U.S. Department of Health and Human Services

Minutes of the Interdepartmental Substance Use Disorders Coordinating Committee
Full Committee Meeting

December 9, 2021
1:00 p.m. to 5:00 p.m. (Eastern Time Zone)
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville, MD 20857

(Via Zoom)
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Call to Order, Committee Roll Call, and Consideration of Minutes

Tracy Goss, Designated Federal Officer (DFO), Interdepartmental Substance Use Disorders Coordinating Committee (ISUDCC) established a quorum following the roll call, and the meeting was called to order at 1:05 p.m.

Federal ISUDCC Members or Designees Present

- Miriam E. Delphin-Rittmon, Ph.D., Assistant Secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration (SAMHSA)
- Yngvild K. Olsen, M.D., MPH, Acting Director, Center for Substance Abuse Treatment (CSAT), SAMHSA
- Joseph Liberto, M.D., Deputy National Mental Health Program Director for Substance Use Disorders, Department of Veterans Affairs (VA)
- Leola Brooks, Social Insurance Specialist, Social Security Administration (SSA)
- June Sivilli, Senior Advisor, Public Health, Education and Treatment, Office of National Drug Control Policy (ONDCP)
- Christopher Jones, PharmD, DrPH, MPH, Acting Director, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC)
- Wilson Compton, M.D., M.P.E., Deputy Director, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH)
- Patricia Powell, Ph.D., Deputy Director, National Institute on Alcohol Abuse and Alcoholism (NIAAA), NIH
- Marta Sokolowska, Ph.D., Associate Director for Controlled Substances, Office of the Center Director, Food and Drug Administration (FDA)
- Dele Solaru, PharmD., MBA, Chief Pharmacy Officer, Office of Personnel Management (OPM)
- Kellie Kubena, Deputy Innovation Officer, Rural Development, Department of Agriculture (USDA).

Federal ISUDCC Members Not Present

- U.S. Department of Justice (DOJ)
- U.S. Department of Labor (DOL)
- U.S. Department of Housing and Urban Development (HUD)
- U.S. Department of Education (ED)
Non-Federal ISUDCC Members Present

- Chad Audi, Ph.D., President and CEO, Detroit Rescue Mission Ministries
- Caleb Banta-Green, Ph.D., MPH, MSW, Principal Research Scientist, Alcohol & Drug Abuse Institute, University of Washington
- Honorable Nancy L. Butts, President Judge, Lycoming County, Pennsylvania
- Meredith Canada, MSW, MPA, LCSW, Public Health Analyst, Indiana High-Intensity Drug Trafficking Area Overdose Response Strategy
- Jamie Chrisman Low, M.Ed., NCC, Recovery Consultant, Statewide Recovery Community, Network Weaver, Certified Peer Support Specialist
- Susan Dawson, Ed.D., PMHNP-BC, Psychiatric Nurse Practitioner, Assisted Recovery Center of America, and State Targeted Response Team for the Opioid Crisis Trainer for Professionals
- Judy Goforth Parker, Ph.D., A.P.R.N., F.A.C.H.E., Commissioner of Health Policy, Chickasaw Nation
- Keith Humphreys, Ph.D., Esther Ting Memorial Professor, Department of Psychiatry and Behavioral Sciences, Stanford University School of Medicine
- Sheryl Ryan, M.D., FAAP, Division Chief, Professor of Pediatrics, Adolescent Medicine and Eating Disorders, Penn State Health
- Amanda S., Patient and Advocate
- Daniel Sledge, BA, LP, Lead Outreach Paramedic, Wilco EMS-MOT
- Richard Spoth, Ph.D., Director, Partnerships in Prevention Science Institute, Iowa State University
- Luis R. Torres, Ph.D., Associate Professor, Center for Drug and Social Policy Research, University of Houston

Non-Federal ISUDCC Members Not Present

- Nicholas Estabrook, Addictive Disease Recovery Support Specialist, Department of Behavioral Health and Developmental Disabilities
- Sara A. Goldsby, MSW, MPH, Director, South Carolina Department of Alcohol and Other Drug Abuse Services
- Erik Hess, M.D., MSc, Professor and Vice Chair for Research, Department of Emergency Medicine, University of Alabama at Birmingham School of Medicine
- Steven Jenkusky, M.D., M.A., F.A.P.A., Vice President and Medical Director of Magellan Healthcare
- Cynthia Seivwright, LCMHC, CQIA, Director, Division of Alcohol and Drug Abuse Programs, Vermont Department of Health, Single State Agency for Substance Abuse Services

The DFO entertained a motion to adopt the minutes from the ISUDCC meeting held on August 26, 2021, noting that the minutes had been certified in accordance with the Federal Advisory Committee Act (FACA) regulations and included edits. Dr. Dawson moved to adopt the minutes. Dr. Goforth Parker seconded the motion. Hearing no response to her call for discussion, the DFO called for a vote to adopt the minutes. A unanimous vote adopted the minutes.
Welcome and Opening Remarks
Yngvild K. Olsen, M.D., MPH, Acting Director, CSAT

Dr. Olsen greeted the group, and she indicated that Dr. Delphin-Rittmon would join the group shortly. Dr. Olsen proceeded to introduce herself, noting that she currently serves as the Acting Director for CSAT. Her background includes training as an addiction medicine specialist physician and a primary care general internist. Prior to joining the Federal Government, Dr. Olsen worked in the field, primarily in the area of opioid use disorder treatment. To this end, she stated that the topics covered by the ISUDCC are near and dear to her heart. After briefly reviewing the day’s agenda, Dr. Olsen invited the non-federal ISUDCC members to introduce themselves. She asked each of them to share a couple of activities they have been involved with since the last ISUDCC meeting. Highlights from the non-federal ISUDCC members’ remarks follow:

- Chad Audi – Serves as the President and CEO of the Detroit Rescue Mission Ministries (DRMM), the 13th largest inpatient and outpatient treatment program in the country. DRMM received a grant to implement its Certified Community Behavioral Health Clinic in Wayne County.
- Caleb Banta-Green – Oversees a group that does community engaged epidemiology, education, and research at the University of Washington. He currently sits on an advisory committee focused on Washington State Supreme Court’s decision in February to decriminalize drug possession and the State Legislature’s subsequent legislation on the matter. Despite implementation challenges and the lack of care models for non-care seeking people, he acknowledged potential opportunities around recovery navigator programs.
- Nancy Butts – Serves on the ISUDCC as a representative of Drug Treatment Courts. She presides over Drug, DUI, Mental Health, and Veterans Court in North Central Pennsylvania. She continues to try to find ways to enable individuals to use medical marijuana and still be in Treatment Courts. Because she also presides in regular criminal cases, she pointed out the struggles in managing issues such as medication administration, medication assisted treatment, and mental health, and other medications individuals take.
- Jamie Chrisman Low – A woman in long-term recovery from substance use disorder, she is a certified peer support specialist and a peer supervisor; and she works in private practice as a licensed professional counselor in Lake Wylie, South Carolina. She is currently working with a recovery community organization, Faces and Voices of Recovery, Piedmont in Rock Hill, South Carolina, which received a grant to create a safe space for a federally recognized tribe in the community. They are also seeking funding to provide peer support for veterans and the Veterans Court in the area.
- Judy Goforth Parker – A member of the Chickasaw Nation, she works in the area of health policy for the Chickasaw Nation. The Chickasaw Nation has a mental wellness initiative that looks at the mental wellness of its tribal members and employees. Loose regulations around medical marijuana in Oklahoma have caused some issues in the state. Her current work involves the implementation of a health impact checklist to see how
their policies impact people’s mental wellness, with the understanding that mental wellness is connected to substance use disorders.

- Keith Humphreys – Works as a Professor of Psychiatry at Stanford University and is a scientist in the Department of Veterans Affairs. He recently finished a two-year process working with the British on their new drug policy, which includes a significant increase in their treatment and recovery budget. He also chairs the Lancet, a British medical journal, and he worked on a Stanford commission that looked at the North American opioid crisis—that work has concluded and will be released soon.

- Sheryl Ryan – Serves as the Program Director for the Interdisciplinary Addiction Medicine Fellowship at Penn State; they just welcomed two new fellows. She is also the Chief of the Division of Adolescent Medicine, which is developing a specialized clinic to see adolescents with substance use disorders. She also represents the American Academy of Pediatrics and looks forward to sharing information to further their advocacy work at the national and state levels.

- Amanda S. – A woman in long-term recovery from illicit substances and a person taking a medication as part of long-term SUD treatment in Michigan who also has chronic pain. She has been initiating conversations with leaders, people who use drugs, those working in the harm reduction space and unions, and methadone patients taking methadone to gain better insight into how agencies and the new Administration can improve access to services and better coordinate care.

- Daniel Sledge – Serves as the lead outreach paramedic for Williamson County Mobile Outreach Team near Austin, Texas, and is a person in recovery. In April 2020, they saw for the first-time overdoses from counterfeit pills outpace overdoses from heroin in his area; this has continued. He continues efforts to raise awareness and share accurate information, as well as flooding the area with naloxone and fentanyl test strips. He cited issues with payment when someone wants to start medications for opioid use disorder; he is in Texas, a non-expansion state. He also noted challenges with not having sanctioned syringe service programs. His work also involves scaling up and implementing mobile OTP programs that provide methadone at the local level.

- Richard Spoth – Recent activities have centered around dealing with the pandemic, especially trying to retain schools in prevention implementation science projects. A new project being undertaken by United Nations Office of Drug Control (UNODC) is building on earlier work he did on international standards for evidence-based prevention and intervention; the work is focused on developing guidelines for helping countries develop prevention systems to support the implementation of interventions/programs that meet those standards that are in the earlier set of guidelines. He is also developing a proposal that builds on PROSPER—a delivery system for working with school districts to implement evidence-based, family-focused, and school-based interventions.

- Luis Torres – Founding Dean and Professor at the University of Texas Rio Grande Valley School of Social Work. In September, he brought on his first three faculty hires. One of them, Dr. Tamara Al Rawwad, came from the University of Houston, finalizing a 3-year postdoc in the College of Pharmacy; she continues to be co-director of a SAMHSA-funded program project, Expansion of Interprofessional Substance Use Disorders Education Project. She is extending the project to the Rio Grande Valley. She has received a small grant to study with pharmacists throughout the Rio Grande Valley on the role they see themselves playing in the opioid prevention and detection of opioid use...
disorders and connecting people with treatment. Dr. Torres also serves on the Advisory Board for the SAMHSA-funded National Hispanic and Latino Mental Health Technology Transfer Center.

- **Susan Dawson** – Working on the practice side in St. Louis, Missouri, she has done inpatient and outpatient withdrawal management protocols for patients (short-term and long-term). A psychiatric specialist, she has a private psychiatric practice and also does co-occurring work. She also teaches classes in psychopharmacology at Maryville University. She is currently working on some textbook rewrites for updating substance use disorder treatment for nurse practitioners to learn. She also does a lot of precepting work with nurse practitioners, specifically psychopharmacology and psychiatric students.

**Welcome and Opening Remarks (continued)**

*Miriam E. Delphin-Rittmon, Ph.D., ISUDCC Chair, Assistant Secretary for Mental Health and Substance Use*

Dr. Delphin-Rittmon greeted the group and thanked Dr. Olsen for opening the meeting and for standing in for her. Next, Dr. Delphin-Rittmon spoke about the Overdose Prevention Strategy, released the month prior. Calling the process of putting the strategy together with a “collaborative and interactive process across the Department,” Dr. Delphin-Rittmon proceeded to share components and objectives of the same.

She noted that the four overarching pillars of the Overdose Prevention Strategy are primary prevention, harm reduction, treatment, and recovery. There are four objectives within each of the pillars, and within each of the objectives are examples of specific program/project areas. She informed the group that more information on the Overdose Prevention Strategy is available via the web at hhs.gov/overdose-prevention/. She encouraged the group to visit the website to find ideas of different initiatives or programs or work areas within the four pillars. Specific to the harm reduction pillar, Dr. Delphin-Rittmon noted the recent release of the Harm Reduction Notice of Funding Opportunity (NOFO), which is currently open for application submissions. The $30 million program ($10 million per year) will focus on innovation in harm reduction.

Dr. Delphin-Rittmon next informed the group that the Substance Abuse Block Grant includes a ten percent set-aside in the President’s budget for recovery, which is another pillar of the Overdose Prevention Strategy. She expressed optimism that the set-aside will remain in the President’s budget, saying it will afford an opportunity for additional recovery-related work in the substance use space to get funded.

Before ending her remarks, Dr. Delphin-Rittmon also noted the four cross-cutting areas of the Overdose Prevention Strategy that undergird its pillars: equity; data and evidence; coordination, collaboration, and integration; and reducing stigma.

**Federal Advances to Address Challenges in Substance Use Disorders**

During this portion of the agenda, Dr. Delphin-Rittmon invited federal partners to introduce themselves and provide updates.
ONDCP
June Sivilli, Senior Public Health Advisor, ONDCP

Ms. Sivilli provided updates on ONDCP and the Biden Administration's progress regarding the Biden-Harris Drug Policy Priorities. Highlights from her presentation include:

- **ONDCP**’s new Director, Dr. Rahul Gupta, was confirmed in October. He is the first physician to lead ONDCP. Dr. Gupta's top priorities are expanding access to naloxone; scaling up treatment to meet the needs of everyone seeking care, getting more timely actionable data to guide our overdose response strategies; and cracking down on illicit finance, a root cause of drug trafficking.
- The American Rescue Plan includes nearly $4 billion for behavioral health services, including an unprecedented $30 million specifically for harm reduction.
- ONDCP made harm reduction a Federal Drug Policy priority for the first time.
- The Administration has indicated that federal funds can be used to purchase fentanyl test strips.
- Unnecessary barriers for prescribing buprenorphine to 30 or fewer patients have been removed.
- The decade-long moratorium on methadone vans has ended.
- ONDCP has dedicated $93 million to preventing youth substance use through its Drug-Free Communities Support Program, which funds community-based coalitions.
- ONDCP has funded the development of model state legislation that states can introduce to expand access to naloxone and expand opioid litigation settlement funds to address addiction and the overdose epidemic strategically.
- ONDCP has released, just the day prior, the state model laws for Syringe Services programs.
- President Biden has called on Congress to deliver $41 billion on our country's efforts to save lives and build the addiction infrastructure the country needs; this is a $669 million increase over last year's funding level, with the most significant increases going to critical public health interventions to expand research, prevention, treatment, harm reduction, and recovery support services, with a focus on meeting the needs of at-risk communities.
- In October, ONDCP released a new holistic U.S.-Colombia counternarcotics strategy in partnership with the Colombian government, broadening the focus to include specific actions on rural security and development, environmental protection, and supply reduction.
- ONDCP designated six new counties as part of the High Intensity Drug Trafficking Areas Program. In states like California, Illinois, Kentucky, and Pennsylvania, these counties will receive support from regional law enforcement efforts to disrupt and dismantle drug trafficking organizations.
- The Drug Enforcement Administration (DEA) launched a "One Pill Can Kill" public awareness campaign and coordinated a major enforcement operation to rid American communities of significant quantities of counterfeit pills laced with deadly fentanyl.
- In September, the Administration released a long-term consensus legislative proposal for the class-wide scheduling of fentanyl-related substances; Congress extended the temporary class-wide scheduling of fentanyl-related substances until February 28, 2022.
Ms. Sivilli closed her presentation by reemphasizing the point that the Biden-Harris Administration is approaching the overdose epidemic by focusing on both the public health and public safety actions that will make a difference and save lives across America.

**SAMHSA**

*Neeraj Gandotra, M.D., Chief Medical Officer (CMO)*

Dr. Gandotra provided an update on work at SAMHSA. Highlights from his presentation follow:

- SAMHSA is accepting applications for its Harm Reduction Grant Program. The funding, authorized by the American Rescue Plan, aims to increase access to a range of community harm reduction services.
- SAMHSA has been preemptively granting Opioid Treatment Programs (OTPs) an exemption during the COVID-19 public health emergency for extending the number of take-homes; they can dispense up to 28 days’ worth of take-homes for the treatment of opioid use disorder for stable patients. SAMHSA has now preemptively granted this exemption for a one-year post public health emergency, allowing for mechanisms to make this flexibility permanent—which it is pursuing. In addition to the methadone take-home flexibility, SAMHSA is also exploring mechanisms to make the telehealth induction of buprenorphine permanent. During the COVID-19 public health emergency, the Secretary of HHS, in concordance with the DEA, has allowed telemedicine to waive the in-person medical evaluation if certain conditions are met.
- SAMHSA’s 988 program is moving forward and is expected to reach communities for behavioral health and provide a mechanism and linkage for those with substance use disorder. This is a major undertaking in all 50 states and territories. SAMHSA is pleased to see that the progress with its private partnerships and state organizations has yielded excellent results.
- SAMHSA has been very busy within its evidence-based resource center, publishing guidebooks on telemedicine and pursuing evidence-based resources for practices, e.g., CBD, teen and adolescent substance use disorder, and behavioral health programs.
- A priority of SAMHSA continues to be working with its partners and stakeholders to integrate primary care into its efforts.

**CDC**

*Christopher Jones, PharmD, DrPH, MPH, Acting Director, National Center for Injury Prevention and Control*

Dr. Jones provided an update on CDC. Highlights from his presentation follow:

- CDC continues to work with its state and local public health partners to provide funding to help build capacity to support overdose prevention work. CDC’s programmatic efforts are highlighted within the Overdose Prevention Strategy.
- CDC continues to release provisional mortality data each month on drug overdose deaths overall and by drugs or drug classes; the latest data are through April 2021, which clearly show a worsening picture for drug overdose in the U.S.
• CDC has started loading provisional mortality data into its CDC WONDER, a point-and-click program that allows users to access more detailed information about causes of death, e.g., demographic information, different drugs, or combinations of drugs involved in overdose deaths. The use of CDC WONDER represents an important step forward in providing more timely drug overdose data that CDC can analyze in much more rich ways than the monthly provisional counts that have been released.

• CDC has partnered with SAMHSA to expand a Harm Reduction Technical Assistance Program at CDC; the expansion will involve providing technical assistance to new grantees under the program and being a general technical resource for communities who are looking to do harm reduction work. This effort is just getting underway with partners from National Association of County and City Health Officials, Harm Reduction Coalition, University of Washington, and others.

NIDA/NIH
Wilson Compton, M.D., M.P.E., Deputy Director

Dr. Compton began his presentation by commenting on the immense coordination and cooperation among agencies represented on the ISUDCC to advance prevention and treatment of persons with substance use disorders. He proceeded to share relevant themes regarding work at NIDA/NIH. Highlights from Dr. Compton’s presentation include the following:

• Implementation science has been a major theme within the NIH broad-based Helping to End Addiction Long-Term (HEAL) Initiative. In this area, he highlighted the implementation of primary prevention across the life span, particularly emphasizing late adolescence and early adult life; developing novel treatments for substance use and drug overdose, including robust distribution of naloxone as well as looking at the need for alternatives, so when opioids are not responsible for the overdose, there are ways to help resuscitate patients and save lives acutely; and improving the uptake and delivery of evidence-based care in justice settings. Regarding the latter, Dr. Compton said that finding ways to link services to persons reentering the community remains an ongoing challenge but an important way to help save lives and help turn lives around.

• Regarding harm reduction, NIH recently published a funding opportunity notice for novel ideas in the form of administrative supplements for research on fentanyl and derivatives.

• NIH recently submitted a required report on research and evidence regarding overdose prevention centers to Congress. This has increased importance given New York City’s recent decision to launch overdose prevention centers.

• In terms of recovery research, identifying best practices for recovery support services is a major theme and a challenge. Dr. Compton welcomed the committee’s ideas about how NIH might build its research program in this area.

• NIH’s Racial Equity Initiative aims to eliminate racism in NIDA's workplace, in its scientific workforce, and in its research portfolio. This broad and diverse initiative seeks to get at some of the structural issues and social inequities that have plagued NIH.

NIAAA/ NIH
Patricia A. Powell, Ph.D., Deputy Director
Dr. Powell echoed Dr. Compton’s sentiment regarding collaboration, noting that NIAAA works closely with NIDA, the National Institute of Mental Health, and others. Before providing specific updates, Dr. Powell encouraged the group to be mindful that many individuals are challenged, for various reasons, during the holiday season and often turn to alcohol or other substances to cope. She said that evidence of the problem could be seen from hepatologists’ accounts of severe liver disease in individuals showing up in the emergency rooms and the hospitals. She said they are also hearing about mental health issues, especially adolescents. To this end, Dr. Powell said she was heartened to hear that Dr. Spoth has continued with some of his programs. Dr. Powell reiterated that even joyful celebrations, which typically involve alcohol, may be challenging for those in recovery or those wishing to abstain for any reason. She reminded the group that a broad range of health conditions are exacerbated by alcohol. Dr. Powell also noted the importance of recognizing the role of alcohol and other substances in pain, i.e., pain management, recovery, and pain treatment. She drew a connection in terms of sleep disorders and overdose deaths. All these issues, she argued, should not be viewed in isolation. To this point, Dr. Powell said NIAAA’s work continues to address how alcohol intersects with other issues and other substances. Highlights from her presentation follow:

- NIAAA is compiling a core resource of what every physician, nurse practitioner, pharmacist, and others need to know about the role of alcohol and other substances; it is close to completion, and talks are underway regarding the development of a core curriculum around the resource.
- NIAAA continues to encourage screening, brief intervention, and referral to treatment in all aspects of healthcare. A big issue in terms of making this a routine part of healthcare, she said, is to remove the stigma around alcohol and other substances; this can be done by normalizing, asking the questions, and providing the treatment.
- NIAAA is increasing its efforts to understand and address health disparities, especially related to the consequences of alcohol misuse. As part of this work, NIAAA is committed to diversifying both its internal workforce and the broader scientific community.
- NIAAA is increasing its focus on health services in long-term recovery, including implementing a “whole person” approach. Success in this area has been hepatologists partnering with addiction medicine specialists to ensure that their patients with co-occurring alcohol-associated liver disease and alcohol use disorder are getting treatment for both—thereby increasing the chances for a positive long-term outcome.
- NIAAA is about to publish its definition of recovery from alcohol use disorder; it’s a process, and it is remission from heavy drinking and alcohol use disorder. There are also time markers to designate how far along someone is in the recovery process, understanding that relapse and slips are part of the process.

FDA
Marta Sokolowska, Ph.D., Associate Director for Controlled Substances, Office of the Center Director

Dr. Sokolowska’s update on FDA focused on the agency’s role in implementing the HHS Overdose Prevention Strategy. In the area of primary prevention, for example, FDA is focusing its efforts on eliminating unnecessary initial prescription drug exposures and improper prolonged prescribing of substances with abuse potential, as well as focusing on protecting the public from
unapproved, diverted, and counterfeit drugs that present a great risk to public health (including Internet sales of such substances). In harm reduction, Dr. Sokolowska said FDA is encouraging innovation and education. Examples include supporting the development of novel overdose prevention options such as naloxone and other forms of overdose prevention strategies. She also noted FDA’s focus on investment in developing evidence-based substance use disorder treatment, especially stimulant use disorder, because of the lack of pharmacological therapies that are currently FDA-approved or with demonstrated effectiveness. Recent activities undertaken by FDA in support of the HHS Overdose Prevention Strategy include the following:

- FDA collaborated with NIDA and the Reagan-Udall Foundation on a workshop that focused on developing a technical research agenda for the treatment development of stimulant use disorder. Discussion topics included innovation in clinical trial design, the best strategies to detect the treatment effect, how to select a proper patient population that would help define the treatment effects and clinically meaningful and patient-centric endpoints. Emphasis was placed on discussing the change in the pattern of use and change in disorder status using diagnostic criteria, Diagnostic and Statistical Manual of Mental Disorders (DSM-5) specifically. Federal partners, clinicians, researchers, patients, persons with lived experiences, patients’ significant others, industry stakeholders, and payers were all engaged in workshop discussions.
- In September, FDA hosted a virtual stakeholder meeting called FDA’s Third Online Opiate Summit. The event addressed the issue of protecting the public from unapproved, diverted, and counterfeit drugs. FDA invited different government entities, academia, and other important partners to discuss how to have cross-country and global collaboration to address the evolving landscape of online opiate and other controlled substances purchasing.
- To support prescribers in appropriate prescribing of substances with abuse potential, particularly opioids, FDA held a meeting to reevaluate if there is a need for additional evaluation of its educational platforms for prescribers of opioids as part of its risk evaluation and mitigation strategies. Central to the discussion was whether there is a need to reevaluate voluntary versus mandatory education requirements.
- To further foster cross-collaboration across agencies regarding fentanyl test strips, FDA recently, together with NIDA and others, conducted two roundtables with clinicians and harm reduction groups to gather input on fentanyl test strips and other drug checking opportunities in clinical and community settings to get a better understanding what are the potential opportunities to develop new technology improvement, research, and practice in this space.

OPM

Dele Solaru, PharmD., MBA, Chief Pharmacy Officer

Dr. Solaru’s presentation focused on highlighting OPM’s activities that are a part of its comprehensive, multi-pronged strategy to address the opioid epidemic. OPM administers the Federal Employee Health Benefit (FEHB), providing comprehensive health benefits to approximately 8.2 million civilian federal employees, retirees, and dependents. OPM’s strategy to address the country’s opioid problem includes prevention efforts to promote awareness of opioid risk to federal employees and FEHB members, providing provider outreach and education through its FEHB carriers, and ensuring the safe dispensing of opioid prescriptions and the safe
disposal of prescription medications. OPM also supports rescue efforts by recognizing naloxone-based rescue agents as essential for preventing opioid overdose-related deaths. Recognizing these rescue agents as preventive care allows FEHB carriers to provide a co-pay waiver and remove financial barriers that would prevent members from obtaining naloxone-based products. This also allows high-deductible health plans to provide some naloxone-based rescue agents without applying a deductible under the Preventive Care Safe Harbor, as implemented by the Internal Revenue Service. Dr. Solaru also shared the following additional OPM updates related to its strategy to address the opioid epidemic:

- OPM has worked on expanding coverage and access to SUD treatment medications by encouraging carriers to add qualified network providers to their network, remove prior authorization requirements, and adjust formulary placements of these drugs.
- OPM has had carriers assess the adequacy of non-opioid pharmacy benefits for pain management and non-pharmacologic benefits for pain management, such as physical therapy, chiropractic care, or other manipulative therapies.
- OPM has encouraged carriers to expand access to care by expanding their mental health provider networks and leveraging telehealth services to address provider shortages; ensure access to programs that identify members at risk for opioid use disorders and substance use disorders; and improve access to opioid addiction treatment programs, family-focused residential treatment programs, and opioid recovery centers.
- OPM is currently encouraging its FEHB carriers to promote comprehensive, coordinated care that includes medical, pharmacy, behavioral, including mental health care, by providing adequate reimbursement for these services. Dr. Solaru ended her presentation by recognizing the work done by different federal agencies, noting that OPM leverages a lot of that work in developing its policies for FEHB members.

VA
Joseph Liberto, M.D., Deputy, National Mental Health Program Director for Substance Use Disorders

Dr. Liberto updated the group on VA activities since the last ISUDCC meeting. Highlights from his presentation follow:

- In collaboration with the Department of Defense, the VA released new national practice guidelines for the management of substance use disorders; the guidelines are available at http://www.healthquality.va.gov/guidelines/MH/sud/.
- In FY21, the VA saw an increase in the number of veterans with substance use disorders accessing care compared to FY20, but the numbers are not quite back to pre-COVID levels.
- The VA’s focus, in the context of the overdose epidemic, is on:

  1) Opioid use disorder treatment
    - From August 2018 through September 2021, pilot clinics in the VA’s Stepped Care for Opioid Use Disorder Train the Trainer (SCOUTT) Program saw a 211 percent increase in the number of patients receiving buprenorphine for opioid use disorder and a 194 percent increase in the number of prescribing providers for buprenorphine;
71 percent of veterans were retained in treatment for at least 90 days or more during that time.

- Currently, the VA’s use of medications for opioid use disorder is around a little less than 47 percent.
- DEA X-waivers of VA providers continue to increase; the VA continues to provide trainings despite changes in requirements, i.e., X-waiver not requiring dedicated eight hours of training if you are prescribing for 30 patients or less.
- The VA added Office Hours sessions for its subject matter experts to meet with providers across the country to answer questions about opioid use disorder and its management.
- The VA’s Ask the Expert program is an email-based program that affords providers across the country an opportunity to ask questions about any type of substance use disorder management and get input from subject matter experts.
- The VA’s work with its clinical pharmacy specialists to “increase the footprint” has resulted in 212 VA clinical pharmacy specialists delivering opioid use disorder care as of the fourth quarter of FY21. This represents over 47,000 encounters during FY ‘21, about a 76.8 percent growth over the last couple of years.

2) Stimulant use disorder treatment

- The VA remains a leader in contingency management treatment. Since its initiation in the VA in 2011, over 5,700 veterans have been treated with contingency management (not all with stimulant use disorder). Nearly 92 percent of the greater than 73,000 urine samples tested negative for target drugs, e.g., stimulants or cannabis.
- The Veterans Health Administration (VHA) plans to launch a stimulant safety initiative focused on increasing evidence-based treatment for stimulant use disorders in January of 2022; the VA will focus on providing both contingency management and cognitive behavioral therapy.
- This year, in alignment with the President’s budget, the VA is the recipient of special purpose funding to increase SUD (substance use disorder) staffing across the enterprise, increase contingency management efforts, and increase access to residential treatment programs.
- The VA is looking to “increase its footprint” regarding peer support within substance use disorders programs and expand to have a supportive employment specialist embedded in programs across the country to help support employment services and homeless program coordinators.
- Current priorities include increasing medications for opioid use disorders, increasing evidence-based treatments for opioid use disorders, and enhancing evidence-based harm reduction efforts.
- The VA is working to increase its overdose education and naloxone distribution; it is now required that patients with opioid use disorder get offered naloxone and get opioid overdose education. Since implementing its Opioid Education and Naloxone Distribution Program in 2014, the VA has had over 36,700 providers prescribing to over 328,000 veterans; at least 2,000 overdose reversals have been documented during that time.
- In May of 2021, the VA’s Assistant Under Secretary for Clinical Services issued guidance recommending that VA medical centers develop Syringe Service Programs
(SSPs) or otherwise ensured veterans enrolled in VHA care have access to SSPs where allowable by law. And at the start of FY 2022, four VA SSPs were operating, with 18 programs close to implementing the operation.

- Recognizing that non-fatal overdoses are a good predictor of future overdose events, the VA has mandated, as of July of 2021, a national medical record; this represents the VA’s attempt to report overdoses, look at the current treatment plan, and line up treatment with risk mitigation strategies that help minimalize risk for patients.

USDA
Jacqueline Ponti-Lazaruk, Chief Innovation Officer, Department of Agriculture Rural Development

Ms. Ponti-Lazaruk began this presentation by reminding the group that USDA Rural Development (RD) is the coordination point for the Department of Agriculture’s rural health issues, including substance use issues. In addition to working across RD as a central connection point for interagency and other partnerships, data sharing and analysis, and other areas, its Innovation Center is also the home of USDA’s Rural Health Liaison. Congress created the role of a USDA Rural Health Liaison in the 2018 Farm Bill to work in support of rural health; lead the coordination of rural health work for USDA; ensure that USDA customers are aware of the support the Department offers in relation to the rural health; and to look across the federal family to find ways where USDA can better address the continuum of rural health issues, from prevention or nutrition matters related to the building of hospitals and treatment facilities. To this end, Ms. Ponti-Lazaruk introduced Ms. Kellie Kubena as USDA’s Rural Health Liaison. She noted that Ms. Kubena would represent the Department of Agriculture on the ISUDCC.

Ms. Kubena first reminded the group that RD provides loans and grants, and loan guarantees to help expand economic opportunities and create jobs that improve the quality of life for millions of Americans in rural areas. She next offered the following updates:

- RD is focusing on three priorities of the Administration: COVID-19, equity, and climate; RD has begun to use those priorities when it has discretionary points in its programs. RD is still working, particularly around equity, to find strategic engagement projects that will reach its most vulnerable rural areas and address barriers to participation in its programs.
- The Rural Workforce Innovation Network has held a few calls this fall. One of particular interest was expanding the rural public health workforce; the calls were recorded and available at https://www.rd.usda.gov/rwin.
- RD plans to have deep-dive workshops around working with Federal programs and regionally focused workshops in 2022.
- The monthly Innovation Matters newsletter continues to announce RD updates and accomplishments. Recent highlights focused on a Disaster Resiliency Guide, the ReConnect Broadband Program, and Emergency Rural Healthcare Grants.

Ms. Kubena ended her presentation by sharing a summary of FY21 updates. She noted the following:
More than $100 million was provided for over 13 funding programs for approximately 60 prevention and treatment-related projects, including 30 opioid and substance use-related projects under the Distance Learning and Telemedicine Program.

The third round of the ReConnect Broadband program funding announcement was released; this represents almost $1 billion in funding for broadband. The application window is open until February of next year.

The USDA announced the Community Facilities Emergency Rural Healthcare Program, funded for up to $500 million from the American Rescue Plan. Track 1 is for Recovery Grants to support rural healthcare services to help them address immediate issues related to the COVID-19 emergency. Track 2 is for Impact Grants; it offers longer-term funding to advance ideas and solutions to solve regional healthcare problems and support the long-term sustainability of rural health. The application window for both tracks opened in August. Applications for Track 1 are still being accepted; Track 2 closed in October.

Xochitl Torres Small joined RD as the new Under Secretary for Rural Development.

Joaquin Altoro joined RD as the new Administrator for Rural Housing Service.

A conference, The Ag Outlook Forum, will be held in February 2022; RD will do a session related to mental health and agriculture, working with its colleagues in SAMHSA, CDC, HRSA, and across USDA.

An Ag Mental Health convening will be held sometime in early 2022, and details are forthcoming.

SSA

Leola Brooks, Social Insurance Specialist, Office of Resource Demonstration and Employment Support

Ms. Brooks began her presentation by sharing information on the Office of Resource Demonstration and Employment Support (ORDE). The Office is primarily responsible for conducting research and analysis related to its disability programs, the Social Security Disability Insurance (SSDI) program, and the Supplemental Security Income (SSI) program. She further explained that ORDE designs, implements, and evaluates demonstration projects and tests the changes to its disability program policies to ensure they’re working for its beneficiaries and those in the public who may be interested in applying. She also noted that ORDE conducts research analysis evaluations and statistical modeling, among other activities, that support the agency’s goals to strengthen its disability programs and improve program integrity.

Noting that ORDE administers the employment support programs for people with disabilities who want to work and manages the Ticket to Work program, Ms. Brooks spent the remainder of her presentation sharing information about one of ORDE’s latest programs. The Promoting Work Through Early Intervention Project, she said, started in February 2020 and is a joint undertaking between the SSA and HHS, Administration for Children and Families (ACF). Through this project, SSA and ACF will support rigorous evaluations—e.g., impact evaluations, implementation research, and cost-analysis evaluations—of existing employment supports and training programs shown by the evidence to be promising to both agencies’ populations. They have a particular interest in understanding the effects of an intervention that would be aimed at improving the employment and economic outcome of low-income individuals with little or no work history and whom either have a current or foreseeable disability and who had not yet
established a work history and applied for any type of supplemental security income, i.e., SSI. Specifically, Ms. Brooks spoke about two existing ACF projects, one of which has more potential to serve people with substance use:

- Launched in 2017 and funded for the specific purpose of looking at opioid use in 2020, the Building Evidence on Employment Strategies (BEES) for Low-income Families project will evaluate the effectiveness of innovative program design to increase employment and earnings for low-income families who have opioid use.
- The Next Generation project will focus primarily on people with mental health issues.

Ms. Brooks indicated that because of COVID-19, both projects have readjusted their start dates in terms of recruitment efforts. She said progress is now underway and stated that she looks forward to sharing more information at the next ISUDCC meeting.

**Harm Reduction**

*CAPT Jeffrey A. Coady, Psy.D., ABPP, Acting Director, Center for Substance Abuse Prevention (CSAP), SAMHSA*

CAPT Coady used his presentation to share information on harm reduction work across SAMHSA and other Federal agencies. One of the HHS Overdose Prevention Strategy pillars, CAPT Coady, outlined four objectives related to harm reduction: Research and Demonstrations; Integrated Evidence-Based Harm Reduction; Sustainable Funding, and Reducing Stigma. For each objective, he noted activities undertaken at SAMHSA and other Federal partners.

Highlights are provided below:

- The CDC-SAMHSA Harm Reduction Technical Assistance Center is expanding its capacity in terms of harm reduction approaches, especially at the state and community levels. Work in this area will focus on supporting enhanced technical assistance to ensure the implementation of evidence-based harm reduction programs and practices and policies in diverse settings. The CDC-SAMHSA Harm Reduction Technical Assistance Center will also focus on equity in decreasing health disparities through the application of culturally informed approaches and strategies and the quality of services.
- SAMHSA has announced its Harm Reduction Program Grant, SAMHSA’s first dedicated grant in the area of harm reduction. The purpose of the grant is to expand the efforts for community-based overdose prevention programs, syringe service programs, and other harm reduction services. Approximately 25 eligible entities, e.g., states, territories, local governments, federally recognized tribes or consortia of tribes, and nonprofit community-based organizations will be awarded the 3-year grant at about $400,000 each.
- In collaboration with the ONDCP and CDC, SAMHSA will hold a national summit on harm reduction, "Field Views on Harm Reduction," in December. The summit will convene diverse stakeholders working in the areas of prevention, harm reduction, treatment, and recovery, as well as users of harm reduction services, to help SAMHSA define harm reduction principles, pillars and measures and incorporate harm reduction strategies into its programming, policies, and practices.
- SAMHSA has launched a harm reduction webpage that will facilitate conversations related to harm reduction and house information on SAMHSA’s harm reduction work.
CAPT Coady closed his presentation by reiterating the cross-cutting nature of harm reduction across SAMHSA, its centers, and the Federal Government. To this end, he explained that SAMHSA is considering harm reduction in the context of policy, payment reimbursement, research, program effectiveness, practices, and the continuum of care, among other areas, as it is being challenged to reconsider some assumptions that were previously held.

Following CAPT Coady’s presentation, Dr. Delphin-Rittmon expressed excitement about SAMHSA’s funding from the American Rescue Plan for the Harm Reduction Program Grant; she noted that the Notice of Funding Opportunity (NOFO) was released the day prior to the ISUDCC meeting. She said she was hopeful that the resources would reach communities that need them to expand and scale up their harm reduction work.

Dr. Olsen also expressed enthusiasm on behalf of CSAT, saying, “I think this is a piece of the continuum from across prevention, harm reduction, treatment, and recovery that has been missing.” She added that she looked forward to working with CAPT Coady and partners across and outside the Government to think through how harm reduction fits into the continuum of care and services for individuals however it may make sense.

Open Discussion

Dr. Delphin-Rittmon opened the floor for discussion. During the time, ISUDCC members were afforded an opportunity to comment and ask questions related to SAMHSA’s harm reduction work or related to any of the other presentations they heard.

Ms. Sivilli commented that ONDCP is very excited about the new initiative and the SAMHSA's funding. She said it’s a transformative moment in drug policy, and she encouraged the group to share successful models as SAMHSA shares them. She said the summit on harm reduction would be a big deal, and the harm reduction funding and the outcomes will change the drug policy trajectory. She also commented that harm reduction will be a new platform for stigma, so she encouraged the group to continue messaging on “evidence-based, saving lives, and evidence-based work matters.” In response, Dr. Delphin Rittmon agreed that there is still much stigma. The messaging will be critical—that harm reduction strategies can save lives, plant important seeds, and ultimately help connect people to needed services and supports.

Dr. Spoth, reflecting on previous comments related to scaling up prevention and drawing from his own experience with studies that suggest “scale-up” that is not happening, questioned how collaboration could apply in terms of realizing the potential of evidence-based prevention. In response, Dr. Delphin-Rittmon said scale-up is always an important area to look towards; she said some work is being done across departments, and there is work to be done in terms of evaluating and digging deeper in certain areas, as well as identifying areas where they want to scale up. She added that resources had been disseminated through the American Rescue Plan and other COVID-related funding, so additional prevention-related services and supports are being funded through block grants, for instance. She said it would be important to identify some of those impacts to know what to scale up or scale back.
CAPT Coady commented that the implementation of evidence-based prevention programs is a challenge. To the point about collaboration, he said SAMHSA is working jointly with NIDA, for example, to get emerging programs to the field and to use training and technical assistance centers to get information out. He also mentioned that SAMHSA is moving forward in terms of its workforce competency related to prevention, including looking upstream in terms of recruitment and retention to ensure that evidence-based programs can be implemented successfully. Related to this point, he said it is important to consider the “fit” of a program to be a practical fit for a community. To this end, he said they are looking at how to move some of the practice-based evidence, what might be evidence-formed, to the “evidence-based.”

Dr. Jones commented that from a CDC perspective, as they think about their overdose prevention work and their adverse childhood experiences prevention work, those types of programs and building resilience are key to advancing prevention efforts. He also noted that CDC has tried to encourage people to adopt evidence-based work by citing in its funding announcements what programs can’t do—because there are plenty of things that people feel are evidence-based prevention that there’s no evidence to support.

Ms. Chrisman Low questioned the interest of Federal program/agency directors in collaborating with community-based organizations (CBOs), and she sought advice on how the CBOs can present themselves as viable, valuable, and vocal. In response, speaking for SAMHSA, Dr. Delphin-Rittmon said they are interested in collaborating and connecting; she felt confident her colleagues would agree. Dr. Delphin-Rittmon offered that something as small as sending out the Harm Reduction NOFO is meaningful because they want to see a range of innovative approaches and strategies in application submissions. She suggested that the potential use of subcommittees on the ISUDCC might present possibilities for collaboration. On the federal side, Dr. Delphin-Rittmon reiterated that they need to hear from organizations and providers working in communities about what is working, what is not working, and where there are gaps.

Dr. Banta-Green shared a link with Ms. Chrisman Low in the chat on a report that speaks to five years’ worth of SAMHSA funding to distribute naloxone in Washington State. To her point, he said, the state and/or the University of Washington could have kept all the money, but instead, they pushed it out and paid for staff to run the service programs—they oversaw the money and distributed those funds. Law enforcement went to them to get trained and to get naloxone, and they recognized the expertise of the local organizations. Dr. Banta-Green indicated that a paper on this work is currently being written.

Noting the long history of syringe exchange in Washington State and reflecting on the major issue of the doubling of its overdose death rate in the last decade (almost entirely driven by fentanyl and methamphetamine, and the vast majority of that being smoked, not injected), Dr. Banta-Green suggested that route of administration data should, in part, guide harm reduction funding. He proceeded to ask Dr. Jones what data are or will be available, as State Unintentional Drug Overdose Reporting System (SUDORS) may be one of the few good datasets that can provide that information. As a follow-up question, he asked about the policy ramifications regarding what the Federal Government will fund, i.e., what is considered harm reduction. In response, Dr. Jones agreed that there is no great data on the route of use. He said they had used
the Treatment Episode Data Set TEDS for certain drugs. Dr. Jones said they have started to look at National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO) data, a proprietary dataset because it provides detailed information on the route of use. He also said a Morbidity and Mortality Weekly Report (MMWR) would come out the following week that looks at some of the SUDORS data, which is looking at the route of use; he said there are some interesting geographic differences when they look at things like fentanyl. Unfortunately, he said, the National Survey on Drug Use and Health (NSDUH) data are not great for a route of use, and most other datasets like Youth Risk Behavior Survey (YRBS) and Monitoring the Future (MTF) provide some data. However, prevalence is so low that it’s hard to make much of it among young people in particular. Dr. Jones did say that the CDC is funding some work to get better data, but the population samples are limited. CAPT Coady said he responded to the second part of Dr. Banta-Green’s question in the chat.

Dr. Compton asked, acknowledging that it is a notorious long-term issue, “How do we go from the development of evidence to its widespread adoption?” He argued that there is no straight path for that. He called Dr. Spoth one of the leaders in developing the evidence of program impact and developing evidence around systems to adopt those programs. He said Dr. Spoth’s PROSPER system is one of several that offer evidence-based ways for communities and organizations to make choices among evidence-based prevention practices. He said NIH is proud to have supported that and looks forward to seeing it continue to thrive.

Dr. Compton commented that a key issue had been the lack of consistent long-term funding. He said one way they address this is by thinking about some new targets with different funding streams. For example, he said they have been supporting research to take some prevention interventions and test them in medical settings, understanding that if the U.S. Preventive Services Task Force accepts prevention approaches with an A or B rating, they are automatically covered by health insurance. He said this strategy continues to look like a possibility for providing a new way to provide some of the broad-based resilience and wellness programs.

CAPT Coady commented that he appreciated the conversation about the data, as he believes that oftentimes the best data come from community data. He also asked to be kept in the loop regarding the availability of data referenced by Dr. Jones.

Dr. Spoth shared an idea that he learned recently about federal agencies using review panels to decide what within their mission has the strongest evidence and then incenting those funded to implement the strongest evidence-based interventions.

Ms. Kubena commented that the Rural Workforce Innovation Network is hoping to support subgroups this year, to focus on certain topics. Notably, she said healthcare is a big issue, including how to provide professional and support staff.

Dr. Ryan asked, reflecting on the incredible increase in overdose deaths that has been witnessed since COVID, if people are looking specifically at additional causes, e.g., lower access, isolation, issues with mental health. She argued that such factors might inform newer ways of approaching harm reduction. In response, Dr. Delphin-Rittmon indicated that SAMHSA asked a few questions on its National Survey on Drug Use and Health (NSDUH) regarding some of the
impacts of COVID related to substance use mental health challenges. She said the data did show that people reported using more substances to cope with the stress of the pandemic. She also said that people with either some mental illness or higher levels of mental health challenges reported that the pandemic exacerbated or negatively impacted their mental health. She encouraged Dr. Ryan to look at the NSDUH data. Dr. Jones also indicated that CDC did a study that looked at the impacts of COVID on mental health, and he said they are looking closely at mortality data because they are not seeing substance use behaviors change as rapidly as they are seeing the number and rates of death go up. He speculated that the proliferation of counterfeit pills, especially the westward movement of fentanyl, is driving much of that increase. He advocated for continued education and investigation of risk factors, saying, “As the illicit drug market continues to change and be highly unpredictable, it introduces additional complexity and challenges because we could have all the naloxone in the world, but if no one is there to administer it, it can't save a life.”

Mr. Sledge commented on the disturbingly exponential rate people are losing their loved ones. He asked if the ISUDCC could appeal to Congress to amend the Controlled Substances Act, saying that would eliminate the need for the DATA 2000 waiver altogether. He argued that the concept of needing the additional waiver to prescribe medicine for opioid use disorder is the epitome of stigma and discrimination. He further commented that robust data show this would translate to saving tens of thousands of lives in the U.S. by preventing overdose fatalities. He reminded the group of the importance of acting with a sense of urgency, as lives literally depend on it. In response, Dr. Olsen said several advocacy groups had made the same argument; and she said there is a proposal in Congress to do what he suggested.

As a follow-up, Dr. Compton thanked Mr. Sledge for his comment and noted that Federal employees could not advocate directly to Congress because their role is to implement the laws they’ve passed. Notwithstanding, he assured Mr. Sledge that his comments would be on the record because the ISUDCC is an outside advisory group. Dr. Compton also encouraged Mr. Sledge to inform his congressperson of his perspective.

Reflecting on an earlier mention about the impact of COVID on mental health, Dr. Compton put in a plug that the annual Monitoring the Future (MTF) survey would be released the following week. He also indicated that there is information in the MTF about the perceived impacts of the pandemic on teens' mental health; he encouraged the group to look at it when it is released.

Dr. Goforth Parker asked, “What relationship do we think that the open borders and the drugs that we hear are coming across Mexico and Texas border have, and how is that impacting the manufactured drugs that are being brought in and the increase in deaths because of that?” In response, Ms. Sivilli commented that part of ONDCP’s portfolio and much of the Government is invested in stopping the flow of drugs into the country, whether it’s at the borders, across the sea, or in the air. She said that ONDCP is working with Mexico, Colombia, and other countries, including China, where fentanyl comes from.

Dr. Torres agreed that significant efforts are being taken to stop the flow of drugs, and he argued that the efforts are paying off. He cautioned the group against believing in political soundbites,
saying the issue is tremendously politicized and only adds to the stigma and the discrimination of living on the border. This area is 94 percent Hispanic.

Dr. Olsen reminded the group about the importance of accepting people for where they are and then doing what can be done to help them, wherever that might be.

Dr. Dawson, referring to Mr. Sledge’s comments about stigma with the X-waiver and the DATA 2000 process, said the other stigma is “numbers.” With the understanding that the DEA wants to limit how many people they can serve, Dr. Dawson said she and many other nurse practitioners and doctors who are DATA waivered would love to have those doors opened. She said it is also stigmatizing to say, “Oh, you’re working with the addicts,” or “You’re working with those people.” She said it is stigmatizing by just having a DATA waiver. In response, Dr. Delphin-Rittmon said SAMHSA is aware of the concern and is looking at what can be done in terms of addressing stigma as it relates to prescribing and substance use, e.g., working on flexibilities and looking at ways to expand or to continue some of the flexibilities that are in place.

Amanda S. offered comments from a patient perspective. Although guidelines around medications for opioid use disorder (MOUD) have been relaxed and telehealth is allowed for new buprenorphine patients, the flexibilities are not as available or used by as many providers as they should be or as one might think. Even as an adherent patient, during the height of the pandemic, she said she was still required to see her provider in person every month. She said she could do her first telehealth visit only when she thought she had contracted COVID. Turning her comments to the increasing rates of overdose, Amanda S. suggested that one cause might be patients’ abrupt discharge from treatment or their being suspended from take-homes if they test negative for a controlled medication like attention deficit hyperactivity disorder (ADHD) medication or benzodiazepine or if they test positive for a “no excuses” item like cannabis. In such cases, she said, their access to crucial medications ends, leaving the patient to navigate the situation alone while trying to find a new provider. She said it would be helpful if Medicare and/or Medicaid could implement some type of safety net for these patients or create guidelines for providers on this issue. Amanda S. also called attention to the problem of providers double-dipping, i.e., charging patients out of pocket for their buprenorphine prescription and billing insurance for the service. She explained the dilemma patients face in such instances, saying they may want to report the abuse but don’t want to risk losing their doctor or their treatment. Finally, regarding the SAMHSA Harm Reduction Grant Program, Amanda S. said many small, community-based organizations distrust federal programming and view grants as unattainable. She suggested that people with lived experience could collaborate/contract with existing community organizations and/or harm reduction coalitions to assist [federal programs] in getting feedback on funding priorities. Dr. Delphin-Rittmon thanked Amanda S. for sharing her experiences and agreed that the goal should be to connect individuals with services and not have barriers that cause them to lose their connections to services and/or supports.

Dr. Gandotra said, to echo Amanda S.’ point, “We should not be surprised if someone with a substance use disorder struggles with substances, or if they’re being treated for opioid use disorder that they might have an issue with some other substance. That should never be grounds on its own to discharge a patient. That seems to be contradictory to the actual treatment goal.”
He assured Amanda S., insofar as SAMHSA can advocate and educate its providers, they will do their best to ensure that that message moves forward.

Dr. Olsen also thanked Amanda S. for her comments. She echoed Dr. Gandotra’s sentiment, saying the country’s “treatment” model was built on an acute care model that does not work for a long-term condition. She advocated for continuing to move towards much more continuity—a longer-term, longitudinal-based model—and the entire framework that comes along with that, which is not based on punishment. She agreed that SAMHSA would need to help move the field in this direction.

**Low Barrier Service Model for Opioids and Stimulants at Community Agencies**

*Caleb Banta-Green Ph.D., M.P.H., M.S.W., Principal Research Scientist*

*Alcohol & Drug Abuse Institute, University of Washington*

Dr. Banta-Green began his presentation by sharing information on his professional background, which started with his first social work internship in an Opioid Treatment Program (“methadone clinic”) in 1995. His current affiliations include working at the Addictions, Drug, and Alcohol Institute, which is a research institute in the Department of Psychiatry and Behavioral Sciences in the School of Medicine; serving as an affiliate professor in the School of Public Health, Health Systems, and Population Health; and serving as an affiliate faculty member in the Injury Center.

After acknowledging and expressing gratitude to our country’s indigenous peoples, Dr. Banta-Green noted that in Washington State, as in much of the country, opioid overdose death is approximately three times higher among Native American and Alaska Native populations. Reflecting on this point, he said the low barrier work referenced in his presentation is about equity, access, social justice, and public health.

After noting several projects that he is currently working on, including one around pre-exposure prophylaxis (PrEP) for methamphetamine, and another aimed at linking people with opioid use disorder to buprenorphine in emergency departments, Dr. Banta-Green said his presentation would primarily focus on a project funded by the Allen Foundation and others around low barrier care, the Community Based Medications First Model for Opioid Use Disorder.

Setting the stage for the discussion, Dr. Banta-Green first spoke about treatment gaps, noting that there are persistent treatment and harm reduction gaps. He said the minority of people with substance use disorder aren’t receiving any treatment, let alone evidence-based treatment. He acknowledged, however, that treatment capacity expansion has been happening, notably through the State Opioid Response SOR grants.

Dr. Banta-Green said methamphetamine use disorder and fatal overdoses are increasing to new highs in the west and emerging in the eastern U.S., and cocaine persists. Additionally, fentanyl and meth use and consequences are increasing much faster than services. These trends, he argued, provide further evidence of continuing gaps around treatment and harm reduction. Dr. Banta-Green also indicated that he is also interested in having dialogue around recovery gaps—an area that is being looked at by researcher John Kelly. He said Dr. Kelly’s research shows that recovery indices by years since problem resolution, i.e., quality of life and recovery capital, that recovery from opioid and stimulant use disorders takes significantly longer than for alcohol and cannabis. He also noted that many in recovery continue to use substances and are often able to
maintain recovery and maintain their functioning. On this point, he emphasized that recovery is not equivalent to abstinence for many people. Bolstering this point, Dr. Banta-Green shared statistics from a statewide syringe exchange survey that showed about 80 percent of people who use opioids said they wanted to stop or reduce their use. About 50 percent of people who use methamphetamine said they wanted to stop or reduce their use. He offered the following points as reasons to focus on truly person-centered, community-based care:

- Brief interventions in the emergency department often have modest or short-lived impact; they are exciting and promising, but they are not long-lived.
- People who use drugs often do not feel welcome in traditional healthcare or SUD treatment settings.
- Treatment, harm reduction, and recovery can and do overlap—often at the same time for the same person.

Dr. Banta-Green said the Medication First model for opioid use disorder (OUD) essential elements is predicated on drop-in visits; a short time to start medication, often same day; allowing initial and ongoing use of other substances; no counseling or support group mandates (but they are offered); and using urine and drug screens to document buprenorphine adherence or to at least understand it and other ongoing substance use. Regarding the latter, he said, knowing the substance(s) a patient is taking is relevant medically and in the context of mental health care and other services. He further indicated that the use of urine and drug screens are not done in a punitive way but rather to increase engagement in services.

Next, Dr. Banta-Green highlighted a Public Health Seattle King County pilot program. In January 2017, he said, the syringe exchange program launched its Buprenorphine Pathways model. The model was set up with a nurse care manager model, adapting the Massachusetts collaborative care model. Dr. Banta-Green explained the process, saying, “Needle exchange staff approach clients to gauge their interest in the program. Clients can also self-present. The nurse does a brief assessment, develops a buprenorphine induction and care plan, then briefly consults with a buprenorphine prescriber, and medications are dispensed.” He proceeded to share data on the project, which he said was successful, noting that a paper was published on the same. Data showed that clients initiated most conversations around buprenorphine by week five. He said, around month 2, people started lining up an hour or two early to get buprenorphine. This, he argued, dispels the myth that people don't want treatment. He said, “They may not want our hard-to-get, hard-to-access, not very kind treatment, but they do want services, and they do want buprenorphine for sure and other treatments.” Other encouraging results included a significant decrease in illicit opioid use (90% to 41%, \( P < .0001 \)) and an increase in the documentation of buprenorphine in urine drug screens (33% to 96%, \( P < .0001 \)).

Among other results, Dr. Banta-Green commented on data related to care episodes, saying he is very interested in further exploring “cumulative time in care” and how to invite people back into care.

Dr. Banta-Green felt confident that the model used in the Public Health Seattle King County pilot did not increase harm; in fact, he said he believed it decreased harm. He explained that it was that Buprenorphine Pathways model that was adapted in the Community-Based Meds First study. He said they added care navigators to the Nurse Care Manager model. He said they
wanted to provide more points of contact, more service and were hoping to ease individuals’ transition into primary care. The latter, he said, did not happen. Dr. Banta-Green clarified that the clinics were built first, and then, after people knew they were going to be prescribed buprenorphine, they were made aware of the research study and invited to participate. Highlights from the Community-Based Meds First study included the following, among others:

- Six sites across Washington State (3 each in Eastern and Western Washington).
- Six-month duration – medication start and protracted stabilization.
- Syringe services programs and/or services for unhoused people.
- Extensive ongoing implementation support from the University of Washington clinician-researchers with site staff and administrator.
- Quasi-experimental study design, synthetic comparison group derived from state records data.
- 833 individuals enrolled (07/2019 – 11/2021); over 1,100 received care.
- Outcomes to include acute care, non-fatal, overdose, death, arrests.
- Preliminary data (N=300) indicate that more than 60% had buprenorphine dispensed on the first day.
- Providers have been saying that this is the model they have been waiting for.

Dr. Banta-Green indicated that the model is now evolving into an “Engagement First” model, and he noted that they are continuing with OUD and adding stimulant use disorder. He reiterated that many people are not ready to stop using stimulants and/or opioids. However, they want connection and an array of services, e.g., care navigation, counseling, a 12-step program. To this end, he said, “We are looking at how to integrate this with harm reduction services as well. It's what people want; it's what people need, and it will improve public health immediately.”

Therefore, he continued to explain that the model they are building involves medical care, mental health support and care, addiction treatment, and harm reduction (both supports and supplies to decrease infectious disease and death). He said this work is being done on a smaller scale in Eastern and Western Washington, and care is not time limited. Notably, he added, the state funder is paying them based on “engagements.”

After briefly touching on some of the care components offered through the Engagement First model, Dr. Banta-Green also noted that this model adds a social work care manager, includes extensive implementation support, and includes contingency management implementation for SUD. On the evaluation side, Dr. Banta-Green said they are doing acceptability evaluations of clients and staff regarding the new service model and the contingency management element, among others. He also said they would be looking at service utilization patterns to understand what people are accessing over time and the acceptability of the services. He said individual sites might also opt to work with their payers to do pre-/post care analyses. He added that he would be knocking on the door of federal funders at some point.

In terms of the next steps, Dr. Banta-Green said they are doing much work around financial sustainability and alternative payment models, as it is tough to pay for nurse care managers, care navigators, and harm reduction services. Recognizing that workforce is a major limitation, he said the University of Washington recently started a bachelor’s level Behavioral Health Tech
program. He also said utilizing the flexibility around telehealth will be necessary, as well as having the more extensive conversation of “When working with individuals who have high tolerance on fentanyl, how do we get methadone to be an important part of that apothecary along with buprenorphine?” Finally, and perhaps most importantly, Dr. Banta-Green said it would be important to co-design and evaluate this work with people with lived and living experiences with substance use disorder.

In closing, Dr. Banta-Green shared a final thought, “Given persistent treatment, harm reduction, and recovery gaps; given the dramatically increased need in terms of mortality rates that we're seeing; and given the promise that we and others are seeing with low barrier care, I'm curious how we, as committee members and Federal agencies, can support transformative models of care.” He ended his presentation by sharing additional available resources on low barrier models of care, and he welcomed feedback and thoughts on his presentation.

Open Discussion

Dr. Delphin-Rittmon opened the floor for questions or comments on Dr. Banta-Green’s presentation.

Dr. Ryan asked Dr. Banta-Green if The University of Washington had done a cost-benefit analysis. In response, Dr. Banta-Green said payers are invited to and attend State Treatment Research Workgroup Meetings that he co-chairs with Mike McDonell; he noted the payers are interested in doing some cost analyses on their dime, which he said he welcomes.

Ms. Chrisman Low asked Dr. Banta-Green to elaborate on how the University of Washington had implemented a trauma-informed approach into the model. Dr. Banta-Green said one way the University of Washington did this was by putting the model in community organizations/harm reduction organizations where people had existing, trusting relationships. Other methods include

- providing care in one site;
- having drop-in accessibility;
- being kind and welcoming providers and care navigators that are people in recovery.

Dr. Dawson echoed the importance of having a “patient first” approach, i.e., going right to treatment. She also noted the importance of having trust and treating a person where they are, i.e., providing a relational type of treatment.

Before opening the floor for public comment, following up on a discussion from the last ISUDCC meeting, Dr. Delphin-Rittmon engaged members in a discussion regarding their interest in having subcommittees as part of the ISUDCC. She suggested that the subcommittees focus on any content area(s) of interest to the committee. CAPT Carlos Castillo joined the call to help answer questions related to the formation of subcommittees.

Dr. Dawson said she would like to be involved on a subcommittee focused on provider support, and she also expressed a willingness to work with Dr. Banta-Green on the data he brings forth to share those with providers. Dr. Goforth Parker expressed an interest in rural health, noting that many First Nations people are in rural areas. Dr. Torres echoed a subcommittee on rural health
suggestion, noting that much of the Rio Grande Valley is rural. Dr. Spoth suggested a subcommittee focused on prevention scale-up, especially translational science, into practice, especially in rural areas. Dr. Banta-Green suggested harm reduction.

Dr. Delphin-Rittmon asked how often the group would like the subcommittees to meet and how the ISUDCC members would populate them. In response, CAPT Castillo said subcommittees could convene as frequently as they wanted. However, he noted that the subcommittees must report on their findings and deliberate with the parent committee. Dr. Banta-Green asked if SAMHSA would provide staff support to the subcommittees to schedule and capture meeting minutes. In response, Dr. Delphin-Rittmon said SAMHSA could provide staff support. Dr. Dawson asked if, in lieu of minutes, a Zoom meeting could be recorded and made available for playback to the larger ISUDCC. She also indicated that, in her opinion, at least two meetings of any subcommittee should be appropriate unless a subcommittee was working on a particular project. In terms of participation, she felt that anyone with a vested interest in the topic should participate. In response, Dr. Delphin-Rittmon asked CAPT Castillo if there were rules about outside individuals serving on subcommittees. CAPT Castillo assured the group that people not appointed to the parent committee could serve on a subcommittee. However, he cautioned that a parent committee member must serve on each subcommittee. Additionally, he said the DFO or alternate DFO should assign a federal person to capture subcommittee discussions. Circling back to the suggestion of videotaping subcommittee meetings, CAPT Castillo said the idea of videotaping was a good idea because the meeting would be “captured.” Notwithstanding, he indicated that the videotape would need to be shared with the parent committee for deliberation prior to any implementation of recommendations.”

Dr. Spoth said it would be helpful to have an agenda and tasks for each subcommittee defined. He suggested that this exercise would enable people to participate in a subcommittee. If his suggestion were to move forward, Dr. Spoth asked about the preferred process for interacting with SAMHSA around the definition of the work that each subcommittee would perform. In response, Dr. Delphin-Rittmon said she was open to recommendations or products for consideration by SAMHSA.

Dr. Liberto recommended having the subcommittees comprise a mixture of ISUDCC members and non-ISUDCC members. He noted that the subcommittees could gain much subject matter expertise from this mix of individuals.

Mr. Sledge suggested that the ISUDCC do some type of “needs assessment” to identify key content areas for the subcommittees. Agreeing with his point, Dr. Delphin-Rittmon cited additional content areas posted in the chat. Those included recoveries, advocacy, stigma reduction, and community support networks. Cognizant of the time, Dr. Delphin-Rittmon suggested that a special meeting be scheduled to refine further ideas concerning the adoption of ISUDCC subcommittees, e.g., content areas, membership, frequency of meetings, committee leads. Amanda S. suggested that they continue to brainstorm through email. In response, Dr. Delphin-Rittmon said they would start by brainstorming through email and then schedule a special meeting to discuss the next steps; she also indicated that SAMHSA would summate the proposed subcommittee content areas to the group.
Before Dr. Delphin-Rittmon opened the floor for public comment, Dr. Torres suggested that the ISUDCC consider having a third meeting each year that is focused on “committee work.” On this matter, he expressed appreciation for the Federal partner presentations and member updates, but he said they take up much time on the agenda. Dr. Delphin-Rittmon liked his suggestion, saying they could either restructure one of the existing ISUDCC meetings or add a third. She also indicated that the next meeting would be the “drill down,” focusing on the group’s charter, specific content areas for subcommittees, areas to move forward on, and next steps.

Dr. Delphin-Rittmon thanked the ISUDCC members for their discussion and comments, and then she turned the meeting over to the DFO to facilitate the Public Comments session.

Public Comment

The DFO stated that SAMHSA received six requests for public comment. She explained that she would be calling upon speakers based on the order in which their comments were received, noting that each had three minutes to speak. Ms. Goss also indicated that all comments would be available as part of the written record of the meeting. Further, she noted, once the ISUDCC members approved the meeting minutes, the comments would also be available in the minutes. The following individuals provided remarks during this portion of the agenda: Elliot Pinsly, the CEO of a nonprofit policy center in Nashville, Tennessee, called the Behavioral Health Foundation; Ted Buckley, representing Braeburn, a company whose mission is to develop treatments for opioid use disorder; Mike Barnes, representing the nonprofit Center for U.S. Policy on Improving Federal Coordination to Reduce SUD and Drug Poisonings; and Andrea Barthwell, an addiction treatment specialist for 40 years, President of Encounter Medical Group, and Chair of the Foundation for Opioid Response Efforts. Anayuk Anoki and Helen Skipper did not respond when the DFO called their names, and the DFO indicated that Susan Stone withdrew her comment.

A summary of the comments and recommendations offered during the Public Comment session are provided below.

- Support for including other participation on subcommittees. (Pinsly)
- Concern regarding the failure of pharmacies to fill legitimate buprenorphine prescriptions. (Pinsly)
- Support for the use of fentanyl test strips as a harm reduction tool. (Pinsly)
- Support for deflection programming and tying into 988. (Pinsly)
- Recommendation to move away from terms that can be harmful from a public health standpoint, like “substance abuse.” (Pinsly)
- A recommendation is that the Administration increase the number of days a practitioner can administer long-acting injectable buprenorphine from 14 to 60 days. (Buckley, Barnes)
- A recommendation that Centers for Medicare and Medicaid Services (CMS) build upon the work of ONDCP, NIDA, and FDA by providing Healthcare Common Procedure Coding System (HCPCS) coding and coverage of FDA-approved digital therapies for substance use and mental health disorders. (Barnes)
- A recommendation that ONDCP, HHS, and Department of Justice (DOJ) coordinate to reign in federal pressure on pharmacies and the indiscriminate raids on controlled medication prescribers, including prosecutions also of an indiscriminate nature. (Barnes)
- A recommendation that HHS requires hospitals whose emergency services are covered by Medicaid or Medicare to implement SUD warm handoff programs and always have an X-waivered practitioner on duty or on call. (Barnes)
- A recommendation that HHS and the Department of Homeland Security and Agriculture coordinate to provide grant funding or grant funding for EMS agencies to implement and improve community paramedicine programs that address SUD. (Barnes)
- A recommendation that HHS requires all federally regulated health plans cover health services provided by community paramedics. (Barnes)
- A recommendation that HHS and DOJ do not pursue refunds to the Federal Government of any portion of state opioid mitigation proceeds. (Barnes)
- A recommendation that each state opioid litigation proceeds law and every opioid litigation settlement reflect the public health priorities outlined in the Model Opioid Litigation Proceeds Act. (Barnes)
- Encouragement for NIDA to expand its racial equity research staff and opportunities workgroups. (Barthwell)
- Recommendations on ways the Federal Government can improve equity through drug policy. (Barthwell)
  - Trained, diverse addiction treatment research education and clinical workforces. (Barthwell)
  - Include Black, Indigenous, and People of Color researchers as participants in addiction clinical study design, implementation, and dissemination of results while using, among others, the NIDA diversity outreach programs. (Barthwell)
  - Promote medical training courses grounded in trauma-informed care and structural competency. (Barthwell)
  - Support research and expedite the review of affordable SUD vaccine, treatment, and overdose reversal medications. (Barthwell)
  - Make permanent the COVID-19 regulatory flexibilities that expanded access to methadone and buprenorphine to treat opioid use disorder. (Barthwell)
  - Provide Medicare and Medicaid coverage for potentially nonbiased or less-biased services that could be delivered virtually or through secure mobile applications to reduce access barriers to effective treatment in underserved areas, including telehealth services and prescription digital therapeutics for SUD. (Barthwell)
  - Attempt to deliver services to BIPOCs outside the criminal legal system, support pre-arrest diversion programs, continue expanding therapeutic courts, provide evidence-based and trauma-informed SUD treatment for justice-involved and reentering persons, and eliminate laws and policies that discriminate against people who have paid their debt to society. (Barthwell)

Complete remarks from each speaker that submitted written comments before the meeting (Barnes, Barthwell, and Buckley) are attached to the meeting minutes. Before closing the Public Comment portion of the agenda, Ms. Goss indicated that any public members who wished to submit written comments to the ISUDCC could do so by sending them to her via email Tracy.Goss@samhsa.hhs.gov no later than Friday, December 17, 2021.
Final Comments/Adjourn
Miriam E. Delphin-Rittmon, Ph.D., ISUDCC Chair, Assistant Secretary for Mental Health and Substance Use

Dr. Delphin-Rittmon thanked the individuals that provided comments, verbally and written, saying that she appreciated their feedback. She again thanked everyone for joining the meeting and sharing the vital work they do to reduce overdose and substance use in general. She also reminded the group that SAMHSA would schedule the special meeting, and a list of the proposed content areas for potential subcommittees would be forthcoming. She encouraged them to think about which subcommittee they might want to participate in, and she asked them to think about possible next steps. The meeting ended with Dr. Delphin-Rittmon wishing everyone a great holiday season.

The meeting adjourned at 5:22 p.m.
Attachment: Public Comments
December 6, 2021

Miriam E. Delphin-Rittmon, Ph.D.
Assistant Secretary for Mental Health and Substance Use
Chair, Interdepartmental Substance Use Disorders Coordinating Committee (ISUDCC)
c/o Tracy Goss, ISUDCC Designated Federal Officer
U.S. Department of Health and Human Services (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA)
5600 Fishers Lane, 13E37B
Rockville, MD 20857

Via email to Tracy.Goss@samhsa.hhs.gov

Subject: Areas for Improved Federal Coordination

Dear Dr. Delphin-Rittmon and Committee Members:

This letter is in response to the ISUDCC Federal Register Notice dated October 19, 2021. The Center for U.S. Policy (CUSP) would like to provide the ISUDCC our recommendations for improving federal coordination as related to substance use disorder (SUD) prevention, interventions, treatment, harm reduction, and recovery support.

CUSP is a nonpartisan, 501(c)(3) not-for-profit research and education organization. Our 2021 and 2022 issue priorities include reducing substance use disorders and their consequences, including drug poisonings. We are home to the Finding the ‘ME’ in Treatment, Warm Handoff, and Prescriber Safety initiatives. Our recommendations to the ISUDCC are structured under those headings. We will also make recommendations related to state and local opioid litigation proceeds.

Finding the ‘ME’ in Treatment

It is essential that Americans have access to individualized health care, including for SUD. The COVID-19 public health emergency has shown that digital health supports the personalization of treatment services. Digital health is especially important to Americans in medically underserved communities and persons whose health requires them to avoid potential exposure to infections in health care facilities.

In response to the COVID-19 public health emergency, HHS and the Department of Justice (DOJ) have temporarily reduced regulatory barriers to medications for opioid use disorder (MOUD). We recommend that HHS and DOJ follow rulemaking procedures to extend MOUD flexibilities after the COVID-19 public health emergency ends. More information on this recommendation is detailed in “Extending Pandemic Flexibilities for Opioid Use Disorder Treatment: Authorities and Methods,” published by Bridget C.E. Dooling & Laura Stanley in the Minnesota Law Review.
Similarly, over the past 20 years, the Office of National Drug Control Policy (ONDCP), National Institute on Drug Abuse (NIDA), and Food and Drug Administration (FDA) have supported the development of, access to, and coverage of evidence-based digital treatments for substance use and mental health disorders.\textsuperscript{1} Prescription digital therapeutics (PDTs) are evidence-based medical interventions using software that can be accessed on a tablet or smartphone to prevent, manage, or treat a range of diseases and disorders.\textsuperscript{2} As of November 22, 2021, the FDA had cleared seven PDTs for conditions including SUD, ADHD, and insomnia.\textsuperscript{3} MassHealth recently enacted a policy enabling program participants to access PDTs for SUDs as covered benefits.\textsuperscript{4}

We recommend that HHS enable Medicare and Medicaid participants to access PDTs for substance use and mental health disorders as covered benefits.

Warm Handoff and Community Paramedicine

A SUD warm handoff is the process of transitioning a patient with SUD from an intercept point, such as an emergency department, to a treatment provider once the patient is stable.\textsuperscript{5} Warm handoffs provide a pathway to treatment and recovery for persons with SUDs and can decrease the risk of SUD progression and drug poisoning.\textsuperscript{6} According to Dr. Nora Volkow, the Director of NIDA, “It is crucial that acute care physicians, and the health care systems in which they practice, become aware of the importance of ensuring that patients are screened for OUD and, if OUD is detected, that they receive OUD treatment, ideally by initiating them on buprenorphine before they are released.”\textsuperscript{7} To ensure that most U.S. hospitals conduct SUD warm handoffs, we recommend that HHS require Medicare- and Medicaid-participating hospitals and non-participating hospitals that provide covered emergency services to implement SUD warm handoff policies and programs, and have a practitioner who is federally qualified to prescribe buprenorphine for OUD on duty or on call at all times.

Community paramedicine (CP) programs are an extension of emergency medical services that cover gaps in health care services.\textsuperscript{8} CP programs provide follow-up services after a health emergency to support access to care and prevent repeat incidents.\textsuperscript{9} They can empower advanced EMS professionals to intervene and activate community resources for individuals who use substances and may benefit from supportive services. CP programs can help people who use substances by dispensing naloxone, arranging for bridge medication between an emergency incident and an appointment with an SUD treatment provider, and connecting individuals with social services, such as food assistance and violence- or substance-free housing.\textsuperscript{10}

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\textsuperscript{2} https://dxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Definition-and-Core-Principles.pdf
\textsuperscript{4} https://pharmacy.services condoment/MHDL/pubdownloadpdfupdates.do?id=6896
\textsuperscript{5} http://dx.doi.org/10.1097/JOP.0000000000000068
\textsuperscript{7} https://www.drugabuse.gov/about-nida/noras-blog/2019/08/emergency-departments-can-help-prevent-opiod-overdoses
Department of Homeland Security should coordinate to provide grant funding to enable EMS agencies to implement and improve CP programs that address SUD. Additionally, HHS should require that all federally regulated health plans cover health services provided by community paramedics.

Prescriber Safety

We appreciate that the Biden-Harris Administration has prioritized expanding access to evidence-based treatment for SUD. For patients to have access to SUD medications, including methadone and buprenorphine for OUD, it is essential that authorized prescribers feel confident and safe in prescribing or dispensing those medications.

The DOJ has implemented an aggressive effort to shut down rogue controlled-medication prescribers and pharmacists. As part of this effort, however, the DOJ has raided, searched, and investigated a past president of the American Academy of Pain Medicine (AAPM), the editor-in-chief of the Practical Pain Management medical journal, a past president of the American Society of Addiction Medicine (ASAM), and a past president of ASAM’s affiliate, the Tennessee Society of Addiction Medicine.

DOJ’s priority of prosecuting controlled-medication prescribers creates fear and reluctance among health care professionals. This chilling effect undermines congressional and Biden-Harris Administration efforts to expand access to medications to treat OUD. To improve access to evidence-based treatment for OUD, the administration should require federal law enforcement to obtain a referral from the appropriate state health-profession licensing board before instituting, aiding in, or defending an investigation or criminal or civil action against a prescriber or dispenser of FDA-approved medications in which medical need or patient care, including the prescribing or dispensing of medications, is at issue.

More information on the DOJ’s enforcement actions, their unintended consequences, and our policy recommendation is detailed in “A More Sensible Surge: Ending DOJ’s IndiscriminateRaids of Healthcare Providers,” published by CUSP’s chairman in the American University Washington College of Law’s Legislation & Policy Brief.

Opioid Litigation Proceeds

Our organization wishes to thank ONDCP for the work it has conducted to date to ensure that state and local opioid litigation proceeds are directed toward prospective SUD prevention, treatment, harm reduction, and recovery support services. We recommend that the DOJ not pursue refunds to the federal government of any portion of state or local opioid litigation proceeds.

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12 [https://digitalcommons.wcu.edu/cgi/viewcontent.cgi?article=1071&context=jpb](https://digitalcommons.wcu.edu/cgi/viewcontent.cgi?article=1071&context=jpb)
13 [https://digitalcommons.wcu.edu/cgi/viewcontent.cgi?article=1071&context=jpb](https://digitalcommons.wcu.edu/cgi/viewcontent.cgi?article=1071&context=jpb)
14 [https://digitalcommons.wcu.edu/cgi/viewcontent.cgi?article=1071&context=jpb](https://digitalcommons.wcu.edu/cgi/viewcontent.cgi?article=1071&context=jpb)
Finally, we direct the ISUDCC to the *Principles for the Use of Funds from the Opioid Litigation*, published by the Johns Hopkins Bloomberg School of Public Health, and the *Model Opioid Litigation Proceeds Act*, developed with support from ONDCP by the Legislative Analysis and Public Policy Association, the O'Neill Institute for National & Global Health Law at Georgetown University Law Center, the Center for U.S. Policy, and Brown & Weinraub, PLLC. We recommend that each state opioid litigation proceeds law and every opioid litigation settlement reflect the public health priorities set forth in the model act.

Thank you for the opportunity to share our perspective. Please contact me at 202-743-5771 if you would like more information on our organization or our recommendations.

Sincerely,

Michael C. Barnes
Chairman
Dear Dr. Delphin-Rittmon and Committee Members:

Thank you for the opportunity to provide my recommendations for improving federal programs related to substance use disorders (SUDs).

I have served as an addiction treatment specialist for 40 years. I am President of Encounter Medical Group, P.C. and the Chair of the Foundation for Opioid Response Efforts (FORE). I am a past president of the American Society of Addiction Medicine (ASAM) and served under President George W. Bush as Deputy Director for Demand Reduction in the Office of National Drug Control Policy (ONDCP).

Through my work with FORE and ASAM, I advocate for a broad range of evidence-based and emerging practices to prevent SUDs and provide treatment, care, and recovery support services to patients with SUDs. My comments to the ISUDCC are limited to advancing equity in drug policy. They are drawn partially from ASAM’s Advancing Racial Justice in Addiction Medicine policy statement, which I am proud to have helped draft.

Never before in my career has there been as great an opportunity to improve racial, income, and geographic equity through drug policy. I appreciate ONDCP’s inclusion of advancing racial equity as

one of its priorities, I thank SAMHSA for identifying equity as a cross-cutting principle that underpins its priority areas, and I encourage NIDA to expand its Racial Equity Research Gaps and Opportunities Workgroup.

Development of American Indian/Alaska Native Scholars. Incorporate assessments of social determinants of health and linkages to social services into clinical practice recommendations and payment policies. 

- Promote medical training courses grounded in trauma-informed care and structural competency.
- Support research and expedite the review of affordable SUD vaccine, treatment, and overdose reversal medications.
- Make permanent the COVID-19 regulatory flexibilities that expanded access to methadone and buprenorphine for the treatment of opioid use disorder (OUD), including telehealth-based treatment for OUD.
- Provide Medicare and Medicaid coverage for potentially non-biased, or less-biased services that can be delivered virtually or through secure mobile applications to reduce access barriers to effective treatment in underserved areas, including telehealth services and prescription digital therapeutics for SUD.
- Attempt to deliver services to BIPOC outside the criminal legal system, before support pre-arrest diversion programs, continue expanding therapeutic courts, provide evidence-based and trauma-informed SUD treatment for justice-involved and re-entering persons, and eliminate laws and policies that discriminate against people who have paid their debt to society.

Thank you for your work on the ISUDCC and for considering my recommendations to advance equity in drug policy. Please contact me at 708-613-4750 if I may be of assistance to you.

Sincerely,

/Andres G Barthwell/

Andrea G Barthwell, MD, DFASAM
Founder/President, Encounter Medical Group, PC
Former Deputy Director of Demand Reduction,
White House Office of National Drug Control Policy

DrBarthwell@gmail.com

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2 https://www.apa.org/about/gr/science/spin/2014/05/interim-report.pdf p 10 of 17
Braeburn would like to thank SAMHSA for the opportunity to submit these written comments to the Interdepartmental Substance Use Disorders Coordinating Committee for the record. These comments were developed and submitted to the DEA in response to the DEA’s request for comments on the interim final rule concerning the Implementation of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018. It contains 3 commonsense recommendations that will help the Administration achieve pillar 3 of the Administration’s Overdose Prevention Strategy – specifically the objective of broadening access to evidence-based treatment delivery.

Sincerely,

Ted Buckley, PhD

December 3, 2020

Timothy J. Shea
Acting Administrator
Drug Enforcement Administration
Department of Justice
8701 Morrissette Drive,
Springfield, VA 22152

Re: Implementation of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018:
Dispensing and Administering Controlled Substances for Medication-Assisted Treatment

Dear Mr. Shea:

Braeburn Inc. appreciates the opportunity to comment on the Interim Final Rule on the Implementation of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018: Dispensing and Administering Controlled Substances for Medication-Assisted Treatment (the “Interim Final Rule”).

Braeburn is a Pennsylvania based healthcare company whose mission is to combat the opioid crisis by developing innovative treatments for opioid use disorder (“OUD”). We look forward to FDA final approval to market a weekly and monthly long acting buprenorphine injection treatment that would be administered via subcutaneous injection directly by a healthcare provider and will never be in the hands of the patient.

I. INTRODUCTION

Two years ago, in the throes of the rising opioid epidemic, the SUPPORT for Patients and Communities Act (“SUPPORT Act”) attempted to balance the need to expand access to long acting injectable (“LAI”) buprenorphine products while guarding against the diversion observed with oral buprenorphine products. Accordingly, Section 3204 of the
SUPPORT Act, *inter alia*, addressed prior dispensing limitations requiring a practitioner to purchase the medication under what is known as “buy-and-bill” by also adding the option of dispensing LAI buprenorphine by a “specialty pharmacy,” but only if the medication was administered to the OUD patient within 14 days of its receipt.

Although Section 3204 was intended as a remedial alternative to buy-and-bill, in practice its implementation did not translate into expanded access to LAI buprenorphine. As confirmed by the U.S. Government Accountability Office (“GAO”) in its August 2020 report, *Opioid Use Disorder: Treatment with Injectable and Implantable Buprenorphine* (“GAO Report”), two years after the launch of the first LAI buprenorphine product on the market and three years after the launch of the implantable buprenorphine, the use of these medications only accounted for approximately one percent out of the total prescriptions for buprenorphine products.

However, the SUPPORT Act anticipated that the 14-day administration limit might need modification to ensure the Act’s intended greater access to LAI buprenorphine. To that end, the Act empowered the Attorney General to modify the 14-day limit. Key to that modification was ensuring that LAI buprenorphine products did not pose a risk of diversion, to be determined by a GAO study. GAO subsequently found a reduced risk of diversion in its August 2020 Report, which states that “because patients lack control over the administration of injectable and implantable buprenorphine, patients receive consistent treatment exposure and therefore experienced improved health outcomes and reduced opportunities for diversion.”

Furthermore, “all of the provider groups GAO spoke with said that diversion of injectable...buprenorphine is unlikely, and representatives from three of the six provider groups said that the design of these formulations reduces opportunities for diversion due to how they are administered.” For these reasons, experts like Dr. Nora Volkow, Director of the National Institute on Drug Abuse, have referred to practitioner-administered products for OUD as potential “game changers.” Nonetheless, the GAO noted,

only about 1% of all patients receiving buprenorphine for OUD receive the practitioner administered LAI formulations.

Against this backdrop, Braeburn urges adoption of the proposed changes and clarifications detailed in this Comment. Without them, practitioners will continue to be disincentivized to use LAI products. In turn, they will default to using oral, self-administered products, which the U.S.

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4. [GAO REPORT, supra note 1.](https://www.gao.gov/assets/710/708581.pdf)
Drug Enforcement Administration ("DEA") has recognized pose a greater risk of diversion. Specifically, in the final rule, we ask that the DEA:

1. Increase the number of days a practitioner can administer LAI buprenorphine after receipt of the medication from 14 days to 60 days pursuant to authority granted under the SUPPORT Act;
2. Clarify that practitioners who are not DATA-waived can administer LAI buprenorphine pursuant to a lawful prescription by a DATA-waived practitioner; and
3. Treat pharmacists as a practitioner who may administer LAI buprenorphine to the extent authorized by state law.

As proposed, these modifications will remove the remaining obstacles preventing responsible, expanded access to LAI buprenorphine. In particular, the focus of this Comment is on 21 CFR part 1306.07(f), which restates section 3204 of the SUPPORT Act.

OVERVIEW OF “BUY AND BILL” AND “SPECIALTY PHARMACY”

Braeburn offers both “buy and bill” and “specialty pharmacy” dispensing options to practitioners. It is the practitioner who selects between these dispensing options for LAI buprenorphine products. Regardless of the dispensing option utilized, under the current rules as applied, both options present barriers to many practitioners, which undercut the expanded use of LAI buprenorphine. To understand the critical need to increase the 14-day administration limit by specialty pharmacy, one must first understand the issues inherent in the current dispensing options.

As noted in the Interim Final Rule, prior to the SUPPORT Act, pharmacies were only allowed to deliver controlled substances to the ultimate user. This posed an issue with long acting injectable ("LAI") buprenorphine products given that pharmacies needed to dispense these products directly to the administering practitioner and not to the patient (i.e., ultimate user). Thus, to obtain LAI buprenorphine products prior to the SUPPORT Act, practitioners were required by law to purchase the products directly from a distributor for the purpose of administering to their patients, a practice known as “buy and bill.”

many practitioners are unable to bear the financial risk that buy and bill entails including:

- uncertainty over whether and how much a patient’s insurance will reimburse them for the product.
- Cash flow considerations associated with holding a meaningfully sufficient volume of product to meet anticipated demand.

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These problems have been further exacerbated during the COVID-19 pandemic with many health care providers facing financial difficulties resulting from the pandemic.7

Given these economic challenges, many practitioners have been unwilling to participate in the buy-and-bill approach, and still other addiction practitioners, due to constraints imposed by the patient’s insurance, could not utilize this approach even if desired.8

To address this dispensing issue, the SUPPORT Act enacted the “specialty pharmacy” provision, in which the pharmacy fills a prescription for LAI buprenorphine and delivers it to the practitioner to administer to the OUD patient, with the requirement that the practitioner does so within 14 days of receipt. Unfortunately, this 14-day limit is infeasible in practice considering the multi-layered coordination required among the pharmacy, provider, practitioner, and patient in combination with medication shipping delays and patient arrangements to appear for injection. Moreover, these same coordination issues apply each time a LAI buprenorphine prescription is filled. The impact of these labor intensive steps with uncontrollable delays and complications are addressed in more detail herein, but, in sum, it is the limited, inadequate number of days to conduct this coordination and administration that is the barrier to achieving the Support Act’s intended expansion of LAI buprenorphine via specialty pharmacy.

II. DEA SHOULD REVISE THE NUMBER OF DAYS THAT A PRACTITIONER CAN ADMINISTER THE MEDICATION POST RECEIPT FROM 14 DAYS TO 60 DAYS

As explained in the Interim Final Rule, section 3204 of the SUPPORT Act amended the Controlled Substances Act (“CSA”) by adding section 309A (codified at 21 U.S.C. § 829a). Section 829a sets forth the conditions under

which a pharmacy may deliver a controlled substance to an administering practitioner. Now, a pharmacy may deliver, notwithstanding the definition of dispense (21 U.S.C. § 802(10)), a prescribed controlled substance (that meets the requirements issued by the Attorney General under title 21 of the U.S.C.) to the prescribing practitioner’s or administering practitioner’s registered location for the purpose of maintenance or detoxification treatment to be administered to a patient under specific conditions. Under section 829a, a pharmacy is allowed to dispense LAI buprenorphine to a practitioner for the purpose of maintenance or detoxification treatment under 21 U.S.C. § 823(g)(2), subject to certain conditions. Among other things, the practitioner

7 Quick COVID-19 Primary Care Survey, The Larry A. Green Center (Sept 21, 2020) https://static1.squarespace.com/static/5d7ff8184cf0e01e4566cb02/t/5f75da37bde1f0691fc28b0d/1601559097041/C19+Series+21+National+Executive+Summary.pdf and URL: https://www.pcpcc.org/covid
8 Addiction treatment services may be covered under the insured patient’s behavioral health benefit, rather than their medical benefit. As a result, treatment provided by these practitioners are not “medical claims” but rather “behavioral health” claims. Medication treatment prescribed by these practitioners is often covered under the pharmacy benefit, which for LAI buprenorphine products can only be delivered through specialty pharmacies, as stated in the SUPPORT Act. Accordingly, without an exemption provided by the patient’s primary insurance company, these practitioners cannot utilize buy-and-bill.
must administer the medication to the patient named on the prescription “not later than 14 days after the date of receipt of the controlled substance by the practitioner.” This provision is referred to below as the “14-day limit.”

In establishing the 14-day limit, Congress also allowed for its modification by expressly authorizing the Attorney General in consultation with the HHS Secretary to modify the 14-day limit following completion of a GAO study. GAO issued its report on August 4, 2020, evaluating the risk of diversion of injectable or implantable buprenorphine. Although the legislative history is silent on the reasoning underlying the 14-day limit, to the extent that Congress linked its modification to the GAO report, Congress was guided by its underlying concerns over the risk of diversion. As previously noted, the GAO report found diversion risk unlikely according to the representatives from all of the provider groups it consulted, particularly since the design of these formulations reduces opportunities for diversion due to how they are administered. As such, the underlying congressional concerns that gave rise to the 14-day limit two years ago were put to rest by GAO in August 2020, and the foundation for its modification has been met.

THE 14-DAY LIMIT IS IMPractical FOR THE DISPEnSing oF LAI, WiLL REDUCE ACCESS TO LAI, AND WiLL RESULT IN INTERRUPTIONS OF CARE AND WASTE

The 14-day limit is impractical, will reduce access to LAI buprenorphine, and will lead to care interruptions and waste – especially with a weekly dose. When the first monthly LAI buprenorphine product was launched, it took an average of 43 to 62 days for the medication to ship to practitioners. The average shipping time remained above 30 days for the first four months that the product was on the

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8 21 U.S.C. § 829a (A)(5)
9 21 U.S.C. § 829a(b)(2) provides “After the date on which the report described in section 3204(b) of the SUPPORT for Patients and Communities Act is submitted, the Attorney General, in coordination with the Secretary may modify the number of days described in subsection (a)(5).” Under the Act, “Secretary” refers to the Secretary of the Department of Health and Human Services.
10 **GAO REPORT, supra** note 1. Pursuant to 21 U.S.C. § 829a(b)(2), which references Section 3204(b) of the Support Act, within two years of passage of the 2018 Support Act (October 24, 2020), the Comptroller General is directed to conduct a study and submit a report “on access to and potential diversion of controlled substances administered by injection or implantation.”

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After a patient receives his or her first dose of LAI buprenorphine, several complicating factors with respect to the timing of ordering, shipping, and administering subsequent doses illuminate why the artificial 14-day limit becomes a barrier to LAI buprenorphine access:

• payer management (e.g., prior authorization)

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9 **Indivior Q3 – 2018 Earnings Presentation** 12 **Indivior H1 – 2019 Earnings Presentation** 13 **GAO REPORT, supra** note 1.
• practitioner and patient communication (e.g., practitioner’s response to shipment confirmation and patient’s consent to ship)
• distribution logistics (e.g., address on the practitioner’s DEA registration does not match the shipment address)

In addition, many of these patients experience challenges that impair their ability to show up for an appointment on a particular day including
• housing insecurity/instability, or homelessness
• lack of reliable transportation, which can be especially problematic for patients residing in rural communities

These factors contribute to increased and unpredictable timeframes for LAI buprenorphine products to be ordered and shipped to practitioners for administration. Accounting for all of these factors while trying to satisfy the short 14-day limit quickly becomes impractical for subsequent doses especially starting at week three of weekly dosing. The graphic attached to this Comment, see Appendix 1, demonstrates the challenges that the 14-day limit presents for practitioners and patients alike.

Problematically, if a LAI buprenorphine product is not administered within 14 days of receipt, it must be destroyed. As noted in the GAO Report, “[i]f the provider is unable to [administer within 14 days of receipt], they may transfer the medication to a DEA-registered company who handles the disposal of controlled substances.”13 As such, unless the practitioner, patient, and specialty pharmacy engage in continuous, precise, and timely coordination of the ordering, delivery, and administration of LAI buprenorphine, there will be care interruptions and unnecessarily wasted LAI buprenorphine products. Such coordination is likely unachievable given the multitude of challenges described above. Notably, many of the patients selected for HCP-administered LAI buprenorphine treatment will be switched back to sublingual buprenorphine, despite the conscious decision by the practitioner to supervise administration.

In contrast, if practitioners engage in buy-and-bill, they can store the same medication in their offices until the medication expires, which can be up to three

years after it is manufactured. All other storage and record keeping requirements for the practitioners are the same whether they engage in buy-and-bill or seek delivery of the product from a pharmacy. Therefore, unless the 14-day limit is modified as permitted by Congress, practitioners who want to prescribe LAI buprenorphine are left two options:

1. risk interruptions in care and constantly dispose of products under the 14-day limit
2. engage buy-and-bill.

Given the lack of appeal of both options, practitioners are likely to continue prescribing oral medications, despite concerns over diversion and treatment adherence.14
III. THE FINAL RULE SHOULD CLARIFY THAT NON-DATA-WAIVED PRACTITIONERS CAN ADMINISTER LAI BUPRENORPHINE PURSUANT TO A VALID PRESCRIPTION FROM A DATA-WAIVED PRACTITIONER

The Drug Addiction Treatment Act of 2000 (“DATA 2000”) amended the CSA to allow “qualifying practitioners” to dispense (including prescribe) schedule III – V medications for the maintenance and detoxification of OUD in office-based settings. Qualifying practitioners (or “DATA-waived” practitioners) include physicians, nurse practitioners, nurse anesthetists, clinical nurse specialists, nurse midwives, and physician assistants. “Dispense” means “to deliver a controlled substance to an ultimate user . . . or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance. . . .” As such, until recently, the DATA 2000 framework permitted only qualifying practitioners to administer long-acting injectable buprenorphine for OUD in office-based settings.

As explained above, 21 U.S.C. § 829a amended the CSA, expressly stating that:

[N]otwithstanding [the definition of dispense], a pharmacy may deliver a controlled substance to a practitioner in accordance with a prescription . . . for the purpose of administering the controlled substance by the practitioner if . . . (1) the controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance, as applicable, at the location listed on the practitioner’s certificate of registration . . .; (emphasis added) (2) the controlled substance is administered for the purpose of maintenance or detoxification treatment . . ., and

The Interim Final Rule merely incorporates these statutory amendments into 21 CFR part 1306.07(f). Accordingly, under a plain reading of 21 U.S.C. § 829a and 21 CFR part 1306.07(f), (1) a qualifying practitioner (i.e., a DATA-waived practitioner) acting within the scope of DATA 2000 must issue a lawful prescription for an injectable buprenorphine product for OUD, and (2) the pharmacy can then deliver the medication to either the DATA-waived prescriber or the practitioner who will administer it to the patient. Congress did not expressly
require that the latter be a qualifying practitioner, rather only a “practitioner” who will administer the medication.

Despite the plain reading of the statute and Interim Final Rule, there is confusion as to whether a non-DATA-waived practitioner can administer an injectable buprenorphine product pursuant to a valid prescription from a DATA-waived practitioner. As such, the current pharmacy practice is to only allow the LAI medication prescribed by the DATA-waived practitioner to be sent to the registered address of the DATA-waived practitioner. We request that DEA clarify in the final rule that 21 CFR part 1306.07(f) permits practitioners who are not DATA-waived to administer buprenorphine injections pursuant to a valid prescription from a DATA-waived practitioner.

IV. DEA SHOULD TREAT PHARMACISTS AS PRACTITIONERS WHO CAN ADMINISTER LAI BUPRENORPHINE TO THE EXTENT PERMITTED UNDER STATE LAW

As described above, 21 CFR part 1306.07(f) will state that a “pharmacy may deliver a controlled substance to a practitioner . . . for the purpose of administering the controlled substance by the practitioner. . . .”

The definitions applicable to 21 CFR part 1306 include “Any term. . . set forth in section 102 of the [CSA] (21 U.S.C. 802) or part 1300 of this chapter.”

The CSA defines “practitioner” as “a physician, . . . pharmacy . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to distribute, dispense, . . . administer . . . a controlled substance in the course of professional practice or research.” As such, a pharmacist who is employed by and acting under the authority of a DEA-

18 21 C.F.R. part 1306.02
19 21 U.S.C. § 802

registered pharmacy, and authorized by state law to dispense controlled substances, should be considered a “practitioner” under the CSA.

At the same time, 21 CFR part 1300 does not define the term “practitioner”; instead, the regulation defines “individual practitioner.” An “individual practitioner” means “a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.”

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V. URGENT NEED FOR ACCESS TO TREATMENT DURING COOCCURRING PUBLIC HEALTH EMERGENCIES

The requests set forth in Sections III and IV of this comment make practical sense and are grounded in strong policy considerations. They are particularly appropriate in light of the cooccurring opioid and COVID-19 public health emergencies, which have led to constraints on treatment access, unemployment, economic pressures, and other stressors related to the virus. As a result, rates of substance use are rising. This could have lasting impact on our nation’s goal of reducing substance use and preventing overdose.

The Centers for Disease Control and Prevention (“CDC”) estimates that drug overdoses killed more than 67,000 Americans in 2018. Of those deaths, most (69.4 percent) involved an opioid.22 The COVID-19 pandemic has exacerbated these statistics. Available 2020 data from the early months of COVID already reflect an alarming increase in OUD overdoses and death during the COVID pandemic. According to data from the Overdose Detection Mapping Application Program, suspected overdoses nationally jumped by almost 18% when comparing the weeks prior to and following the commencement of state-mandated stay-at-home orders.23 Moreover, according to the American Medical Association, opioid-related deaths have increased in more than 40 states during the pandemic.24 Further, a study in September 2020 found that patients with a recent diagnosis of substance use disorder – especially opioid use disorder – are at significantly increased risk for COVID-19 and that COVID-19 patients with substance use disorder had higher rates of hospitalizations and death than those without substance use disorder.10 This highlights the need to screen and treat individuals with substance use disorder – and especially opioid use disorder – to help control the pandemic.

Additionally, only a very small percentage of health care practitioners in the U.S. are DATA-waived. Among those with waivers, a majority are either not prescribing buprenorphine at all or

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20 21 C.F.R. part 1300
21 The injection of long-acting buprenorphine is within the scope of practice for pharmacists pursuant to a valid prescription in numerous states including, but not limited to: California, Georgia, Pennsylvania, Ohio, Indiana, Kentucky, Colorado, Arizona, Washington, Oregon, New Mexico, and Virginia.
22 Holly Hedegaard, et al., Drug Overdose Deaths in the United States, 1999-2018, CDC (Jan. 2020), https://www.cdc.gov/nchs/products/databriefs/db356.htm; The Drug Overdose Epidemic: Behind the Numbers, CDC (Mar. 19, 2020); https://www.cdc.gov/drugoverdose/data/index.html#•text=Overdoses%20involving%20opioids%20killed%20nearly%20those%20deaths%20involved%20in%20prescription%20opioids.&text=Learn%20more%20about%20the%20Data.epidemic%20in%20the%20United%20States.mandated stay-at-home orders. Moreover, according to the American Medical Association, opioid-related deaths have increased in more than 40 states during the pandemic. Further, a study in September 2020 found that patients with a recent diagnosis of substance use disorder – especially opioid use disorder – are at significantly increased risk for COVID-19 and that COVID-19 patients with substance use disorder had higher rates of hospitalizations and death than those without substance use disorder. This highlights the need to screen and treat individuals with substance use disorder – and especially opioid use disorder – to help control the pandemic.

Additionally, only a very small percentage of health care practitioners in the U.S. are DATA-waived. Among those with waivers, a majority are either not prescribing buprenorphine at all or
not treating up to their approved patient limit (i.e., 30, 100, or 275 patients). According to a January 2020 report by the HHS Office of the Inspector General (“OIG”), while the number of DATA waived practitioners has been increasing since 2015, approximately 72 percent of DATA-waived practitioners are only authorized to treat up to 30 patients at any one time with buprenorphine—the lowest patient limit. Low numbers of DATA-waived practitioners, combined with low patient limits among such practitioners, result in low treatment capacity. Specifically, the OIG noted that “[a]pproximately two-thirds of U.S. counties either have low or no patient capacity to provide buprenorphine services to patients in the office setting (emphasis added). Forty percent of counties nation-wide do not have any waived practitioners and another 24 percent have low patient capacity.”

A majority of such high-need counties are in rural areas. Therefore, allowing non-DATA-waived practitioners to administer LAI buprenorphine pursuant to a valid prescription from a DATA-waived practitioner and in accordance with state law would increase access to necessary treatment in these areas.

Fortunately, the Ryan Haight Act permits qualified practitioners to prescribe buprenorphine via telemedicine to patients with OUD in rural and underserved areas. Pursuant to DEA’s guidance document on prescribing buprenorphine during the COVID-19 public health emergency, practitioners (1) have a better understanding of how to prescribe these medications through telemedicine during the public health emergency, and (2) currently have unprecedented flexibility to connect with patients using telephone communications without video capabilities. This is especially useful when prescribing oral buprenorphine products, as patients can simply go to their local pharmacy to pick up their medication.

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14 Id. 30 Id. 31 Id.
15 See 21 U.S.C. § 802(54)
However, with respect to LAI buprenorphine products, restricting their administration to only DATA-waived practitioners versus all DEA registered practitioners almost entirely defeats the purpose and public health benefit of prescribing through telemedicine. Specifically, even if a new or existing patient is evaluated virtually pursuant to the Ryan Haight Act or DEA’s current guidance, the patient must nevertheless travel to their DATA-waived prescriber’s office for each and every medication injection. For some, the prescriber’s office may not be near their home, whereas a pharmacy or DEA-registered rural health clinic may be. If the patient is unable to return to the DATA-waived practitioner’s office right away or the DATA-waived practitioner is not able to see the patient in a timely manner, then this could result in delays in care; medication nonadherence and disease progression; relapse; or worse, overdose and death.

If the DATA-waived practitioner is only utilizing telehealth, restricting the administration of LAI buprenorphine to DATA-waived practitioners means that they can only utilize oral forms of buprenorphine to treat OUD. They cannot utilize LAI buprenorphine as there is no one to administer the treatment. Clarifying that non-DATA waived practitioners can administer LAI buprenorphine subject to a valid prescription and clarifying that pharmacists are practitioners will allow DATA-waived practitioners using telehealth to utilize LAI buprenorphine treatments.

Finally, LAI buprenorphine products are only available through a Risk Evaluation and Mitigation Strategy (REMS) that ensures safe use conditions through education, training, implementation of controls, and certification. The integrity of these REMS programs is consistently monitored through an auditing process that is presented on a semi-annual or annual basis to FDA. The requests set forth in Sections III and IV of this comment would be subject to the same REMS conditions and monitored accordingly to ensure the safety of patients.

VI. CONCLUSION

Given the need for better access to all treatments for OUD – especially during the COVID-19 pandemic, we ask that the DEA:

1. Increase the number of days a practitioner can administer LAI buprenorphine after receipt of the medication from 14 days to 60 days pursuant to authority granted under the SUPPORT Act.
2. Clarify that practitioners who are not DATA-waived can administer LAI buprenorphine pursuant to a lawful prescription by a DATA-waived practitioner.
3. Treat pharmacists as a practitioner who may administer LAI buprenorphine to the extent authorized by state law.

Undertaking these steps will increase access to LAI buprenorphine products, which GAO has found to have a low risk of diversion. Increasing access to these products also is consistent with the HHS goal to “[i]ncrease uptake of medications for the treatment of opioid use disorder

17 GAO Report, supra note 1.
... [b]y 100 percent the number of prescriptions for long-acting injectable or implantable buprenorphine …”\textsuperscript{18}

Sincerely,

Mike Derkacz
President & CEO
Braeburn Inc.
APPENDIX 1

Weekly scenario:

- **Day 1**: Shipment containing doses 1 and 2 arrives at healthcare practitioner’s (“HCPs”) office.
- **Day 2**: HCP administers 1st dose to patient. HCP orders 3rd dose.
- **Day 9**: HCP administers 2nd dose to patient.
- **Day 14 – 19**: Shipment containing doses 3 and 4 arrives at HCPs office.
- **Day 16**: HCP administers 3rd dose to patient – if it has arrived at the office.

**Why not order 3 weekly doses at once?**
- **Shipping time**: 12 – 17 days.
- **Day 1**: Shipment containing doses 1, 2, and 3 arrives at HCPs office.

*days (note: this remains the shipping time 2 years after launch according to data from manufacturer of the only LAI buprenorphine product currently on the market).*
• Day 2: HCP administers 1st dose to patient.
• Day 9: HCP administers 2nd dose to patient.
• Day 15: HCP destroys 3rd dose due to 14-day limitation.
APPENDIX 2

Authority to increase the 14-day limit to 60 days

The Interim Final Rule states that “DEA has no discretion not to amend its regulations as is being done in [the rule]” because the rule “simply updates DEA regulations to reflect these new provisions; thus, no alternative approaches are possible.” Yet, the SUPPORT Act explicitly granted the Attorney General the authority to change the 14-day limit (i.e., take an alternative approach with respect to the limit).

Specifically, 21 U.S.C. § 829a (b)(2) expressly authorized the Attorney General (in coordination with the U.S. Department of Health and Human Services (“HHS”)) to modify the number of days within which LAI buprenorphine is to be administered to the patient after a practitioner receives delivery of the medication from a pharmacy. The modification has to follow the GAO Report that reviewed “access to, and the potential for the diversion of, controlled substances administered by injection or implantation.” The report was published in August 2020.

The Attorney General’s office “supervises and directs the administration and operation of the offices, boards, divisions, and bureaus that comprise the Department” of Justice. The DOJ, under the authority of the Attorney General, has tasked the DEA with implementing and enforcing the controlled substances laws and regulations of the United States. Therefore, DEA could, in coordination with HHS, amend the 14-day limit. Additionally, HHS is likely to be supportive of this increase given that one of its goals in FY 2021 is to “[i]ncrease uptake of medications for the treatment of opioid use disorder . . . [b]y 100 percent the number of prescriptions for long-acting injectable or implantable buprenorphine from retail, long-term care, and mail-order pharmacies in the U.S.”

Additionally, this change can be made as part of the Interim Final Rule. As explained in the Interim Final Rule, such rulemaking is appropriate if the agency finds good cause to exempt a rule from certain provisions of the Administrative Procedure Act, including those requiring the publication of a prior notice of proposed rulemaking and the pre-

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19 U.S.C. § 829a
20 GAO Report, supra note 1.
promulgation opportunity for public comment, if such actions are determined to be unnecessary, impracticable, or contrary to the public interest.41

In addition to the explicit statutory authority, there is further showing of good cause to expand the 14-day limit as part of the Interim Final Rule given that we are midst of an opioid epidemic, the current 14-day limit makes it impractical for practitioners to use LAI buprenorphine products, and, according to the GAO Report, “diversion of injectable...buprenorphine is unlikely.”

41 5 U.S.C. § 553