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2 October 2020

Ms. Seema Verma Administrator, Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, MD 21244

#### Re: Comments on the CY 2021 Physician Fee Schedule and other Changes to Part B Payment Policies Proposed Rule [CMS-1734-P]

Dear Ms. Verma:

On behalf of the National Association for Behavioral Healthcare (NABH), thank you for the opportunity to comment on the Center for Medicare & Medicaid Services (CMS) proposed rule regarding calendar year (CY) 2021 "Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies". We have focused our comments on Medicare coverage of services provided via telehealth, the opioid treatment program benefit and coverage of services to treat other substance use disorders (SUDs), and the need for on-going flexibility regarding scope of service rules.

NABH represents behavioral healthcare provider systems that include inpatient psychiatric facilities, residential treatment settings, partial hospitalization and intensive outpatient programs, medication assistant treatment centers including opioid treatment programs (OTPs), and other facility-based outpatient services. Our members offer behavioral healthcare services in almost every state and are focused on providing high-quality mental healthcare and addiction treatment. NABH members operate more than 380 OTPs across the country, representing about one-quarter of our nation's OTPs.

Even before the global Covid-19 pandemic, the incidence of serious mental illness (SMI) had increased significantly from 2018 to 2019, especially among those aged 18 to 25 years old.<sup>1</sup> Major depressive episodes increased most dramatically for youth and young adults, and suicidal thoughts, plans, and attempts also increased at an alarming rate during this period.<sup>11</sup> However, almost 44% of young adults with SMI and 35% of all adults with SMI did not receive treatment in 2019.<sup>111</sup> Suicide rates have continued to increase, up 35% between 1999 and 2018,<sup>112</sup> and drug overdose deaths climbed to a record high again last year.<sup>11</sup> Moreover, recent research has found evidence that substance use disorders (SUDs) constitute a risk factor for COVID-19.<sup>11</sup>

Furthermore, Covid-19 is having a considerable negative impact on the population's behavioral health. A recent report found that symptoms of anxiety disorder are approximately three times higher and prevalence of depression about four times higher among adults compared with the same time last year.<sup>vii</sup> Social distancing and isolation can worsen anxiety and depression often associated with suicide.<sup>viii</sup> In addition, economic downturns, such as the one America is experiencing now, are associated with higher rates of suicide.<sup>ix</sup> Meanwhile, overdoses have spiked during the pandemic with over 40 states reporting increased opioid-related deaths.<sup>x</sup> Past experiences with epidemics have shown that the detrimental impacts on mental health and substance use disorders among affected populations will continue for years to come.<sup>xi</sup>

#### **Telehealth for Mental Health and Addiction Treatment Services**

During the pandemic, CMS demonstrated strong leadership in expanding coverage of additional healthcare services via telehealth. These actions have been critical in enabling our members to continue providing care for individuals with mental health and/or SUDs. Given the increased incidence of SMI and addiction as well as a growing need for treatment due to the pandemic, we urge CMS to support broader availability of behavioral

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healthcare telehealth services, including via audio-only technology on a permanent basis. We also urge the agency to ensure that behavioral

healthcare clinicians are deferred to in determining which patients could benefit from receiving services via telehealth and which mental health and addiction treatment services can be effectively delivered through those modalities.

Telehealth is particularly effective in behavioral healthcare delivery.<sup>xii</sup> Examples of behavioral healthcare services that can be delivered effectively via telehealth include depression screening, follow-up care after hospitalization, behavioral counseling for SUDs, medication management, and psychotherapy for mood disorders.<sup>xiii</sup> Telehealth can also facilitate collaboration and consultation between behavioral healthcare specialists and primary care and emergency department clinicians to expand capacity to provide care for mental health and SUDs.<sup>xiv</sup> In addition, telehealth has been found to increase retention in SUD treatment, including medication treatment, especially when treatments are not otherwise available or require lengthy travel to treatment.<sup>xv</sup> Moreover, there is evidence of reduced utilization of higher-cost services associated with providing access to behavioral healthcare services via telehealth technologies.<sup>xvi</sup>

Our members' experiences delivering behavioral healthcare during this pandemic is consistent with these research findings. Shortly after the pandemic began, our members rapidly adjusted their programs and services to implement telehealth technologies so they could continue providing critically needed mental health and addiction treatment services during this stressful time.

According to our members, increased telehealth use has resulted in improvements in patient engagement in behavioral healthcare even compared with the time period before the pandemic; for example, average time to first appointments decreased, attendance at first appointments increased, days to first appointment after inpatient care decreased, and average numbers of services per consumer increased significantly. These reports are also consistent with a recent National Committee for Quality Assurance report on telehealth finding reductions in patient missed appointments and increases in behavioral healthcare utilization.<sup>xvii</sup>

Moreover, consumer surveys consistently show very high rates of satisfaction using telehealth technologies to access treatment.<sup>xviii</sup> Information from our members has confirmed high levels of consumer satisfaction as well, with a majority of consumers indicating the services received via telehealth were as or more helpful, and consumers reporting they would like to continue receiving services via telehealth.

In general, many individuals who could benefit from behavioral healthcare are reticent to access treatment. Moreover, many who do access treatment discontinue therapy prematurely or do not stay engaged for various reasons. The experience of our members during this pandemic indicate that making services available via telehealth could significantly increase access to behavioral healthcare that is a critical need at this time.

We support the provisions of the Physician Fee Schedule proposed rule that would continue some of the expanded Medicare coverage of services provided via telehealth, including provisions to extend permanently Medicare coverage of group psychotherapy and psychological testing. We also support provisions clarifying that clinical social workers and clinical psychologists and therapists can furnish online assessment and management services, virtual check-ins, and remote evaluations.

We urge you to continue covering evaluation and management services and behavioral health counseling as well as opioid/addiction treatment program counseling and periodic assessment services provided via audio-only technology, i.e., telephone.

Coverage for services provided via audio-only technology is particularly important for the most vulnerable among our members' patient populations, including Medicare beneficiaries who are older and/or challenged

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with disabilities. These individuals often face additional barriers to accessing care through the newer videobased technologies and platforms. Requiring use of the video technology will undermine the improved access that CMS has advanced. Our members are also concerned that many of

their more vulnerable patients are unemployed or under-employed and sometimes homeless and simply do not have access to internet service to support video technology.

Moreover, access to broadband service to support video technology is often very limited in rural areas that also face severe behavioral healthcare provider shortages. Almost 120 million people live in mental health professional shortage areas, most of which are in rural areas,<sup>xix</sup> and about 80% of rural counties have no practicing psychiatrists.<sup>xx</sup> Coverage for telehealth services for mental health and addiction treatment can enable people who live in underserved areas to access specialists including behavioral healthcare providers residing in other areas. Limiting coverage to services provided via video will limit telehealth's ability to improve access to mental health and addiction treatment services for individuals in areas lacking good broadband coverage and with very limited access to behavioral healthcare providers.

Covering a longer virtual check-in via audio-only technology, as the CY 2021 Physician Fee Schedule rule proposes, would not be sufficient to support continued widespread access to behavioral healthcare services via telehealth. Currently, virtual check-ins can be used only to help existing patients. Telehealth visits can reportedly support developing a sufficient clinician/patient relationship that makes the previous in-person relationship unnecessary.<sup>xxi</sup>

Moreover, there is a large unmet need for services among those with SMI and/or addiction that telehealth could help address. Limiting coverage to existing patients and only for quick check-ins significantly undercuts the potential for telehealth to improve access to behavioral healthcare. We urge CMS to extend coverage of audio-only evaluation and management services for Medicare beneficiaries to improve access among many vulnerable populations who may not qualify as existing patients and may need a fuller set of services than a virtual check-in would support.

**Furthermore, we recommend continuing to pay for these services at the same or comparable rates as in-person care–as well as paying for administrative fees to help cover the costs of this technology.** Behavioral healthcare providers operate in general with very low margins partly because reimbursement rates for services are often much lower for behavioral healthcare than they are for other specialty care providers. Reimbursement for behavioral healthcare telehealth services should account for the overhead and administrative costs of providing these services in office settings, as well as the cost of purchasing technology and staff training. We urge CMS to maintain full reimbursement for telehealth services comparable to in-person rates in order to take advantage of this unexpected opportunity to improve access to behavioral healthcare that the growth in telehealth has made possible.

We also support the proposed rule's provisions that continue the flexibility provided during the pandemic to allow direct supervision of incident-to and diagnostic services provided virtually via telehealth. Flexibilities such as this have enabled our members to extend the capacity to provide behavioral healthcare services during these difficult times. Physician supervision requirements mandating that supervising clinicians be onsite when a service is provided have impeded the use of telehealth in the past. We urge CMS to allow permanently direct supervision to be done remotely when clinically appropriate rather than extending this flexibility only until the end of the year when the public health emergency (PHE) ends.

Finally, we appreciate the proposed rule's clarification regarding how CMS plans to implement Section 2001 of the *SUPPORT Act* extending Medicare telehealth coverage to include services provided to patients in their homes for treatment of an SUD or co-occurring mental health disorder. CMS proposes to limit permanent coverage to evaluation and management of an *established* patient for *less complex* 

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conditions. CMS also proposes to cover *temporarily* (until the end of the calendar year when the PHE ends) telehealth visits for established patients in their homes for moderate to severe SUDs or co-occurring mental health disorders.

However, there is no indication that Congress intended Medicare coverage of in-home telehealth services for SUD and/or co-occurring mental health disorders to be limited to established patients and treatment for less complex conditions. As CMS highlights in the proposed rule: "due to the vulnerability of this particular patient population, who are receiving treatment for a diagnosed substance user disorder or co-occurring mental health disorder, [CMS] should maximize the availability of telehealth services for the treatment of substance use disorders and co-occurring mental health disorders."<sup>xxii</sup> Individuals with more complex conditions are often more at risk and in greater need of easy access to treatment services including services via telehealth while at home. We therefore urge CMS to implement fully the statutory authority to cover permanently all medically necessary and clinically appropriate home visits via telehealth – including via audio-only technology – to improve access to treatment for SUDs and/or co-occurring mental health conditions.

#### Other Substance Use Disorder and Opioid Treatment Program Provisions

**NABH supports including naloxone medication formulations in the definition of OTP services and as an add-on to the OTP bundle**. Dispensing naloxone through OTPs is more effective than prescribing, as it builds on the trust of the patient-provider relationship and increases the chance that patients will obtain the medication, use it, and use it appropriately. It also reduces the burden for a patient to be able to receive naloxone as part of the OTP comprehensive services and supports social distancing by reducing additional medical encounters. For the 12-month period ending February 2020, deaths from drug overdoses are expected to exceed 74,000 individuals. With the reported increase in overdoses by almost 18% during the Covid-19 crisis,<sup>xxiii</sup> improving access to naloxone is critical.

Unfortunately, the CMS proposal to reimburse at ASP + 0% would disincentivize the provision of naloxone by OTPs. The ASP methodology includes rebates and discounts that are not available to many OTP providers. Thus, an OTP would pay \$125.00 for a nasal two-pack but receive only \$89.63 in reimbursement. This is not economically viable and would undermine the goal of increasing access to naloxone. Instead, we recommend a reimbursement formulation of cost+6% for the nasal and auto-injector. We believe this reimbursement rate would address the federal interest in containing costs by providing a cap. Importantly, it avoids imposing a financial loss on OTPs for providing naloxone and takes into account OTP overhead costs (e.g., training, security), thereby encouraging OTPs to provide this critical medication.

**NABH does not support imposing frequency limitations on the provision of naloxone to once per month.** Repeat and more frequent dosing is sometimes required to reverse potent fentanyl derivatives and stimulantinvolved overdoses. Twenty-four percent of patients who received naloxone through a nasal spray needed an additional "rescue dose," compared with 9 percent of those who received naloxone through injection.<sup>xxiv</sup> Other research shows that six administrations of generic naloxone with an atomizer may be necessary to reach the naloxone blood levels achieved with one spray of Narcan.<sup>xxv</sup> We believe provision of medication should be individually, clinically determined by medical necessity, not administrative pricing policy.

**NABH supports including community education for naloxone as an add-on** service to the OTP bundle. However, the proposed reimbursement for the service (96161 health risk assessment – depression inventory at \$2.53) is not commensurate with the cost of the service nor reflective of the required staff involvement and overhead costs. We recommend a reimbursement rate of \$20.00 at 15-minute increments.

**NABH does not support recoupment of duplicative payments made to OTPs for naloxone**. OTPs do not have the structural capacity to be aware of and/or prevent other providers from prescribing naloxone through Medicare Part D. This will be especially difficult alongside federal and other national policy initiatives to encourage physicians

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to increase the co-prescribing of naloxone for individuals who are receiving opioid medications. It is inappropriate to require OTPs to absorb the cost for decisions made by other providers.

NABH supports continued coverage of periodic telehealth assessments beyond the PHE, but we urge that these assessments be reimbursed every 60-90 days, consistent with many state requirements to perform such assessments. As previously stated, during the Covid-19 PHE, telehealth has expanded access to services for very vulnerable populations. Reimbursement at in-person rates is critical, not only to support the additional costs of the use of audio-visual platforms, but to maintain the basic organizational infrastructure, staffing, and security that support the telehealth services. OTPs are often geographically distant from their patients or patients may have long and costly travel times that can discourage program participation. Continued telehealth services will therefore yield important new access for these individuals.

**Furthermore, we believe it is necessary to continue coverage of audio-only periodic assessments to maintain and further expand access.** Many individuals who participate in OTPs do not own audio-visual devices. During the PHE, audio-only encounters have proven to be effective tools in clinically engaging some individuals in treatment who otherwise would not engage face-to-face. We support including the audio-only periodic assessments in the bundle as part of a framework in which periodic telehealth assessments are permitted more than annually, consistent with state requirements.

Under the current rules, programs that have Substance Abuse and Mental Health Services Administration (SAMHSA) *provisional certification* are unable to receive reimbursement. This means, for example, that an existing medication unit functioning under a certified OTP is not permitted to receive coverage for services during its oneyear transition from provisional to full certification. We urge CMS to reconsider this provision. The *SUPPORT Act* requires that an OTP have "…in effect a certification by the Substance Abuse and Mental Health Services Administration for such a program…" and is silent on the issue of full or provisional certification. We read the intent and language of the *SUPPORT Act* as requiring that an OTP align with the SAMSHA certification *rubric and process*, and we urge CMS to recognize provisional certification as one level of a valid SAMHSA certification and sufficient for participation in Medicare.

We want to emphasize how important it is that OTPs be permitted to continue providing take-home medications. In order to deliver care to those who need it, the federal government must offer providers the regulatory flexibility to expand essential treatment. During the PHE, providers and patients have demonstrated the ability to engage in therapeutic care that preserves public and individual safety through the greater use of take-home medication coupled with telehealth treatment services. All federal government agencies should support both elements of this effective service model—covering telehealth treatment services as well as allowing and reimbursing for take-home medications.

We reiterate our support for a suggestion we made last year to address the higher level of opioid overdose and death rates that exist in rural areas. Specifically, there were 20 deaths per 100,000 in rural counties in 2017. Exacerbating the problem is the inadequate number of OTPs in 88.6% of the larger rural counties. There is a dangerous gap between service capacity and treatment need, and it must be bridged if the federal government is to improve access and quality of care and reduce national rates of opioid overdose and death.

# NABH recommends a rural adjustment of 17% be offered to OTPs who develop new facilities in federally designated rural counties, consistent with the adjustment in the CMS Inpatient Psychiatric Facility Prospective Payment System.

Our members have said the Medicare OTP benefit has been very successful. We believe this is due to the structure of the bundle and its simplicity. We reiterate our recommendation from last year that CMS maintain a simple one-bundle structure through which providers receive adequate compensation for

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treatment services. This approach helps to ensure each individual patient receives the care he or she needs in the right setting, at the right time, and with appropriate treatment intensity.

Bundles are structured to account for a range of services of variable intensity over time and across patient populations without being overly prescriptive about the individual patient services. In a bundled payment arrangement, it is expected that some individuals will receive a higher level of service while some will receive a lower level of service, and a consistent payment methodology will account for both situations. The current bundle structure addresses the needs of patients in the induction and maintenance periods of treatment.

If CMS develops a stratified payment structure, then we urge a delay of another year and request additional stakeholder engagement. This first year of the benefit was highly unusual in clinical patterns and business practices, making it difficult to determine fair and appropriate reimbursement strategies and disrupting OTP transition to this new Medicare benefit.

Furthermore, we appreciate the flexibility offered to providers to enable standardizing dates of service and the ability to use institutional claims forms to bill for OTP services.

**NABH supports the agency's proposal to expand the PFS bundled payments for OUD to all SUDs** while revising the relevant procedure code descriptions. This will permit comprehensive services for individuals with SUDs, the majority of whom have a polysubstance use disorder. We also support an additional evaluation and management add-on G-code for the initiation of medication assisted treatment in the emergency department. Reimbursement for this service will encourage hospitals to engage in this evidence-based practice.

#### Scope of Service and Additional Regulatory Flexibilities

Thank you for proposing to extend some flexibilities in the scope-of-service requirements. In particular, we support allowing certain nonphysician practitioners to supervise diagnostic tests to the extent authorized under state law. We also appreciate the clarification that non-physician practitioners can review and verify documentation entered into the medical record by members of the treatment team for their own services that Medicare covers. We urge the agency to extend other changes in the scope-of-service rules that have been allowed during the PHE. These changes would help behavioral healthcare programs to use their staff more fully to provide mental health and addiction treatment services they are qualified and otherwise authorized to provide.

### **Budget Neutrality**

Finally, we are concerned how proposed modifications to payment rates for evaluation and management will affect reimbursement for other critical behavioral healthcare services. We appreciate the adjustments made to the psychiatric diagnostic interview and several psychotherapy codes.

However, we are concerned these adjustments will be insufficient to mitigate the impact of changes to the evaluation and management rates. We urge CMS to determine a method to implement budget neutrality requirements that avoids reducing payment for and access to critical mental health and addiction treatment services while also working with Congress to address this budget neutrality issue in legislation.

Thank you for considering these important provisions. If you have questions, please contact me directly at <u>shawn@nabh.org</u> or 202-393-6700, ext. 100, or contact NABH Director of Policy and Regulatory Affairs Kirsten Beronio at <u>kirsten@nabh.org</u> or 202-393-6700, ext. 115, or Director of Quality and Addiction Services Sarah Wattenberg at <u>sarah@nabh.org</u> or 202-393-6700, ext. 114.



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Sincerely,

Shawn Coughlin President and CEO

#### About NABH

The National Association for Behavioral Healthcare (NABH) represents provider systems that treat children, adolescents, adults, and older adults with mental health and substance use disorders in inpatient behavioral healthcare hospitals and units, residential treatment facilities, partial hospitalization and intensive outpatient programs, medication assisted treatment centers, specialty outpatient behavioral healthcare programs, and recovery support services in nearly all 50 states. The association was founded in 1933.

<sup>i</sup> Substance Abuse and Mental Health Services Administration, "Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health", 2020, available <u>online</u>. <sup>ii</sup> *Ibid.* 

iii Ibid.

<sup>iv</sup> Hedegaard H, Curtin SC, Warner M, "Increase in suicide mortality in the United States, 1999–2018", Data Brief No. 362, National Center for Health Statistics, 2020, available <u>online</u>.

<sup>v</sup> National Vital Statistics System, "Rapid Release Provisional Drug Overdose Death Counts" (based on data available for analysis on 9/13/ 2020), available <u>online</u>.

<sup>vi</sup> Wang QQ, Kaelber DC, Xu R, Volkow ND, "COVID-19 risk and outcomes in patients with substance use disorders: analyses from electronic health records in the United States", Molecular Psychiatry, September 2020, available <u>online</u>.

<sup>vii</sup> Czeisler MÉ, Lane RI, Petrosky E, et al., "Mental Health, Substance Use, and Suicidal Ideation During the COVID-19
Pandemic — United States", June 24–30, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1049–1057, available <u>online</u>.
<sup>viii</sup> Petterson S, Westfall JM, Miller BF, "Projected Deaths of Despair During the Coronavirus Recession", Well Being Trust, May 8 2020, available <u>online</u>.

<sup>ix</sup> Oyesanya M, Lopez-Morinigo J, Dutta R, "Systematic review of suicide in economic recession", *World J Psychiatry*, vol. 5, no. 2, 243-54, June 22, 2015, available online.

<sup>x</sup> American Medical Association, "Issue brief: Reports of increases in opioid-related overdose and other concerns during Covid pandemic", updated Sept. 8, 2020, available online.

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<sup>xii</sup> Mace S, Boccanelli A, Dormond D, "The Use of Telehealth within Behavioral Health Settings: Utilization, Opportunities, and Challenges", Behavioral Health Workforce Research Center, University of Michigan, March 2018, available <u>online</u>; Bashshur RL, Shannon GW, Bashshur N, Yellowlees PM, "The empirical evidence for telemedicine interventions in mental disorders", *Telemed J E Health*, vol. 22, no. 2, pp. 7-113, Jan. 2016.

x<sup>iii</sup> National Quality Forum and American Hospital Association Center for Health Innovation, "Redesigning Care : a How-To Guide for Hospitals and Health Systems Seeking to Implement, Strengthen and Sustain Telebehavioral Health", 2019, available <u>online</u>. <sup>xiv</sup> Mace S, Boccanelli A, Dormond M, "The Use of Telehealth within Behavioral Health Settings: Utilization, Opportunities, and Challenges", Behavioral Health Workforce Research Center, University of Michigan, March 2018, available <u>online</u>;

<sup>xv</sup> Lin L, Casteel D, Shigekawa E, et al., "Telemedicine-delivered treatment interventions for substance use disorders: A systematic review", *Journal of Substance Abuse Treatment*, vol. 101, pp. 38-49, June 2019.

<sup>xvi</sup> Shigekawa, E, Fix, M, Corbett, G, et al., "The current state of telehealth evidence: A rapid review", *Health Affairs*, 37(12), 1975-1982 (2018).

<sup>xvii</sup> National Committee for Quality Assurance, Taskforce on Telehealth Policy, Findings and Recommendations, Sept. 2020, available <u>online</u>.

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<sup>xviii</sup>Polinski J, Barker T, Gogliano N, et al., "Patients' Satisfaction with and Preference for Telehealth Visits," *J Gen Intern Med,* vol.31, no. 3, pp. 269-275, March 2016.

<sup>xix</sup> Bureau of Health Workforce, Health Resources and Services Administration (HRSA), U.S. Department of Health & Human Services, Designated Health Professional Shortage Areas Statistics: Designated HPSA Quarterly Summary, as of March 31, 2020, available <u>online</u>.

 <sup>xx</sup> McKinsey & Company, "Covid-19 Response: Behavioral Health & Health-related Basic Needs", April 7, 2020 presentation; Merritt Hawkins, "2017 Review of Physician and Advanced Practitioner Recruiting Incentives", available <u>online</u>.
<sup>xxi</sup> National Committee for Quality Assurance, Taskforce on Telehealth Policy, Findings and Recommendations, Sept. 2020, available <u>online</u>.

<sup>xxii</sup> Centers for Medicare and Medicaid Services, Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed Reg 50074, 50098, August 17, 2020.

<sup>xxiii</sup> Alter A, Yeager C, "COVID-19 Impact on US National Overdose Crisis" (Overdose Detection Mapping Application Program is a syndromic surveillance system that provides near real time suspected overdose data nationally), June 2020, available <u>online</u>. <sup>xxiv</sup> Dietze, P, Jauncey M, et al., "Effect of Intranasal vs Intramuscular Naloxone on Opioid Overdose: A Randomized Clinical Trial." JAMA Netw Open 2(11): e1914977 (2019), available <u>online</u>.

<sup>xxv</sup> Krieter PA, Chiang CN, Gyaw S, McCann DJ, "Comparison of the Pharmacokinetic Properties of Naloxone Following the Use of FDA-Approved Intranasal and Intramuscular Devices Versus a Common Improvised Nasal Naloxone Device", J Clin Pharmacol, 59(8):1078-1084, Aug. 2019, available <u>online</u>.