance providers, as well as many other stakeholders, including multiple federal agencies within the Department of Health and Human Services. Health insurance providers have long been committed to preventing OUD/SUD, intervening early to engage patients and others, and supporting treatment and recovery for those with OUD/SUD. For health insurance providers, clinicians, and patients to have confidence in OUD/SUD treatment and related care, those services must be evidence-based and free of stigma or other barriers to access.

In August 2022, AHIP's Board of Directors released a Statement of Commitment and a detailed advocacy vision to further improve access to mental health care and OUD/SUD treatment for every American.[2] These commitments build on health insurance providers' long history of providing access to effective, high-quality care and treatment choices, while offering new solutions for the public sector and private market partners to work together to overcome remaining barriers.

Access to OUD/SUD Care

Telemedicine has been a lifeline for millions of Americans throughout the COVID-19 pandemic, especially for those with behavioral health conditions like OUD/SUD. Data shows that telemedicine can be a cost-effective, convenient means of delivering high quality care, particularly to traditionally underserved areas.[3] As discussed in the proposed rule, this approach has proven to be a safe and convenient way to connect patients with OUD/SUD with needed evidence-based treatment.[4] Telemedicine can reduce disparities, especially for people residing in rural communities where there is limited access to in-person care for OUD/SUD[5] and help reduce or eliminate access barriers such as transportation, childcare needs, time needed off work, and other challenges some patients may face in accessing needed care.[6]

We strongly support the inclusion of telemedicine as a modality by which buprenorphine treatment for OUD/SUD can be initiated. However, we are extremely concerned that the proposed 30-day limit on the supply of buprenorphine for patients with OUD/SUD may

[2] https://www.ahip.org/resources/ahip-board-of-directors-statement-of-commitment-improving-access-to-and-quality-of-mental-health-and-addiction-support
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8430850/
[4] https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2795953
[5] https://www.ama-assn.org/practice-management/digital/telehealth-lifeline-patients-substance-use-disorders
[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8898700/

inappropriately and arbitrarily limit access and disrupt continuity of care for patients on this lifesaving treatment.

We recommend that the proposed rule follow evidence-based clinical best practices, which does not support a blanket 30-day limit on supply of this type of care for patients experiencing a chronic condition in need of ongoing treatment. Additionally, for many patients, a 30-day limit will not be enough time for patients to be able to get an appointment with a provider for an in-person visit, especially in rural and underserved communities, where access to providers may be even more limited, and given the limited number of clinicians prescribing these medications.

There is also insufficient evidence to indicate that an in-person visit has any impact on reducing diversion of buprenorphine. On the contrary, research shows that relaxing the in-person requirements of the Ryan Haight Act showed no signs of increased buprenorphine diversion.[7] And telemedicine to facilitate access to buprenorphine-based treatment for OUD during the COVID-19 pandemic was not associated with increases in buprenorphine-involved overdose deaths.[8]

We recommend the DEA consider this existing evidence and provide treating clinicians with the flexibility to determine the need for a patient to have an in-person visit to continue their therapy, based on clinical appropriateness.

If the requirement for a subsequent in-person visit is finalized, we recommend the 30-day supply limit for initial applicable telehealth prescriptions be extended to a longer period of time, at least 90 days.

We also recommend the inclusion of an exceptions process by which a provider could prescribe buprenorphine without a subsequent in-person visit where there is a valid reason, with documentation in the patient's medical record.

Lastly, we encourage the DEA to support further studies of virtual, in-person, and hybrid care for SUD/OUD treatment.

We note that prescriptions for combined buprenorphine-naloxone are a more common best practice than buprenorphine alone when used to treat addiction. Moreover, combination buprenorphine-naloxone does not carry the same risk of abuse or diversion as other controlled substances, nor does it have the same overdose risk. Because of these reasons, the DEA could consider eliminating barriers to treatment when providers prescribe this combination medication

[7] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787656
[8]https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=012023

to support patients in their ongoing recovery as an alternative or complement to the current proposal.

As an alternative or complement to the proposed rule, the DEA could consider allowing combination buprenorphine-naloxone to be prescribed via telemedicine without a specified requirement for in-person follow-up, rather than requiring all prescriptions for buprenorphine to require an in-person visit.

Equity Issues and the Social Determinants of Health

Not all individuals or communities have sufficient access to buprenorphine for the treatment of OUD/SUD. In some communities, access to this type of care is limited because there are not enough providers willing to treat patients experiencing OUD/SUD or there are not enough providers overall in certain communities, such as rural and underserved areas. The shortage of behavioral health providers and primary care providers is a well-documented problem, with some 130 million Americans living in places with fewer than one mental health care provider for every 30,000 people.[9] These shortages are particularly acute in rural areas and the impacts of these shortages disproportionately fall on people facing other challenges posed by social determinants of health (SDOH).

In fact, the SDOH that impact many people are why telemedicine provides a lifeline. Transportation, childcare, work schedules, and other challenges including concerns about stigma may prevent people from accessing in-person care. The convenience of telemedicine is often cited as the reason people in underserved communities choose virtual care.[10] We are extremely concerned that the proposed rule shifts the burden of seeking care to the patient, which is counter to the goal of increasing access to needed care for underserved and vulnerable populations.

For example, we have heard from our member health insurance providers that their enrollees currently using telehealth to access MOUD are deeply concerned about the impacts the proposed rule will have on their ability to remain fully employed. Enrollees are also expressing concerns about how a lack of childcare and transportation will make it difficult to complete the in-person visits that would be required by the new rule. Many of our member health insurance providers have programs specifically designed to benefit underserved communities by improving access to buprenorphine to treat OUD. One member described their program in an inner-city that uses telemedicine to decrease barriers to timely access to buprenorphine to treat OUD that has proven to be especially important for Black, Indigenous, and people of color (BIPOC).

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[9] https://www.kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/
[10] https://www.ahip.org/news/press-releases/new-survey-americans-value-the-convenience-and-simplicity-of-telehealth-for-their-care

Requiring an in-person visit before the 30-day supply of buprenorphine runs out threatens to undermine these types of programs designed to promote access to care and would likely exacerbate disparities. Those in areas with sufficient access to providers delivering this type of care may have an easier time meeting this requirement. But those who do not have sufficient access to this type of care will be at a disadvantage, potentially unable to refill their life-saving medication, and at greater risk of relapse.

The DEA should seek to align its rules with evidence-based clinical best practices in recognition of the challenges presented in some communities with limited access to care and experiencing SDOH.

Quality and Continuity of Care

The recent proposed rule from SAMHSA to amend 42 CFR Part 8 states that there are no significant differences between telemedicine and in-person buprenorphine for continued substance use treatment, retention in treatment, or engagement in services.[11]

Moreover, requiring in-person visits may be disruptive to some who are already stable on buprenorphine treatment, progressing with their ongoing recovery, successfully attending school or work, and engaging with their families and communities. Throughout the COVID-19 pandemic, patients have been able to use telemedicine to access treatment for OUD/SUD, including buprenorphine therapy, under the flexibilities granted during the public health emergency (PHE). As a result, some patients have been receiving buprenorphine for three years without the requirement for an in-person visit. Studies have shown comparable outcomes among those who received telemedicine-based OUD/SUD care under the PHE waivers.[12]

The proposed rule runs the risk of reversing the benefits people achieved during the PHE. Some patients may choose to forego their treatment, given the challenges with accessing in-person care, and may relapse into substance or opioid use. Others may simply seek out another doctor via telemedicine who can provide a 30-day supply of buprenorphine to allow for continued treatment – creating a new challenge with "doctor shopping."

Consistent with our recommendations above, the DEA should seek to align its rules with evidence-based clinical best practices and not risk reversing the benefits people being treated for OUD/SUD achieved during the PHE, given there is little evidence that quality of care is negatively affected when buprenorphine treatment is administered via telemedicine.

We also recommend that the DEA collaborate with stakeholders on studies to advance best practices and guidelines for implementation and modernization of SUD/OUD virtual care.

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[11] https://public-inspection.federalregister.gov/2022-27193.pdf
[12] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800718

Prescription Drug Monitoring Programs

Prescription Drug Monitoring Programs (PDMP) are powerful tools that have been used to protect patients from potential drug interactions, support coordination of patients' medications, and combat drug diversion and fraud, waste, and abuse within the system. PDMPs have been used to flag "doctor shopping," as well as "pill mill" providers who inappropriately prescribe medications to their patients. Throughout the opioid epidemic, AHIP and its members have supported the consistent use of PDMPs, including allowing health insurance provider access to these databases, and have advocated for improved interoperability across systems to enhance their oversight capabilities. These approaches would further promote patient safety and coordination of care.

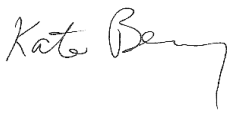
In the proposed rule, the DEA indicates that providers will be required to review the PDMP prior to prescribing buprenorphine via telemedicine. We support this requirement for providers, whether they deliver care via telemedicine or in-person, to help ensure safe prescribing and coordinated patient care and to reduce potential diversion. However, not all state PDMPs include the same medications since what drugs are included and for what purposes (prescribed to treat pain or OUD/SUD) is determined by each state. To improve coordination of care and protect patient safety, federal oversight should require that buprenorphine be included in all state PDMPs, regardless of whether they are dispensed via telemedicine or in-person, or to treat pain or OUD/SUD. Additionally, PDMPs should be accessible for providers to view in states other than those in which they practice since patients may seek care in multiple states.

AHIP supports continued use of PDMPs and recommends consistent inclusion of buprenorphine in PDMPs for both telemedicine and in-person care. Additionally, data in a PDMP should be accessible to providers viewing the information across states as well as to health insurance providers.

Throughout the COVID-19 pandemic, we have learned from patients, clinicians, and our member health insurance providers that regulatory barriers impacted the number of clinicians willing to prescribe MOUD, which, in turn, hindered patient access to care for OUD/SUD. The elimination of the DATA 2000 waiver removed a significant barrier to accessing OUD/SUD treatment. We are still in an opioid epidemic, with tens of thousands of Americans dying each year from overdoses, and we are committed to improving access to OUD/SUD treatment through telemedicine.

We look forward to continuing our partnership with the Administration and other stakeholders to promote affordable patient access to safe and effective treatment and reduce disparities.

Sincerely,



Kate Berry
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