

**March 30, 2023**

**[TO BE SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV]**

Drug Enforcement Administration  
Attn: DEA Federal Register Representative/DPW  
8701 Morrissette Drive  
Springfield, VA 22152

**RE: Docket No. DEA-948**

To the Drug Enforcement Administration (DEA):

AMERSA, Inc (Association for Multidisciplinary Education and Research in Substance use and Addiction) supports the DEA's efforts to update federal regulations related to buprenorphine telehealth.

AMERSA, founded in 1976, is a non-profit professional organization with a mission to improve health and well-being through interdisciplinary leadership and advocacy in substance use education, research, clinical care, and policy. Its membership consists of 450 experts in the field of addiction from multiple disciplines, including but not limited to, physicians, nurses, social workers, psychologists, dentists, pharmacists, and public health professionals. Many of us serve on the frontlines of the overdose crisis as federally funded scientists, teachers, treatment providers, and expert public health consultants, including to the DEA. As an organization deeply committed to improving health and well-being among people with substance use disorders, we have provided detailed comments on several topics related to the proposed regulations, as well as making several added considerations that are currently not included.

For the last three years during the COVID-19 pandemic and associated public health emergency, telehealth has been used effectively and often exclusively by patients to receive buprenorphine for opioid use disorder (OUD) treatment. Patients and providers are highly satisfied with this treatment model, which has shown high treatment retention, treatment follow up, and reductions in overdose deaths.

**To maintain and improve OUD treatment access and reduce overdose deaths, we are urging the DEA to 1) remove the 30-day in person visit requirement and 2) maintain audio-only telehealth for buprenorphine treatment as a permissible primary modality for the delivery of buprenorphine telehealth. We recommend these actions be taken through the allowances granted by the Opioid Public Health Emergency, pursuant to section 319 of the Public Health Service Act.**

## **COMMENTS RELATED TO PROPOSED RULES BY TOPIC**

**The requirement for an in-person visit and physical exam to continue buprenorphine after an initial 30-day prescription will impose inordinate barriers to care, is not based on scientific evidence, and will lead to disruptions in care that may likely result in increased overdose deaths.**

**Specific requirements for timing of an in-person evaluation should be removed. If the regulation must include a time-limit for an in-person evaluation, DEA should extend it from 30 to 180 days and this requirement should reset after 90 days of an individual being out of treatment.**

AMERSA has significant concerns that the proposed DEA 30-day in-person requirement will impose yet another barrier to accessing lifesaving buprenorphine treatment that will result in significant harm. The DEA proposal that would require the buprenorphine prescriber (or another DEA licensed prescriber in coordination with the buprenorphine prescriber) to conduct an in-person examination within 30 days is not reasonable.

**Requiring an in-person evaluation, especially one within 30 days of an initial buprenorphine prescription, will remove any option of buprenorphine access using telehealth for hundreds of thousands of people.** As DEA Administrator Anne Milgram has said in the proposed regulations, “DEA is committed to ensuring that all Americans can access needed medications.” Unfortunately, the proposed 30-day in-person requirement would undermine this goal, limiting access to these needed, lifesaving medications.

**Most individuals cannot reasonably obtain an in-person evaluation within 30 days that meets the proposed DEA criteria for buprenorphine prescribing.** Scheduling in-person visits with a primary care clinician is already challenging regardless of OUD status. Currently, more than 100 million individuals in the US do not have a primary care provider, and the average wait time for a new primary care visit is 26 days.<sup>1</sup> For others who have a primary care provider, the average wait time for a routine follow up visit is on the order of weeks to months. For people with OUD, access to a buprenorphine prescribing clinician who can offer in-person visits is further constrained. Almost 40% of US counties do not have any buprenorphine prescribers, and the median buprenorphine capacity is 4 prescribers per 100,000 people.<sup>2</sup> Appointment wait times with existing buprenorphine prescribing clinicians range from 2 weeks to 4 months, while nearly 75% of clinicians do not have any available appointments.<sup>3</sup> Although the recent elimination of the buprenorphine X-waiver is expected to increase the supply of

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<sup>1</sup> National Association of Community Health Centers. *Closing the Primary Care Gap: How Community Health Centers Can Address the Nation’s Primary Care Crisis*. National Association of Community Health Centers; 2023. Accessed March 26, 2023. <https://www.nachc.org/wp-content/uploads/2023/02/Closing-the-Primary-Care-Gap-Full-Report-2023-digital-final.pdf>

<sup>2</sup> Shatterproof. *A Report: County Buprenorphine Access in the United States*. Shatterproof; 2020.

<sup>3</sup> Flavin L, Malowney M, Patel NA, Alpert MD, Cheng E, Noy G, Samuelson S, Sreshta N, Boyd JW. Availability of Buprenorphine Treatment in the 10 States With the Highest Drug Overdose Death Rates in the United States. *Journal of Psychiatric Practice* 26(1):p 17-22, January 2020. | DOI: 10.1097/PRA.0000000000000437

buprenorphine prescribers, this increase will likely take years before an adequate supply of buprenorphine prescribers is reached. **Requiring an in-person evaluation within 30 days for patients seeking buprenorphine treatment is unrealistic given the existing barriers to accessing in-person care and will create unnecessary and stringent barriers to treatment access.**

**Patients with OUD already face inordinate barriers to lifesaving treatment, and imposing a 30-day in-person evaluation requirement for telehealth treatment initiation adds to these barriers.** For decades, we have barely moved the needle on the OUD treatment gap, with less than 20% of people with OUD in the US receiving any form of medical treatment.<sup>4</sup> The many barriers for people with OUD seeking treatment include: long commutes to nearest treatment or lack of transportation to get to in-person treatment; lack of paid time off or back up childcare to attend frequent required appointments; work and insurance policies that discourage the disclosure of addiction treatment; lack of insurance or being underinsured. These barriers to addiction care disproportionately affect those living in rural areas, persons who are Black, Indigenous, Latinx, and other socially and economically disadvantaged groups. Telehealth has been an important tool that helps bridge some of these treatment barriers for patients with OUD, and high-quality telehealth for buprenorphine treatment is feasible and essential. **People with OUD who face many existing barriers to care will likely face significant disruptions in buprenorphine treatment if they are required to complete an in-person evaluation within 30-days of initiating treatment through telehealth.**

**People with OUD who are initiating treatment are particularly vulnerable to return to using non-prescribed opioids and are at high risk for overdose death with any disruption in buprenorphine treatment.** Robust scientific and public health data show that buprenorphine saves lives, and patients do best when they are retained on buprenorphine for at least 6 months.<sup>5</sup> Individuals who are tapered off buprenorphine within 28-day period have higher likelihood of returning to non-prescribed opioid use in 3 months,<sup>6</sup> and 93% of individuals with OUD who complete shorter than a month's worth of buprenorphine treatment will return to non-prescribed opioid use.<sup>7</sup> The supply of non-prescribed opioids is easily accessible, dramatically variable in potency, and dangerous, dominated by fentanyl and fentanyl analogs. Still, patients who experience opioid withdrawal symptoms will seek out this supply for relief, knowingly risking the chance of a fatal overdose. **It is imperative to allow patients to continue buprenorphine for as long as is needed for their treatment.** Even a single day of sudden discontinuation of buprenorphine results in withdrawal that is traumatic, discouraging, and poses risk of recurrent

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<sup>4</sup> Krawczyk N, Rivera BD, Jent V, Keyes KM, Jones CM, Cerdá M. Has the treatment gap for opioid use disorder narrowed in the U.S.?: A yearly assessment from 2010 to 2019". *International Journal of Drug Policy*. Published online August 4, 2022:103786. doi:[10.1016/j.drugpo.2022.103786](https://doi.org/10.1016/j.drugpo.2022.103786)

<sup>5</sup> Shulman, M., Wai, J. M., & Nunes, E. V. (2019). Buprenorphine Treatment for Opioid Use Disorder: An Overview. *CNS drugs*, 33(6), 567–580. <https://doi.org/10.1007/s40263-019-00637-z>

<sup>6</sup> Ling, W., Hillhouse, M., Domier, C., Doraimani, G., Hunter, J., Thomas, C., Jenkins, J., Hasson, A., Annon, J., Saxon, A., Selzer, J., Boverman, J., & Bilangi, R. (2009). Buprenorphine tapering schedule and illicit opioid use. *Addiction* (Abingdon, England), 104(2), 256–265. <https://doi.org/10.1111/j.1360-0443.2008.02455.x>

<sup>7</sup> Weiss RD, Potter JS, Fiellin DA, et al. Adjunctive counseling during brief and extended buprenorphine-naloxone treatment for prescription opioid dependence: a 2-phase randomized controlled trial. *Arch Gen Psychiatry*. 2011;68(12):1238-1246. doi:10.1001/archgenpsychiatry.2011.121

use of non-prescribed opioid use. Given the toxic nature of the current drug supply, a return to use has a high likelihood of death.

**The proposed rule that an in-person evaluation be completed within 30-days of telehealth-initiated buprenorphine for OUD is not backed by evidence.** The 30-day time period is arbitrary and does not reflect the realities of barriers that patients with OUD face. The regulation as it is currently proposed suggests that no treatment after 30 days is superior to ongoing virtual care regardless of the quality or lack of alternative options that patients may have. During the ongoing opioid public health emergency, we urge DEA to not require an in-person examination. If the regulation must include a temporal requirement for receipt of in-person evaluation, we recommend this time limit be extended to 180-days or longer to ensure continuity of care and to prevent the negative health outcomes of stopping medication treatment including withdrawal, return to use, overdose, and increased utilization of health care resources. If a patient has not received an in-person evaluation within 180 days of a telehealth prescription, we recommend that prescribers be permitted to provide a subsequent prescription by telehealth if the patient has not been in their care in the last 90 days.

### **INFEASIBILITY OF PHARMACY VERIFICATION OF AN IN-PERSON VISIT**

**The requirement for an in-person visit after an initial 30-day telehealth buprenorphine prescription cannot practically be verified by pharmacists, thereby placing an undue burden on pharmacists, patients, and prescribing clinicians. This verification would be infeasible in many situations and thus create a new barrier to dispensing buprenorphine in addition to existing pharmacy-related barriers**

**As pharmacies already face deficits in willingness to stock and dispense buprenorphine, these proposed rules would significantly limit buprenorphine prescription refills, and essentially revert back to pre-COVID-19-era buprenorphine prescribing only following in-person visits.**

**Whether the prescribing practitioner has conducted the required in-person visit after an initial telehealth buprenorphine prescription cannot practically be verified by pharmacists. DEA's proposed rules do not explicitly describe the pharmacist's role nor their needed process to verify the requisite in-person visit has been completed. Current regulations on pharmacists' controlled substance "corresponding responsibility" would likely be interpreted as requiring them to take actions to verify fulfillment of in-person exam requirements to meet the "legitimate medical use" legal standard before dispensing. Without these defined processes, and with very limited time before the COVID-19 PHE ends, we expect pharmacists and pharmacy businesses to refuse refills beyond the arbitrary 30 days.** Sublingual buprenorphine products for OUD are most often dispensed for outpatient use by community pharmacies. Thus, it is critical that the impact of this proposed restriction on pharmacists be carefully considered. Concerning deficits in pharmacists' willingness to stock and dispense buprenorphine for OUD have been identified even under

current regulations.<sup>8,9</sup> Particular bias against non-local and telehealth prescribers has been noted and appears related to concerns about DEA scrutiny and opaque wholesaler limitations.<sup>10,11,12</sup>

AMERSA supported abolition of the X-waiver and believed this action would have a positive impact on pharmacy stocking, dispensing, and future collaborative prescribing. However, implementation of this proposed restriction on telehealth prescribing would spoil this achievement by adding a new layer of confusion – and an undue and unpaid burden on pharmacists – related to buprenorphine dispensing. Recent civil cases in states and counties across the country targeting pharmacy chains have sought to establish a far-ranging definition of a pharmacist's corresponding responsibility related to controlled substance dispensing. As a result, pharmacists and pharmacy chains reasonably fear that their failure to aggressively police every buprenorphine prescription will lead to future punitive actions by regulators and financial penalties in court.

Thus, it is a relative certainty that, although the DEA's proposed rules do not place specific requirements on pharmacists, pharmacists would interpret the DEA's proposed rule to require them to undertake a proactive process for investigation and documentation of the origin of EVERY buprenorphine prescription. Pharmacies would be faced with at least three major challenges when considering how to meet this new obligation: (1) lack of interoperability between prescriber electronic health records and pharmacy dispensing systems, (2) lack of interoperability between dispensing systems in different pharmacy chains, and (3) episodic use of buprenorphine due to the chronic nature of OUD. **Given these challenges, pharmacies would be likely to implement policies with the following components for the following reasons:**

1. Refusal to dispense any telehealth (if indicated) prescription for buprenorphine regardless of whether an in-person evaluation for OUD had already been completed by a referring clinician, due to:
  - Infeasibility of confirming the validity of the prior in-person evaluation for OUD completed by a different referring clinician; and
  - Infeasibility of confidently determining that the patient had not already received an initial 30-day telehealth prescription filled by another pharmacy

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<sup>8</sup> Hill LG, Loera LJ, Torrez SB, et al. Availability of buprenorphine/naloxone films and naloxone nasal spray in community pharmacies in 11 U.S. states. *Drug and Alcohol Dependence*. 2022;doi:10.1016/j.drugalcdep.2022.109518

<sup>9</sup> Kazerouni NJ, Irwin AN, Levander XA, et al. Pharmacy-related Buprenorphine Access Barriers: An Audit of Pharmacies in Counties with a High Opioid Overdose Burden. *Drug and Alcohol Dependence*. 2021;doi:10.1016/j.drugalcdep.2021.108729

<sup>10</sup> Textor L, Ventricelli D, Aronowitz SV. 'Red Flags' and 'Red Tape': Telehealth and pharmacy-level barriers to buprenorphine in the United States. *Int J Drug Policy*. May 10 2022;105:103703.

<sup>11</sup> Cooper HL, Cloud DH, Freeman PR, et al. Buprenorphine dispensing in an epicenter of the U.S. opioid epidemic: A case study of the rural risk environment in Appalachian Kentucky. *Int J Drug Policy*. Nov 2020;85:102701. doi:10.1016/j.drugpo.2020.102701

<sup>12</sup> Hill LG, Light AE, Green TC, Burns AL, Sanaty Zadeh P, Freeman PR. Perceptions, policies, and practices related to dispensing buprenorphine for opioid use disorder: A national survey of community-based pharmacists. *J Am Pharm Assoc* (2003). Jan-Feb 2023;63(1):252-260 e6. doi:10.1016/j.japh.2022.08.017

2. Requirement to call the prescriber's office and confirm that any initial in-person prescription was issued following an in-person evaluation prior to dispensing, due to:
  - Uncertainty regarding the setting of the prescriber visit even when their physical address is proximal given the increased prevalence of telehealth programs; and
  - Fear of future punitive action by regulators and financial penalties for anything less than documentation of a live discussion with a representative of the prescriber.

Prior research shows it can be challenging for pharmacists to reach buprenorphine prescribers with these types of clarifying questions, and that responding to these types of questions can be disruptive to the prescriber's workflow.<sup>11</sup> The additional administrative burden associated with these policies would lead some pharmacists to simply refuse to dispense buprenorphine altogether. This type of blanket refusal may even be codified as policy governing all pharmacists by some independent and small chain pharmacies. Short of refusing to dispense buprenorphine altogether, pharmacists and pharmacies may establish approximate physical distances from the pharmacy's physical address (e.g., 10 miles) that they deem likely to indicate that an in-person visit did not occur and to refuse to even consider those prescriptions. Stringent requirements like this have already been implemented by Wal-Mart pharmacies, leading clinicians to seek alternative locations to send prescriptions. These actions would have a disproportionate negative impact on people living in rural communities given the lower density of both pharmacies and buprenorphine prescribers.<sup>13,14</sup>

For the reasons outlined above, this proposed restriction on telehealth prescribing of buprenorphine would, for many patients, effectively mark a return to telehealth prescribing restrictions that were in place prior to the COVID-19 Public Health Emergency. Given the publicity that this announcement would bring and the far greater prevalence of telehealth prescribing of buprenorphine in 2023, this proposed restriction would also prompt increased scrutiny of in-person prescriptions for buprenorphine. The result would be life-threatening delays and disruptions in care leading to recurrence of use and death for many people with OUD.

## **RISK OF RISING OVERDOSE DEATHS FROM LIMITING TREATMENT ACCESS SHOULD BE PRIORITIZED OVER RISK OF BUPRENORPHINE DIVERSION**

**Expanded use of buprenorphine by telehealth increases treatment access and retention and reduces overdose deaths. In the fentanyl era, the risk of overdose from ongoing fentanyl use outweighs risks of buprenorphine diversion.**

**Buprenorphine access is critical for reducing overdose deaths and improving innumerable outcomes for people who use opioids.** We applaud DEA's acknowledgement

<sup>13</sup> Berenbrok LA, Tang S, Gabriel N, et al. Access to Community Pharmacies: A Nation-Wide Geographic Information Systems Cross-sectional Analysis. *J Am Pharm Assoc.* 2022;doi:10.1016/j.japh.2022.07.003

<sup>14</sup> McBain RK, Dick A, Sorbero M, Stein BD. Growth and Distribution of Buprenorphine-Waivered Providers in the United States, 2007-2017. *Ann Intern Med.* Apr 7 2020;172(7):504-506. doi:10.7326/m19-2403

of the importance of access to buprenorphine and other medications for OUD in stemming the current overdose crisis, the agency's belief that "increasing patient access to MOUD is necessary to both prevent and ameliorate the catastrophic drug poisonings that are occurring as a result of fentanyl", and its goal to "do everything in its power to safely expand access to treatment to prevent further drug poisoning deaths." Given buprenorphine's safety profile and its proven ability to reduce overdose risk among people with opioid use disorder, undue barriers to access, including requirements for in-person appointments and limitations on audio-only telehealth, should be eliminated.

**Buprenorphine treatment reduces all-cause and overdose mortality by more than 50%,<sup>15</sup> and unintentional overdose involving buprenorphine is exceedingly low.** Buprenorphine treatment is associated with a more than 50% reduction in all-cause and drug-related mortality across numerous contexts.<sup>16,17</sup> Buprenorphine improves other outcomes that are important for individual and public health, including treatment retention, infectious disease transmission, criminal justice involvement, and quality of life. In one study, buprenorphine treatment was associated with a 37% reduction in all-cause mortality during the year after a nonfatal overdose.<sup>18</sup> Buprenorphine is far more effective than almost any common medication used for other chronic conditions and, as the DEA has recognized, it is one of our most critical tools to address the current overdose crisis.

**AMERSA recognizes that the DEA is aiming to reduce potential harms of buprenorphine diversion without limiting treatment access when drafting these proposed regulations.** In the proposed rule, DEA writes that it "believes increasing patient access to MOUD is necessary to both prevent and ameliorate the catastrophic drug poisonings that are occurring as a result of fentanyl." AMERSA agrees and notes that the risk of overdose from a poisoned drug supply from fentanyl is and will be a more pressing societal issue than the risk of buprenorphine diversion for the foreseeable future. This is due to 1) the pharmacologic safety profile of buprenorphine; 2) maintenance of other strategies to prevent buprenorphine diversion (patient health information confirmation and review of PDMP databases); and 3) the fact that diverted and non-prescribed buprenorphine use is primarily a consequence of insufficient buprenorphine access.<sup>19</sup> In fact, when barriers related to pharmacy dispensing, insufficient prescriber supply, or

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<sup>15</sup> National Academies of Sciences E, Medicine. Medications for Opioid Use Disorder Save Lives. Washington, DC: The National Academies Press; 2019.

<sup>16</sup> Sordo L, Barrio G, Bravo MJ, et al. Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies. *BMJ (Clinical research ed)*. 2017;357:j1550

<sup>17</sup> Santo T, Jr, Clark B, Hickman M, et al. Association of Opioid Agonist Treatment With All-Cause Mortality and Specific Causes of Death Among People With Opioid Dependence: A Systematic Review and Meta-analysis. *JAMA Psychiatry*. 2021;78(9):979-993.

<sup>18</sup> Laroche MR, Bernson D, Land T, et al. Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality: A Cohort Study. *Annals of internal medicine*. 2018.

<sup>19</sup> Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. Factors contributing to the rise of buprenorphine misuse: 2008-2013. *Drug Alcohol Depend*. 2014;142:98-104. doi:10.1016/j.drugalcdep.2014.06.005

other reasons prevent patients from accessing buprenorphine, diverted buprenorphine use increases.<sup>20</sup> When access to buprenorphine increases, diversion rates will decrease.

**Expanded buprenorphine access via telehealth has not increased buprenorphine-related overdose deaths; limiting buprenorphine access increases overdose risk among people with opioid use disorder.** Buprenorphine is a partial opioid agonist that when taken as prescribed does not cause respiratory depression among people with opioid tolerance and has a favorable safety profile compared to full agonist opioids. As a result, buprenorphine-involved overdose is very rare and typically occurs in association with other respiratory depressant substances. Widespread access to buprenorphine has been associated with substantial reductions in overdose death.<sup>21</sup> Recent U.S. data from the COVID-19 pandemic were consistent with prior findings: very low rates of buprenorphine-involved overdose that did not increase despite reduced barriers to buprenorphine during the public health emergency.<sup>22</sup> Furthermore, receipt of telehealth services for OUD treatment during the COVID-19 pandemic was associated with *lower* odds of medically-treated overdose.<sup>23</sup> Given the substantial benefit of buprenorphine access for preventing overdose, the low risk of overdose from the medication itself, and the high risk of overdose deaths in the non-prescribed opioid agonist supply, every effort should be made to reduce barriers to this essential treatment.

#### **AUDIO-ONLY TELEHEALTH FLEXIBILITIES FOR BUPRENORPHINE SHOULD BE MAINTAINED BEYOND THE COVID-19 PUBLIC HEALTH EMERGENCY**

**Buprenorphine can be safely prescribed by audio-only telehealth with high rates of treatment follow up. Current audio-only telehealth flexibilities should be maintained as a primary option for addiction treatment initiation and linkage.**

**We commend the DEA for maintaining allowances to audio-only telehealth for buprenorphine treatment, but the current regulation does not go far enough to preserve recent gains in treatment access.** Since March 2020, buprenorphine has successfully and safely been provided via audio-only telehealth across the United States with high rates of treatment follow up.<sup>24</sup> This was a breakthrough in treatment access, as 21.3 million Americans

<sup>20</sup> Winstanley EL, Thacker EP, Choo LY, Lander LR, Berry JH, Tofighi B. Patient-reported problems filling buprenorphine prescriptions and motivations for illicit use. *Drug and Alcohol Dependence Reports*. 2022;5:100091. doi:[10.1016/j.dadr.2022.100091](https://doi.org/10.1016/j.dadr.2022.100091)

<sup>21</sup> Auriacombe M, Fatséas M, Dubernet J, Daulouède JP, Tignol J. French field experience with buprenorphine. *The American journal on addictions*. 2004;13 Suppl 1:S17-28.

<sup>22</sup> Tanz LJ, Jones CM, Davis NL, et al. Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic. *JAMA Network Open*. 2023;6(1): e2251856-e2251856.

<sup>23</sup> Jones CM, Shoff C, Hodges K, et al. Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. *JAMA Psychiatry*. 2022.

<sup>24</sup> Frost, Madeline C., et al. "Use of and Retention on Video, Telephone, and In-Person Buprenorphine Treatment for Opioid Use Disorder During the COVID-19 Pandemic." *JAMA Network Open*, vol. 5, no. 10, Oct. 2022, p. e2236298. PubMed, <https://doi.org/10.1001/jamanetworkopen.2022.36298>; Langabeer,



live in “digital deserts”<sup>25</sup>, lacking access to sufficient internet, almost a third of rural Americans lack broadband access, and hundreds of thousands of Americans are unstably housed and lack access to permanent phones.<sup>26</sup> **Limiting buprenorphine access to audiovisual health platforms excludes the most vulnerable Americans who already lack access to opioid use disorder treatment.**

CMS has recognized the importance of audio only telehealth in improving access to health care and defines “interactive telecommunications systems” to include real time, audio-only communication when necessary and appropriate, such as for the diagnosis, evaluation, or treatment of a mental health disorder, including opioid use disorder. Allowing audio-only telehealth, particularly in areas where broadband may be limited (“digital deserts”), would greatly expand access among populations who face the greatest barriers to life-saving treatment. **The current DEA regulation contradicts CMS’s telehealth definition and would significantly roll back gains in treatment access under the COVID public health emergency which successfully and safely expanded buprenorphine treatment access.**

**We support the option of audio-only telehealth as it is supported and allowed for other conditions by CMS.**<sup>27</sup> While we agree that the option of audio-visual communication should be made available to patients, **we strongly support allowing individuals continued access to buprenorphine through a telephonic modality.** Removal of this allowance would be reinstating an unnecessary barrier. Audio-only buprenorphine telehealth has been provided for two years with great success. Making it harder for people who want to access buprenorphine through legitimate means (phoning a DEA registered prescriber) is bad for patients, bad for public health, and goes against the DEA’s own goals. All measures utilized in audio visual

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James R 2nd et al. “Telehealth sustains patient engagement in OUD treatment during COVID-19.” *Journal of Substance Abuse Treatment* vol. 122 (2021): 108215. doi:10.1016/j.jsat.2020.108215; Krawczyk N, Rivera BD, King C, Dooling BCE. Pandemic telehealth flexibilities for buprenorphine treatment: A synthesis of evidence and policy implications for expanding opioid use disorder care in the U.S medRxiv 2023.03.16.23287373; doi: <https://doi.org/10.1101/2023.03.16.23287373>; Samuels EA, Khatri UG, Snyder H, Wightman RS, Tofighi B, Krawczyk N. Buprenorphine Telehealth Treatment Initiation and Follow-Up During COVID-19. *J Gen Intern Med.* 2022 Apr;37(5):1331-1333. doi: 10.1007/s11606-021-07249-8. Epub 2022 Jan 3. PMID: 34981357; PMCID: PMC8722662.; Wunsch C, Wightman R, Pratty C, Jacka B, Hallowell BD, Clark S, Davis CS, Samuels EA. Thirty-day Treatment Continuation After Audio-only Buprenorphine Telehealth Initiation. *J Addict Med.* 2023 Mar-Apr 01;17(2):206-209. doi: 10.1097/ADM.0000000000001077. Epub 2022 Sep 14. PubMed PMID: 36102540.

<sup>25</sup> Federal Communications Commission. 2020 Broadband Deployment Report. Available at: <https://www.fcc.gov/reports-research/reports/broadband-progress-reports/2020-broadband-deployment-report>

<sup>26</sup> Pew Research Center. Some digital divides persist between rural, urban, and suburban America. August 19, 2021. Available at: <https://www.pewresearch.org/fact-tank/2021/08/19/some-digital-divides-persist-between-rural-urban-and-suburban-america/>; Pew Research Center. Digital divide persists even as Americans with lower incomes make gains in tech adoption. June 22, 2021. Available at: <https://www.pewresearch.org/fact-tank/2021/06/22/digital-divide-persists-even-as-americans-with-lower-incomes-make-gains-in-tech-adoption/>

<sup>27</sup> Office for Civil Rights. Guidance on How the HIPAA Rules Permit Covered Health Care Providers and Health Plans to Use Remote Communication Technologies for Audio-Only Telehealth. June 13, 2022. Available at: <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-audio-telehealth/index.html>

telehealth to evaluate for and prevent diversion remain intact with audio-only telehealth including confirming patient identity, electronic prescribing, review of prescription drug monitoring program databases, and individual receipt of medication at a pharmacy. The person who cannot access buprenorphine through audio-only telehealth is likely to continue accessing illicit opioids, which are likely to include fentanyl (placing them at increased risk for overdose) or potentially even diverted buprenorphine (due to lack of supply of prescribed buprenorphine). Patient-centered buprenorphine access by telehealth should be permitted while minimizing documentation burdens on clinicians. Nonetheless, practitioners should follow CMS-issued guidelines<sup>28</sup> on conducting audio-only visits, and should gather all relevant clinical information needed for both diagnosis and treatment plan formulation, as they would do with an in-person visit.

Thank you again for your leadership and tireless work to finalize the proposed rules, and for providing ongoing support to expanding treatment access which will affect hundreds of thousands of people across the country. If you have questions, or if our organization can be of further assistance, please contact our Executive Director, Rebecca Northup, at [rebecca@amersa.org](mailto:rebecca@amersa.org).

Sincerely,

A handwritten signature in cursive script that reads "Deborah S. Finnell".

Deborah S. Finnell, PhD, CARN-AP, FAAN  
President, AMERSA, on behalf of the 2022-2023 AMERSA Board of Directors

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<sup>28</sup>Centers for Medicare and Medicaid. Telehealth for Providers: What You Need to Know. March 2021. Available at: <https://www.cms.gov/files/document/telehealth-toolkit-providers.pdf>