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October 28, 2021

BY ELECTRONIC DELIVERY

Honorable Ron Wyden
Chairman
Committee on Finance
221 Dirksen Senate Office Building
Washington, D.C. 20510

Honorable Mike Crapo
Ranking Member
Committee on Finance
239 Dirksen Senate Office Building
Washington, D.C. 20510

Re: Addressing Unmet Behavioral Health Needs

Dear Chairman Wyden and Ranking Member Crapo:

Thank you for your many efforts on behalf of people living with serious mental illnesses and substance use disorders[1] and for your invitation to provide input on how we can best care for the millions of Americans who are struggling with these challenges. We appreciate that you have chosen to focus on mental health [2, 3] and agree that there are numerous opportunities for improving the mental well-being of our nation.

Alkermes is a biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop, and commercialize, both with third parties and on our own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. Alkermes' marketed drug products include:

- VIVITROL® (naltrexone for extended-release injectable suspension; XR-NTX) [4, 5] and counseling indicated for adults in the treatment of alcohol dependence for patients who are able to abstain from alcohol in an outpatient setting, and for the prevention of relapse to opioid dependence following opioid detoxification;
- ARISTADA® (aripiprazole lauroxil)[6], indicated for the treatment of adults for schizophrenia;

[1] Throughout this comment we use the terms "behavioral health disorders" and "mental disorders" as umbrella terms to include the full spectrum of serious mental illnesses and substance use disorders.
[2] U.S. Senate Finance Committee. To Members of the Behavioral Health Community and Other Interested Stakeholders. September 21, 2021. https://www.finance.senate.gov/imo/media/doc/092221%20Bipart%20mental%20health%20RFI.pdf
[3] U.S. Senate Finance Committee, Subcommittee on Health Care. The COVID-19 Pandemic and Beyond: Improving Mental Health and Addiction Services in Our Communities. May 12, 2021. https://www.finance.senate.gov/hearings/the-covid-19-pandemic-and-beyond-improving-mental-health-and-addiction-services-in-our-communities
[4] Alkermes, Inc. (March 2021 revision). VIVITROL® Prescribing Information. Accessed at: https://www.vivitrol.com/content/pdfs/prescribing-information.pdf
[5] Alkermes, Inc. (March 2021). VIVITROL® Medication Guide. Accessible at: https://www.vivitrol.com/content/pdfs/medication-guide.pdf
[6] Alkermes, Inc. (March 2021 revision). ARISTADA® Prescribing Information. Accessible at: https://www.aristadahcp.com/downloads/ARISTADA-PI.pdf

- ARISTADA INITIO® (aripiprazole lauroxil)[7], which in combination with oral aripiprazole is indicated for the initiation of ARISTADA; and
- LYBALVI® (olanzapine and samidorphan), indicated for the treatment of adults with schizophrenia, and for the treatment of adults with bipolar 1 disorder, as a maintenance monotherapy or for the acute treatment of manic or mixed episodes as monotherapy or an adjunct to lithium or valproate.[8]

We offer comments in the following areas:

STRENGTHENING WORKFORCE
Questions from the Committee:

- **What barriers, particularly with respect to the physician and non-physician workforce, prevent patients from accessing needed behavioral health services?**

Findings: The Serious Mental Illness (SMI) and Substance Use Disorder (SUD) Workforces are Faced with a Burdensome Reimbursement System - In summarizing challenges associated with improving access to evidence-based treatment for substance use disorders, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) of the U.S. Department of Health and Human Services summarized the challenge: *"Many barriers to accessing evidence-based treatment for substance use disorder (SUD), particularly medication assisted treatment, are related to the workforce. Barriers include workforce shortages for certain providers, insufficient training, education and experience, lack of institutional and clinician peer support, provider stigma and inadequate or burdensome reimbursement."*[9]

In particular, ASPE reported that SUD clinicians were paid less ($5 to $13 lower) than other comparably credentialed healthcare professionals.[10] ASPE goes on to state: *"On the supply side, low wage rates for SUD treatment professionals are associated with high turnover and difficulty in hiring qualified staff. Individuals trained to provide SUD treatment quickly move on to other professions that offer better working conditions, wages, and benefits."*[11]

There is evidence that addiction physicians also face inadequate reimbursement for treatment services provided. In a study of access to specialty physicians in the United States, the researchers found that there was less access to addiction medicine specialists than any of the other specialties in their study. According to their analysis, only 8% of counties had even one addiction medicine physician.[12] According to the researchers, availability of addiction medicine specialists was related to the reimbursement rates: the highest paid specialists are the most prevalent - and vice versa. This study concludes: "*The opioid crisis and lack of addiction medicine specialists offer a cautionary tale. Ultimately, a shift toward a more balanced workforce requires meaningful changes in how Medicare's $90 billion of professional service payments are allocated*."

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[7] Alkermes, Inc. (March 2021 revision). ARISTADA INITIO® Prescribing Information. Accessible at:. https://www.aristadahcp.com/downloads/ARISTADA-INITIO-PI.pdf
[8] Alkermes, Inc. (May 2021). LYBALVI™ Prescribing Information. Accessed at: https://www.lybalvi.com/lybalvi-prescribing-information.pdf
[9] U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. *Substance Abuse Disorder Workforce* (2018). https://aspe.hhs.gov/system/files/pdf/259346/ExamSUDib.pdf
[10] ASPE. Examining Substance Use Disorder Treatment Demand and Provider Capacity In A Changing Health Care System: Final Report. (Dec. 2017). Page xiii. https://aspe.hhs.gov/system/files/pdf/259356/ExamSUDfr.pdf
[11] Ibid. Page 34.
[12] Goodson, J.D., Shahbazi, S. and Song, Z., 2019. Physician Payment Disparities and Access to Services—a Look Across Specialties. *Journal of general internal medicine*, pp.1-3.

Additionally, a health services study[13] of physician-reported barriers to XR-NTX and buprenorphine in office-based practices reported that "*Participants with experience prescribing buprenorphine and/or extended-release naltrexone emphasized insurance prior authorization requirements for MAT as a time-consuming and resource-consuming barrier. Delays caused by prior authorization may also cause patients to lose treatment motivation."* [14] Similarly, in a separate study of SUD treatment providers, the authors report that "*Preauthorization processes can inhibit treatment programs and patients from initiating XR-NTX treatment."* [15] As one treatment provider stated: "*…with the whole process of preauthorization, that's a real area of difficulty for me because they, I would have to imagine, intentionally make the process somewhat difficult…I don't want to put my bias, but I think that the insurance companies are hoping that I give up.*" As the authors of this study note, "*…step therapy may require that the patient fail in abstinence-based counseling and fail with daily dosing of oral naltrexone before authorizing XR-NTX. Fail first requirements increase the risk of return to use, overdose, or death.*"

Finally, in many states, physicians and non-physician clinicians must navigate a wide range of different prior authorization requirements in the same state. For example, according to an internal review Alkermes conducted[16], California, New York, Michigan, and Florida each have *12 or more different managed Medicaid plans* operating, and each of these plans have unique requirements with which treatment providers must comply to receive reimbursement for treatment services provided. The diversity of PA policies among these managed Medicaid plans introduces additional work and risk, of mistakes which could lead to non-payment.

Recommendation #1: Expand Bundled Payments for SUD Treatment - CMS recently implemented bundled payment codes for the treatment of opioid use disorder (OUD) in opioid treatment programs (OTPs) under Medicare. These new billing codes provide bundled payment for the full range of Food and Drug Administration (FDA)-approved drugs, as well as payment for the associated "non-drug costs".[17] We encourage the Committee to consider expanding the use of the bundled payment model for the treatment of all SUDs in certain healthcare settings such as residential SUD rehabilitation centers; hospitals; recovery housing[18]; and correctional settings[19]. Further, we encourage CMS to disseminate guidance to State Medicaid Directors on bundled payment models that could streamline reimbursement for the full range of SUDs in all healthcare settings.

Recommendation #2: Allow Additional Reimbursement in Hospitals and Residential Treatment Centers for SUD Treatment – CMS should modify Medicare to allow hospitals to receive additional reimbursement for the purchase and administration of FDA-approved extended-release injectable medication. The bundled payment model, discussed above, is one potential reimbursement methodology for achieving this, although other approaches may also be viable.

[13] Andraka-Christou, B. and Capone, M.J., 2018. A qualitative study comparing physician-reported barriers to treating addiction using buprenorphine and extended-release naltrexone in US office-based practices. *International Journal of Drug Policy, 54*, pp.9-17.
[14] Ibid, page 13.
[15] Alanis-Hirsch, Kelly, et al. "Extended-release naltrexone: A qualitative analysis of barriers to routine use." Journal of substance abuse treatment. 62 (2016): 68-73. See page 71 for discussion of prior authorization and health plan barriers.
[16] Data on file.
[17] CMS. Opioid Treatment Programs Medicare Billing and Payment Fact Sheet. https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf
[18] National Association of Recovery Residences, **Level IV Recovery Residence** deliver clinical services. https://narronline.org/wp-content/uploads/2016/12/NARR_levels_summary.pdf
[19] Discussed in next section.

INCREASING INTEGRATION, COORDINATION, AND ACCESS TO CARE
Questions from the Committee:

- What are the best practices for integrating behavioral health with primary care? What federal payment policies would best support care integration?
- What programs, policies, data, or technology are needed to improve access to care across the continuum of behavioral health services?
- What policies could improve and ensure equitable access to and quality care for minority populations and geographically underserved communities?

Findings: Need for Healthcare System Integration Approach to SMI and SUD Treatment – SMIs and SUDs are complex disorders which our healthcare system has had difficulty treating in an integrated and coordinated manner. Illustrating this point, our National Institutes of Health are organized into 27 distinct Institutes, with three dedicated to different behavioral health conditions: mental health,[20] alcoholism [21] and drug addiction. [22] While the existence of separate Institutes for each condition implies that these are distinct conditions, in fact each Institute has noted[23, 24, 25] that patients often have one or more mental illnesses and addictions. To address the complexity and variety of behavioral health disorders, the Substance Abuse Mental Health Services Administration (SAMHSA) has proposed that our healthcare system needs to be able to provide a *No Wrong Door* approach to SMI and SUD care. This approach would "… ensure that a person needing treatment will be identified, assessed, and receive treatment, either directly or through appropriate referral, no matter where he or she seeks services."[26]

According to SAMHSA[27]:

> In 2018, 47.6 million (19.1 percent of all adults) adults ages 18 and older had any mental illness during the previous year, including 11.4 million (4.6 percent of all adults) with SMI.
> - Among these 47.6 million adults with any past-year mental disorder, 9.2 million (19.3 percent) also had an SUD, but only 5 percent of adults without any mental illness in the past year had an SUD.
> - Of the 11.4 million adults with an SMI in the previous year, approximately 28 percent also had an SUD.

Findings: Comprehensive Opioid Recovery Centers - A second innovation introduced by Congress to address the problem of system integration are Comprehensive Opioid Recovery Centers (CORCs). CORCs were explicitly designed to address the task of providing and integrating care. In this instance, however, the focus of CORCs is the provision of "…comprehensive centers which provide a full spectrum of treatment and recovery support services to address the opioid epidemic" including all

[20] National Institute on Mental Health. https://www.nimh.nih.gov/
[21] National Institute on Alcoholism and Alcohol Abuse. https://www.niaaa.nih.gov/
[22] National Institute on Drug Abuse. https://www.drugabuse.gov/
[23] National Institute on Mental Health. https://www.nimh.nih.gov/health/topics/substance-use-and-mental-health
[24]National Institute on Alcoholism and Alcohol Abuse. https://www.niaaa.nih.gov/news-events/news-noteworthy/alcohol-use-disorder-and-schizophrenia-or-schizoaffective-disorder
[25]National Institute on Drug Abuse. https://www.drugabuse.gov/publications/drugfacts/comorbidity-substance-use-disorders-other-mental-illnesses
[26] Ibid.
[27] Substance Abuse and Mental Health Services Administration. Substance Use Disorder Treatment for People With Co-Occurring Disorders. Treatment Improvement Protocol (TIP) Series, No. 42. SAMHSA Publication No. PEP20-02-01-004. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020. Accessible at: https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-02-01-004_Final_508.pdf

categories of medication-assisted treatment, psychosocial services, recovery housing, peer recovery support, child care, family counseling, job training and support reentering following incarceration, and returning to work.[28, 29] Since the passage of the CORCs authorizing legislation, SAMHSA has provided grant support to help establish the creation of the four CORCs launched in Illinois, California, Arizona, and Indiana[30, 31] as well as an evaluation of at least one of the CORC pilot sites.[32]

Findings: The Need to Expand Treatment for Alcohol Use Disorder - While the focus of CORCs on OUDs is warranted, Americans are struggling with multiple SUDs, including alcohol use disorder (AUD). According to SAMHSA, alcohol is the most widely misused substance in the United States.[33] The 2019 National Survey on Drug Use and Health reported that more than 14.5 million Americans were classified as having AUD.[34] According to the CDC, excessive alcohol use is responsible for about 95,000 deaths a year in the United States - accounting for 1 in 10 total deaths among working-age adults aged 20 to 64 years. In 2010, excessive alcohol use cost the U.S. economy $249 billion, or $2.05 per drink. About 40% of these costs were paid by federal, state, and local governments.[35] Fortunately, there are several FDA-approved medications used in the treatment of AUD[36] however, an insufficient number of treatment programs or practicing healthcare providers offer these treatment options.[37] Researchers have identified numerous barriers that undermine the use of AUD treatment medications, including appropriate reimbursement for this care.[38,39,40] For example, with respect to extended-release injectable naltrexone, researchers stated that 91% of the SUD programs that were using this medication reported that the cost-related barriers limited its use.[41] The authors went on to state:

> In some states, the medication may not be listed on the formulary, limiting its adoption within treatment programs. Even if the medication is covered, if it is listed under medical benefits, the program must first purchase the medication and may bill Medicaid only after it has been administered. The visits to receive a prescription or the injection itself could be handled separately as a medical benefit. Further, at least 20 states require prior authorization, and some states require documented noncompliance or prior failure with other medications in order to approve prior authorization.[42]

[28] SAMHSA. CORCs Program Description. https://www.samhsa.gov/sites/default/files/grants/pdf/fy-2020-corc-foa.pdf
[29] H.R.6 - SUPPORT for Patients and Communities Act. https://www.congress.gov/bill/115th-congress/house-bill/6
[30] https://www.samhsa.gov/grants/awards/2021/TI-20-006
[31] https://www.samhsa.gov/grants/awards/2020/TI-20-006
[32] Chestnut Health Systems, Christy K. Scott, Ph.D., Haymarket Center Evaluation. https://www.chestnut.org/lighthouse-institute/research-projects/
[33] SAMHSA. 2021. Prescribing Pharmacotherapies for Patients With Alcohol Use Disorder. Advisory. https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-02-02-015.pdf
[34] Ibid.
[35] CDC. Excessive Alcohol Use. https://www.cdc.gov/chronicdisease/resources/publications/factsheets/alcohol.htm
[36] Ibid cit. 26.
[37] U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health. Washington, DC: HHS, November 2016, page 156. https://addiction.surgeongeneral.gov/sites/default/files/surgeon-generals-report.pdf
[38] Williams, E.C., Achtmeyer, C.E., Young, J.P. *et al.* Barriers to and Facilitators of Alcohol Use Disorder Pharmacotherapy in Primary Care: A Qualitative Study in Five VA Clinics. *J GEN INTERN MED* **33,** 258–267 (2018). https://doi.org/10.1007/s11606-017-4202-z
[39] Aletraris, L., Edmond, M.B. and Roman, P.M., 2015. Adoption of injectable naltrexone in US substance use disorder treatment programs. *Journal of studies on alcohol and drugs*, *76*(1), pp.143-151. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4263776/pdf/jsad143.pdf
[40] Alanis-Hirsch, K., Croff, R., Ford, J. H., 2nd, Johnson, K., Chalk, M., Schmidt, L., & McCarty, D. (2016). Extended-Release Naltrexone: A Qualitative Analysis of Barriers to Routine Use. *Journal of substance abuse treatment*, *62*, 68–73. https://doi.org/10.1016/j.jsat.2015.10.003
[41] Ibid cit. 32, page 149.
[42] Ibid cit. 32, page 149.

Recommendation #3*:* Expand the Number of CORCs. We encourage the expansion of CORCs with an expanded focus on all substance use disorders, not just opioids. The concept of comprehensive treatment, especially for individuals returning to their community post-incarceration, applies equally to individuals with any SUD, including AUD. Consequently, we encourage the Committee to consider expanding the scope of CORCs to all SUDs, and in so doing consider changing the names of these centers to Comprehensive Addiction Recovery Centers (CARCs).

Findings: Integration of Care for Justice-Involved Individuals with SMIs and SUDs - A related integration challenge concerns the millions of individuals with SMIs and SUDs in our justice system. According to the U.S. Department of Justice (DOJ), 63% of the people released from jails have an SUD[43] - over 6,000,000 individuals in 2016[44] and 37% of prisoners and 44% of jail inmates reported they were told by a mental health professional that they had a mental disorder.[45] Individuals with SMIs such as schizophrenia, in particular, are at increased risk for arrest and incarceration.[46, 47, 48, 49,50]

In most states, when an accused person is jailed and awaiting trial (but not yet tried or convicted), their *Medicaid coverage is suspended or terminated*. This policy of discontinuing Medicaid is estimated to impact over 700,000 people on any given day, and several million people annually.[51] For pre-trial detainees who require medical, mental, or substance use disorder treatment, suspension of their Medicaid enrollment may undermine their ability to access medically necessary care upon release. *By maintaining Medicaid enrollment for pre-trial detainees*, the risks associated with disrupted benefits upon release can be mitigated. Likewise, the administrative burden associated with suspending and then re-instituting enrollment upon release is eliminated.

While the practice of suspending or disenrolling incarcerated Medicaid beneficiaries is common, under current authority[52], states can exercise their discretionary authority to maintain Medicaid benefits for pre-trial detainees – as well as individuals who have been sentenced. States can maintain Medicaid enrollment without seeking a Waiver or State Plan Amendments from CMS. States may also expedite new Medicaid applications prior to releasing detainees and reactivate Medicaid for incarcerated persons whose benefits had been suspended.[53] Similarly, State Medicaid enrollment can even be maintained after sentencing. When implementing these changes, suspension of the Federal Financial Participation (FFP) and payments

[43] DOJ, Office of Justice Programs (OJP). Special Report: Drug Use, Dependence, and Abuse Among State Prisoners and Jail Inmates, 2007-2009. (June 2017). Available at https://www.bjs.gov/content/pub/pdf/dudaspji0709.pdf
[44] DOJ/OJP. Prisoners in 2016. (January 2018). Available at: https://www.bjs.gov/content/pub/pdf/p16.pdf
[45] DOJ. Indicators of Mental Health Problems Reported by Prisoners and Jail Inmates, 2011-12. Published 2017. Accessible at: https://bjs.ojp.gov/content/pub/pdf/imhprpji1112.pdf
[46] U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. ***Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC) Report to C***ongress, December 17, 2017. Available at: https://www.samhsa.gov/ismicc page 17.
[47] Ascher-Svanum H et al. Involvement in the US criminal justice system and cost implications for persons treated for schizophrenia. BMC Psychiatry. 2010;10:11.
[48] Reingle Gonzalez JM et al. Mental health of prisoners: identifying barriers to mental health treatment and medication continuity. Am J Public Health. 2014;104(12):2328-33.
[49] Swanson JW et al. Costs of criminal justice involvement among persons with serious mental illness in Connecticut. Psychiatric Serv. 2013;64(7):630-7.
[50] Hawthorne, William B., et al. "Incarceration among adults who are in the public mental health system: Rates, risk factors, and short-term outcomes." *Psychiatric Services* 63.1 (2012): 26-32.
[51] Zhen Zeng, Jail Inmates in 2016 (NCJ 251210), Bureau of Justice Statistics, U.S. Department of Justice. (February 2018). Url: https://www.bjs.gov/content/pub/pdf/ji16.pdf
[52] CMS Letter to State Health Officials, April 28, 2016 re: To facilitate successful re-entry for individual transitioning from incarceration to their community. SHO# 16-007. Accessible at: https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21002.pdf
[53] Ibid.

to the state Medicaid managed care organizations (MCOs) need to be taken into account.[54] At this time, Alkermes is aware of only three states (Ohio, Massachusetts, and Washington) that maintain Medicaid enrollment for pre-trial detainees.

Recommendation #4: **Provide Guidance to State Medicaid Directors re: Maintaining Medicaid Enrollment.** Disseminate to State Medicaid Directors, in the form of guidance, the models adopted by Ohio, Massachusetts, and Washington to maintain Medicaid for pre-trial detainees and potentially, other incarcerated individuals. In addition, we encourage the Committee to pass the *Due Process Continuity of Care Act (S. 2697).*[55] This legislation would have a significant impact in helping to facilitate continuity of care as individuals transition back into the community following a period of incarceration.

Findings: Justice-Involved Individuals Need Integrated Care - As noted previously, mental illnesses are common among incarcerated individuals, and individuals living with schizophrenia are at increased risk for arrest and incarceration. According to SAMHSA, medications are essential in the treatment of psychosis.[56] Loss of benefits during incarceration and inadequate access to medication upon release from correctional settings disrupts medically necessary treatments[57,58,59] which may contribute to the return of the illness and undermine the successful reentry to the community. [60, 61, 62, 63, 64] At the end of 2020, Congress passed the Crisis Stabilization and Community Reentry Act[65] which "*creates a new program allowing law enforcement agencies to partner with community mental health providers to provide increased access to mental health treatment and crisis stabilization for incarcerated individuals and promote warm hand-offs to community-based care upon re-entry ….*" More specifically, the bill authorized "*Targeted training programs related to increasing medication adherence, including the use of long-acting antipsychotic medications.*"[66]

Recommendation #5: We encourage this Committee to work with the Appropriations Committee to support expansion of the Crisis Stabilization and Community Reentry Act, and to consider ways in which the training and funding provided through this grant program can be permanently incorporated into how individuals with SMIs are able to be cared for during incarceration and during community reentry.

[54] Ibid.
[55] S. 2697 (IS) - Due Process Continuity of Care Act. https://www.govinfo.gov/app/details/BILLS-117s2697is
[56] U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. Understanding a First Episode of Psychosis. Available at: https://store.samhsa.gov/sites/default/files/d7/priv/sma16-5006.pdf . Page 3.
[57] Morrissey, Joseph P., et al. "Assessing gaps between policy and practice in Medicaid disenrollment of jail detainees with severe mental illness." *Psychiatric Services* 57.6 (2006): 803-808.
[58] Bandara SN, Huskamp HA, Riedel LE, et al. Leveraging the Affordable Care Act to enroll justice-involved populations in Medicaid: state and local efforts. Health Aff (Millwood). 2015;34(12):2044-2051.
[59] Centers for Medicare and Medicaid Services, US Department of Health and Human Services. Code of federal regulations, § 435.1009 Institutionalized individuals.
[60] *Practice Guidelines: Core Elements for Responding to Mental Health Crises.* HHS Pub. No. SMA-09-4427. Rockville, MD: Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, 2009. Page 9.
[61] Citation 1, page 48.
[62] Kane KM. Returning home Illinois policy brief: health and prisoner reentry. Urban Institute, Justice Policy Center. August 2005.
[63] La Vigne N, Davies E, Palmer T, Halberstadt R. Release planning for successful reentry: a guide for corrections, service providers, and community groups. Urban Institute, Justice Policy Center. September 2008.
[64] U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. Criminal and Juvenile Justice. https://www.samhsa.gov/criminal-juvenile-justice
[65] S.3312 - Crisis Stabilization and Community Reentry Act of 2020 https://www.congress.gov/bill/116th-congress/senate-bill/3312
[66] NCMW. Crisis Stabilization and Community Reentry Act of 2020 (S. 3312) https://www.thenationalcouncil.org/wp-content/uploads/2020/06/HillDayAtHome_FactSheet_CrisisStabilizationCommunityReentryAct.pdf?daf=375ateTbd56

Findings: Reimbursement under Buy-and-Bill is Burdensome - Coverage of long acting antipsychotic injectable medications for the treatment of SMIs and extended-release injectable medication for the treatment of OUD[67] under the medical benefit requires providers to utilize a buy-and-bill reimbursement process in which the practitioner must first purchase the medication, and then seek reimbursement after it has been administered. A recent study sponsored by the National Institute on Drug Abuse (NIDA) reported that "*Most programs refuse to buy-and-bill because of the financial risks.*"[68] Clinicians treating OUD often function as small, single-practitioner offices and do not have the capacity to fill the paperwork requirements associated with buy-and-bill. While larger treatment providers have the administrative resources required to manage the buy-and-bill reimbursement process, most smaller treatment providers do not. Consequently, the buy-and-bill requirement can function as a significant disincentive to offering patients this form of treatment even though it may be clinically indicated.

In Alkermes' review of Fee-for-Service (FFS) Medicaid coverage for XR-NTX, six states maintained a buy-and-bill policy.[69] In these six states, utilization of XR-NTX is significantly lower than states that allow this medication to be billed under the pharmacy benefit. Alkermes' request regarding buy-and-bill applies equally to all CMS funded plans, including Medicaid Managed Care program.

Recommendation #6: Allow Reimbursement for Extended-Release Injectable Medications Under the Pharmacy Benefit or Medical Benefit

We request that consideration be given to allowing Medicare and Medicaid Plans to reimburse treatment with extended-release injectable medications under both the pharmacy benefit *and* the medical benefit, so that treatment providers can utilize the approach that best suits their practice.

Findings: Following Opioid Detoxification, Medication for the Prevention of Relapse and Counseling Should be Offered

In 2018, SAMHSA published an announcement that included these statements: *"XR-NTX treatment should always be considered to reduce the likelihood of return to use after medically supervised withdrawal is completed and an adequate period of abstinence achieved…"*[70] And *"If medical withdrawal (detoxification) is performed, it must be accompanied by injectable extended-release naltrexone to protect such individuals from… relapse and improve treatment outcomes."*[71]

Similarly, the Surgeon General's published ***Facing Addiction in America, Spotlight on Opioids***, states: *"Therefore, a person with opioid use disorder who undergoes medical withdrawal should be offered injectable naltrexone…."*[72]

This guidance from SAMHSA and the Surgeon General is particularly relevant to the 2,981 SUD treatment facilities that provide opioid detoxification services.[73] Recently published SAMHSA guidance

[67] Ibid cit. 20
[68] Alanis-Hirsch, Kelly, et al. "Extended-release naltrexone: A qualitative analysis of barriers to routine use." Journal of substance abuse treatment. 62 (2016): 68-73. See page 8 for discussion of buy-and-bill.
[69] Alkermes review of FFS Medicaid coverage in all 50 states, January 2019. Details available upon request.
[70] Substance Abuse and Mental Health Services Administration. ***Medications for Opioid Use Disorder.*** Treatment Improvement Protocol (TIP) Series 63, Full Document. HHS Publication No. (SMA) 185063FULLDOC. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018. See page 3-11 (pagination 97).
[71] SAMHSA. Targeted Capacity Expansion Funding Opportunity Announcement: ***State Opioid Response Grants.*** **June 2018**, page 6.
[72] Surgeon General Spotlight on Opioids: ***Facing Addiction in America The Surgeon General's Spotlight on Opioids***. **September 2018.** *Page 21.*
[73] SAMHSA. National Survey of Substance Abuse Treatment Services (N-SSATS): 2018. Data on Substance Abuse Treatment Facilities. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2019. See: ***Detoxification Services,*** on page 17.

on medications used in the treatment of OUD states controlled environments such as jails and residential treatment centers should consider initiating XR-NTX prior to release because XR-NTX *"may be useful in preventing return to opioid use after release"* [74] and because short-term medically supervised withdrawal alone [without XR-NTX] is associated with "*high rates of return to illicit opioid use*."[75] Moreover, controlled environments such as residential treatment centers and hospitals *"are typically associated with extended periods of opioid abstinence, so maintaining abstinence for sufficient time to start naltrexone is less challenging than initiating it among outpatients in the community."*[76]

Based on an internal analysis of federal databases,[77,78,79,80,81] we estimate that in 2016 there were approximately *3 million opioid detoxification episodes* in the United States. This estimate may be conservative since it only includes opioid detoxification episodes occurring in controlled settings, i.e., jails, prisons, rehab centers, and hospitals and does not consider opioid detoxification episodes in OTPs or office-based opioid treatment programs (OBOTs). Considering only those individuals who completed opioid detoxification in a controlled environment, an estimate of the number of individuals who received the treatment recommended by SAMHSA and the Surgeon General can be established. Of the 3 million opioid detoxification episodes in *2016, we estimate that only about 46,000 individuals were treated with XR-NTX for opioid dependence which is only about 1.5% of all opioid detoxification episodes.*[82]

As previously stated, according to SAMHSA in 2018 only about 28% of SUD facilities report using XR-NTX. To a large degree, the absence of XR-NTX in residential treatment centers may be due to the lack of reimbursement for the medicine and the medical services associated with administering the medication. Currently, hospitals and residential treatment centers are not able to request reimbursement for XR-NTX that is administered prior to a patient being discharged. Hence, reimbursement under Medicare and Medicaid does not cover the SAMHSA-recommended, post-detox recommendation, in hospitals or residential treatment centers.

Recommendation #7: Provide Coverage for Relapse Prevention Medications and Counseling following Opioid Detoxification

The Committee should encourage CMS to streamline reimbursement for relapse prevention medications, including XR-NTX and counseling, following opioid detoxification, in all SUD settings of care including rehabilitation centers, hospitals and correctional settings, when clinically appropriate.

Findings: Patients Requiring Medications for the Treatment of Psychosis and Depression Benefit from these Medication being Among the Six Protected Classes

[74] SAMHSA. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63, Full Document. HHS Publication No. (SMA) 18-5063FULLDOC. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018. Page 3-7 (pagination 93).
[75] Ibid, page 3-11.
[76] Ibid, page 3-7.
[77] Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS): 2015. Discharges from Substance Use Treatment Services: Tables. Data received through March 16, 2018. Available at: https://wwwdasis.samhsa.gov/dasis2/teds_pubs/2015_teds_rpt_d.pdf
[78] Substance Abuse and Mental Health Services Administration, National Survey of Substance Abuse Treatment Services (N-SSATS): 2016. Data on Substance Abuse Treatment Facilities. BHSIS Series S-93, HHS Publication No. (SMA) 17-5039. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2017. Available at: https://wwwdasis.samhsa.gov/dasis2/nssats/2016_nssats_rpt.pdf
[79] U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. Prisoners in 2016. (January 2018). Available at: https://www.bjs.gov/content/pub/pdf/p16.pdf
[80] U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. Jail Inmates in 2016. www.bjs.gov/content/pub/pdf/ji16_sum.pdf
[81] U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. Special Report: Drug Use, Dependence, and Abuse Among State Prisoners and Jail Inmates, 2007-2009. (June 2017). Available at https://www.bjs.gov/content/pub/pdf/dudaspji0709.pdf
[82] Data on file at Alkermes.

For patients living with serious mental illnesses such as psychosis and depression, access to the full range of FDA approved medications is a crucial component of a successful treatment plan. Medicare's "Six Protected Class" policy provides certain guarantees to patients that they will have access to all available medications, albeit with certain limitations. While proposals to alter the protected classes have frequently been suggested in the context of reducing program costs, there are in fact already numerous limitations on access. For example, as noted in a recent Avelere study:

> Part D plans are leveraging formularies and utilization management tools for Medicare beneficiaries across drugs in the protected classes. For example, in 2019, the most recent year for which data is available, plans covered just 54% of drugs across the protected classes — a decrease of nearly 20% since 2016 when the coverage rate was 67%. For covered drugs, nearly two-thirds of all medications in the six protected classes were placed in a nonpreferred or specialty category, with 89% of branded products categorized as non-preferred or specialty and 37% of generics also subject to placement on the higher tiers. In aggregate, Part D plans placed drugs from the protected classes on high tiers (non-preferred or specialty) 64% of the time.[83]

Recommendation #8: Preserve the Six Protected Classes – We thank the Committee for its ongoing support for the Six Protected Classes and ask that those protections continue to be maintained.

EXPANDING TELEHEALTH
Questions from the Committee:

- How do the quality and cost-effectiveness of telehealth for behavioral health care services compare to in-person care, including with respect to care continuity?
- How does the level of severity of a mental illness impact the appropriateness of a telehealth visit?
- How can Congress craft policies to expand telehealth without exacerbating disparities in access to behavioral health care?

Findings: The Benefits of Telehealth for People Living with Schizophrenia - According to a recent report from the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, in February 2020 only about one-tenth of one percent (0.1%) of Medicare beneficiaries had received primary care services using telehealth. By April of 2020 over 40% of these services were provided by phone or another telehealth technology.[84] This rapid transformation in healthcare service delivery was enabled by the federal declaration of the COVID-19 public health emergency (PHE)[85], followed by actions taken by Congress, the Centers for Medicare and Medicaid Services (CMS), and the transformational work of hundreds of thousands of patients, healthcare professionals, and payers.

[83] Partnership to Protect Part D Access. Coverage Policies Create Access Challenges for Patients with Complex, Chronic Conditions. file:///C:/Users/forman_robert/Documents/Government%20Affairs/CMS/Six%20Protected%20Classes/avalere_report_on_six_protected_classes_--_february_2021.pdf
[84]Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. Medicare Beneficiary Use of Telehealth Visits: Early Data From the Start of The Covid-19 Pandemic. Accessed at: https://aspe.hhs.gov/sites/default/files/private/pdf/263866/hp-issue-brief-medicare-telehealth.pdf
[85]U.S. Department of Health and Human Services. https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx

The expansion of Medicare coverage for telehealth services significantly eased access to healthcare services while minimizing the exposure of patients, providers, and caretakers to COVID-19.[86, 87] The impact of this development on healthcare delivery has already been significant and is likely to continue.

To better understand how telehealth was impacting behavioral healthcare, Alkermes commissioned The Harris Poll to conduct an online ***Telepsychiatry & Mental Health Survey*** with over 2,000 adults ages 18 and older from May 27- 29, 2020.[88] Among the findings of this survey, more than 1 in 4 (27%)—or 569 respondents—indicated that they were currently using telehealth for a mental health condition (hereafter referred to as "telepsych"). Among those respondents who reported current use of telepsych services, 62% agreed that they would not be able to get the care they needed without telepsych services and 67% agreed that telepsych services have helped them maintain their treatment regimen (such as taking their medication and accessing other support services). Further, approximately three-fourths (74%) of current telepsych users surveyed were interested in continuing to use these services after the coronavirus pandemic, highlighting the long-term potential of these technologies.

Our findings parallel those recently reported by the American Psychiatric Association. In their national survey of over 500 psychiatrists, telepsychiatry was reported to improve access to care and reduced "no-show" rates (missed appointments). At the same time, telepsych services received high patient satisfaction ratings.[89] As noted in this report, "Prior to the public health emergency, most respondents were not using telehealth at all: 64% responded seeing zero percent of their patient caseload via telehealth. Two months into the public health emergency, this number shifted dramatically to 85% of respondents seeing more than ¾ or all of their patients via telehealth."

These and other supportive findings[90,91,92,93] are underscored by a recent report on telepsychiatry by SAMHSA released earlier this year titled ***Telehealth for the Treatment of Serious Mental Illness and Substance Use Disorders***[94]. In it, SAMHSA outlines how telehealth helps to achieve all four of healthcare's "Quadruple Aims"[95]: "improved provider experience; improved client experience; improved population health and decreased costs."[96] In short, the emergence of telepsychiatry during the COVID-19

[86] Koma, W., Cubanski, J. and Neuman, T. (May 19, 2021). *Medicare and Telehealth: Coverage and Use During the COVID-19 Pandemic and Options for the Future*. Kaiser Family Foundation. https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future/

[87] Park, S., Langellier, B.A. and Burke, R.E., 2021. Telehealth benefits offered by Medicare Advantage plans in 2020. *Medical Care*, *59*(1), pp.53-57.

[88] Alkermes, Inc. Alkermes-Harris Poll Survey Offers Insights into Potential of Telepsychiatry During and After the COVID-19 Pandemic . https://investor.alkermes.com/news-releases/news-release-details/new-harris-poll-survey-offers-insights-potential-telepsychiatry Note: This online survey was not based on a probability sample and therefore no estimate of theoretical sampling error can be calculated. For complete survey methodology, including weighting variables and subgroup sample sizes, or for any additional question regarding the survey, please send requests tomediainfo@alkermes.com .

[89] American Psychiatric Association. Psychiatrists Use of Telepsychiatry During COVID-19 Public Health Emergency. Accessed at: https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/Telepsychiatry/APA-Telehealth-Survey-2020.pdf

[90] Bipartisan Policy Center. (August 2021). Telehealth Visit Use Among U.S. Adults. Accessed at: https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2021/08/SSRS-Telehealth-Report_confidential_FINAL_08.02.21-1.pdf

[91] Chen, J.A., Chung, W.J., Young, S.K., Tuttle, M.C., Collins, M.B., Darghouth, S.L., Longley, R., Levy, R., Razafsha, M., Kerner, J.C. and Wozniak, J., 2020. COVID-19 and telepsychiatry: Early outpatient experiences and implications for the future. *General hospital psychiatry*, *66*, pp.89-95.

[92] Yellowlees, P., Nakagawa, K., Pakyurek, M., Hanson, A., Elder, J. and Kales, H.C., 2020. Rapid conversion of an outpatient psychiatric clinic to a 100% virtual telepsychiatry clinic in response to COVID-19. *Psychiatric Services*, *71*(7), pp.749-752.

[93] Talley, Rachel M. et al. Telehealth and the Community SMI Population, The Journal of Nervous and Mental Disease: January 2021 - Volume 209 - Issue 1 - p 49-53.

[94] Substance Abuse and Mental Health Services Administration (SAMHSA). *Telehealth for the Treatment of Serious Mental Illness and Substance Use Disorders.* SAMHSA Publication No. PEP21-06-02-001 Rockville, MD: National Mental Health and Substance Use Policy Laboratory. Substance Abuse and Mental Health Services Administration, 2021.

[95] Feeley, D. (2017, November 28). *The triple aim or the quadruple aim? Four points to help set your strategy.* http://www.ihi.org/communities/blogs/the-triple-aim-or-the-quadruple-aim-four-points-to-help-set-your-strategy

[96] Ibid citation 19, page 4.

PHE represents a historic advance in the delivery of behavioral health services, with the potential to dramatically improve access to care while simultaneously reducing risk for infection, travel-related costs, inefficiencies and health care disparities.[97]

Findings: Hybrid Telehealth Models and Access to Long-Acting Antipsychotic Medications - Considering the many benefits associated with the expansion of telepsych services, we enthusiastically support its continued expansion for all Medicare (and Medicaid) beneficiaries. However, along with the expansion of telehealth services, it is important to note that there are many clinical circumstances under which in-person visits are necessary. For example, there are numerous assessments that need to be administered in-person[98, 99, 100, 101] and most medical procedures need to be administered directly to the patient by trained and licensed clinicians.[102, 103, 104] Even when in-person care is needed, telehealth services can often be utilized, in tandem with the in-person services. This combination of in-person and telehealth is referred to as a "hybrid telehealth" model.[105, 106]

For people living with schizophrenia who are being treated with a LAI , in-person visits are required since LAIs are administered by licensed healthcare providers[107] once every few weeks or months, depending upon the LAI being administered.[108] According to the National Council on Behavioral Health, as of 2019 there were eight LAIs approved by the FDA for the treatment of schizophrenia.[109]

SAMHSA has recognized the important role of LAIs with its establishment of a "Long-Acting Injectable Center of Excellence"[110] that "…focuses on increasing and improving the use of long-acting injectable (LAI) drugs in individuals with schizophrenia…and provides resources, CME/NCPD-certified education, and clinical consultations."[111] As noted in the American Psychiatric Association's recently published ***Practice Guideline for the Treatment of Patients with Schizophrenia,*** patients may prefer LAIs because of difficulty "swallowing pills, ambivalence about medications" [112] and LAIs "may be particularly useful for patients with a history of poor or uncertain adherence."[113]

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[97] Ibid cit. 19., page 5.
[98] Ibid citation 19, page 17.
[99] Shifali Singh & Laura Germine (2021) Technology meets tradition: a hybrid model for implementing digital tools in neuropsychology, International Review of Psychiatry, 33:4, 382-393, DOI: 10.1080/09540261.2020.1835839.
[100] Lundt, Leslie. No One Size Fits All: The Case For A Balanced Approach To Telehealth And In-Person Care. Mental Health America. Published online August 10, 2021 at: https://www.mhanational.org/blog/no-one-size-fits-all-case-balanced-approach-telehealth-and-person-care
[101] Mayo Clinic. Upper Endoscopy. Accessed online at: https://www.mayoclinic.org/tests-procedures/endoscopy/about/pac-20395197
[102] Mayo Clinic. Electroconvulsive therapy (ECT). Accessed online at: https://www.mayoclinic.org/tests-procedures/electroconvulsive-therapy/about/pac-20393894
[103] Administering Vaccines to Adult: Dose, Route, Site, and Needle Size. Accessed online at: https://www.immunize.org/catg.d/p3084.pdf
[104] Mayo Clinic. Wisdom Tooth Extraction. Accessed online at: https://www.mayoclinic.org/tests-procedures/wisdom-tooth-extraction/about/pac-20395268
[105] Shifali Singh & Laura Germine (2021) Technology meets tradition: a hybrid model for implementing digital tools in neuropsychology, International Review of Psychiatry, 33:4, 382-393, DOI: 10.1080/09540261.2020.1835839
[106] Ibid cit. 19, see for example pages 3, 16 and 17
[107] American Psychiatric Association SMI Advisor. What should a provider consider when administering long-acting injectable (LAI) antipsychotics? Accessed online: https://smiadviser.org/knowledge_post/what-should-a-provider-consider-when-administering-long-acting-injectable-lai-antipsychotics.
[108] National Council for Behavioral Health. (2019). Guide to Long-Acting Medications for Providers and Organizations. Accessed at: https://www.thenationalcouncil.org/topics/long-acting-medications/
[109] National Council for Behavioral Health. (2019). Guide to Long-Acting Medications for Providers and Organizations. Accessed at: https://www.thenationalcouncil.org/topics/long-acting-medications/
[110] Serious Mental Illness Adviser, Long-Acting Injectable Center of Excellence. Accessed at: https://smiadviser.org/knowledge_post/long-acting-injectable-center-of-excellence
[111] Ibid.
[112]Keepers, George A., et al. "***The American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia***." *American Journal of Psychiatry* 177.9 (2020): 868-872. See page 25.
[113] Ibid cit. 23, page.62

Finally, last year, Congress passed the ***Crisis Stabilization and Community Reentry Act of 2020*** "…for the purpose of providing clinical services for people with serious mental illness…"[114] which, among its provisions, is support for access to LAI antipsychotic medications for incarcerated individuals during detainment and reentry back into the community.[115]

Hybrid telepsych service models for people living with schizophrenia may be especially helpful in expanding access to care in underserved communities.[116] We have observed the emergence of hybrid models that provide case management and counseling through telehealth, while supporting the administration of LAIs in traditional mental health settings, such as community mental health centers and certified community behavioral healthcare centers (CCBHCs) [117, 118] - as well as alternative LAI administration settings, such as community pharmacies[119], and even supermarkets that have embedded healthcare services.[120] Similarly, access to healthcare services for individuals with SUDs and SMIs is a serious challenge for individuals in rural and underserved communities due to long-distances and limited public transportation. Mobile crisis units are also being successfully deployed as an alternative "setting of care", bringing mental health services, including LAI antipsychotic medications, into rural and underserved communities.[121, 122,123] These van-based behavioral healthcare teams maintain regular schedules at diverse community locations; deliver medical care and medication management; and provide other related support services, such as homeless outreach.

***Recommendation #10*:** As the Committee considers policies advancing the appropriate use of telehealth services, we encourage support for hybrid telehealth models that improve access to LAI antipsychotic medication for individuals living with SMIs and extended-release injectable medication for people living with AUD and OUD, especially in underserved urban and rural communities in traditional and alternative mental health settings of care. Likewise, consideration should be given to how mobile vans might be deployed to further improve access to face-to-face visits that can enable injectable medication preparation and administration.

Thank you for your attention to these important matters and for your consideration of our comments. Please do not hesitate to contact me at (202) 304-1763 or robert.forman@alkermes.com if you have any questions regarding our comments.

Sincerely,

Policy & Government Relations
Alkermes, Inc.

[114]PUBLIC LAW 116–281—DEC. 31, 2020 1 Crisis Stabilization and Community Reentry Act of 2020. Accessed at: https://www.congress.gov/116/plaws/publ281/PLAW-116publ281.pdf
[115] Ibid.
[116] Mehrotra A, Huskamp HA, Souza J, Uscher-Pines L, Rose S, Landon BE, Jena AB, Busch AB. Rapid Growth In Mental Health Telemedicine Use Among Rural Medicare Beneficiaries, Wide Variation Across States. Health Aff (Millwood). 2017 May 1;36(5):909-917. doi: 10.1377/hlthaff.2016.1461. PMID: 28461359.
[117]SAMHSA. CCBHCs Using Telehealth or Telemedicine. https://www.samhsa.gov/section-223/care-coordination/telehealth-telemedicine
[118] Ibid cit. 19, page 2.
[119] https://www.genoahealthcare.com/telepsychiatry/
[120] Lin, C., Strauss, R., Hong, J., Hamper, J.G., Hoy, E.S., Lazar, A.A. and Kroon, L., 2019. Impact of a pharmacist-administered long-acting injectable antipsychotic service in a supermarket-based community pharmacy on medication adherence. *Journal of the American College of Clinical Pharmacy*, *2*(4), pp.343-348.
[121] Couser, G.P., Taylor-Desir, M., Lewis, S. *et al*. Further Adaptations and Reflections by an Assertive Community Treatment Team to Serve Clients with Severe Mental Illness During COVID-19. *Community Ment Health J* **57,** 1217–1226 (2021).
[122] PEW. Federal Ban on Methadone Vans Seen as Barrier to Treatment. March 23, 2018. Accessed at: https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2018/03/23/federal-ban-on-methadone-vans-seen-as-barrier-to-treatment
[123] https://www.phila.gov/media/20190110101212/The-Opioid-Epidemic-in-Philadelphia-.pdf