SUBSTANCE USE RECOVERY TASK FORCE

Minutes of the 6th Meeting of the 2020 Interim

November 10, 2020

Call to Order and Roll Call

The 6th meeting of the Substance Use Recovery Task Force was held on Tuesday, November 10, 2020, at 3:00 PM, in Room 171 of the Capitol Annex. Senator Ralph Alvarado, Chair, called the meeting to order, and the secretary called the roll. The minutes for the Task Force's October 13, 2020 meeting were approved.

Present were:

Members: Senator Ralph Alvarado, Co-Chair; Representative Russell Webber, Co-Chair; Senators Julie Raque Adams, Johnny Ray Turner, and Max Wise; Representatives Danny Bentley, and Lisa Willner.

Guests: Tiffany Cole Hall, Chief Operating Officer Volunteers of America (VOA) Mid-States; Dr. Allen Brenzel, Clinical Director, Office of the Commissioner, Kentucky Department of Behavioral Health and Intellectual Disabilities, Cabinet for Health and Family Services (CHFS); Dr. Katie Marks, KORE Project Director, Kentucky Department of Behavioral Health and Intellectual Disabilities, CHFS; Alex Waldron, Chief Strategy Officer, Pear Therapeutics BIO; Yuri Maricich, Chief Medical Officer and Head of Department, Pear Therapeutics BIO; Chad Grant, Senior Vice President, Grant Consulting Group; Michelle D. Ford, Senior Director of State Government Affairs, Mid-Atlantic Region, Emergent BioSolutions; Marc Wilson, Partner, Top Shelf Lobby; Dr. Nick Casale, Associate Director, Medical Outcomes and Value Global Medical Affairs and Safety, Indivior Treatment Services, Inc.

LRC Staff: Ben Payne, Samir Nasir, and Christina Williams.

Substance Use Treatment Programs and Therapeutics Discussion - State Perspective

Dr. Allen Brenzel, Clinical Director, Office of the Commissioner, Kentucky Department of Behavioral Health and Intellectual Disabilities (BHID), CHFS, and Dr. Katie Marks, KORE Project Director, Kentucky Department of Behavioral Health and Intellectual Disabilities, CHFS gave a brief presentation on the state perspective of substance use treatment programs and therapeutics. Dr. Brenzel stated that the Department of Behavioral Health and Intellectual Disabilities works with the Department for Public Health, the Department for Community Based Services, the Office of Inspector General, and the Department for Medicaid in opioid response efforts. Outside of CHFS, BHID works with the Governor's Office, the Justice and Public Safety Cabinet, the Office of

Drug Control Policy, the Education and Workforce Development Cabinet, the Labor Cabinet, and the Administrative Office of the Courts in opioid response efforts.

Dr. Brenzel stated Kentucky has been fortunate that federal funding has been received in order to assist with the effort. These dollars come from the Substance Abuse and Mental Health Services Administration (SAMSA) which is a part of the United States Department of Health and Human Services (HHS). From October 2018 to September 2021, $78.8 million in federal funds has been allocated and used towards the response effort. It is yet to be seen what will fully be awarded from October 2021 to September 2022, however, the State Opioid Response II effort has recently been awarded $35.4 million. Those funds do not come unrestricted. A proposal has been made which utilizes the objectives set forth. The objectives in the Kentucky opioid response effort is to increase access to medications for opioid use disorder (MOUD), reduce the unmet treatment need, reduce opioid overdose related deaths, and expand evidence-based services to address stimulant misuse and use disorders.

A chart was provided to highlight Kentucky resident drug overdose deaths from January 2017 to September 2020. The data shown is as of October 26. 2020, and the data for 2017 to 2020 is provisional. The data for July through September 2020 is incomplete at this time. Dr. Brenzel pointed out an overdose death spike that occurred in May and early June of 2020. He added the overdose deaths have now decreased to a base-line. There is a concern that some of these overdose deaths were younger people, and relapse scenarios. He added that both urban and rural areas were affected.

Dr. Brenzel stated that telehealth networking has been critical in providing access to care. The expansion of Narcan distribution, and the removal of preauthorization for services through third party payers has also been helpful in fighting substance use. He added it is also critical to make sure people know that places are open and treatment is available. He added continuing Medicaid eligibility is key in continuing access to treatment.

Dr. Brenzel stated they organized responses in large categories because this problem is complex. He stated there are initiatives in prevention which include harm reduction and treatment as well as recovery support. Dr. Brenzel stated they partner with many agencies, and Dr. Marks presented data around services in each of those categories.

Dr. Marks spoke about infrastructure prevention treatment and recovery. She stated the infrastructure is what is going to build the capacity to implement evidence-based practices in a data driven manner and it allows for the support of communities and residents towards positive health behaviors.

Dr. Marks highlighted a few of the infrastructure priorities. She stated work with the Kentucky All Schedule Prescription Electronic Reporting System (KASPER) has been

instrumental in reducing overdose risk and it provides safer opioid prescribing. She stated they partnered with KASPER to enhance the Kentucky Health Information Exchange System to enable prescribers to be able to access patient health records related to past toxicology screens and non-fatal overdoses. Dr. Marks stated they have also worked aggressively to expand their workforce by providing training to prevention specialists and peer support specialists.

Dr. Marks stated that since 2018 approximately 22,338 individuals have participated in more than 325 trainings that support dissemination of evidence-based prevention treatment recovery support services. There have been 277 physicians that have received data waiver training to prescribe buprenorphine. The Hazelden Betty Ford Recovery Champions curriculum has been delivered to 5,034 DCBS staff, partners, and parents; 1,576 judges and court staff; 187 Citizen Foster Care Review Board volunteers; and 400 employers. There have been 1,025 people trained in peer support and recovery support services. To improve quality housing, they have established the Kentucky Recovery Housing network which has adapted the National Alliance of Recovery Residence standards for Kentucky. Dr. Marks added that these houses meet a minimum standard for safety quality and provide a supportive environment for recovery. She added that this is a way that they can drive individuals and treatment providers towards certified houses and away from predatory or unscrupulous housing.

Dr. Marks stated that prevention ranges from primary prevention and working with those individuals who have not developed an opioid use disorder, to those at risk, to also reducing harm. This must be a data-driven and research-based process. Dr. Marks stated they have partnered with many different entities from K-12 schools, to the Kentucky hospital association, to early childhood mental health associates. She stated they are also expanding their reach to address issues that intersect with opioid use disorder, such as suicide risk.

Dr. Marks stated that since 2017 there have been 53,509 naloxone units distributed through the statewide program. Nearly 130,000 youth participated in universal prevention programming. There were 298 K-12 schools that implemented "Too Good for Drugs" and "Sources of Strength" programs. There were 87 percent of schools that committed to assessing their policies and procedures related to substance use and mental health. Approximately 120 hospitals committed to the Statewide Opioid Stewardship program. There were also 166 opioid overdose prevention trainings delivered to 588 prescribers, 726 first responders, and 2,216 community members.

Dr. Marks reviewed some treatment priorities. She stated she knows awareness must be increased, and there must be utilization of treatment resources for both clients and providers. She added that there must be an expansion of the number of settings in which services are delivered which includes primary care, hospitals, syringe services programs, and criminal justice settings. She added that an expansion of access to medications for

opioid use disorder is necessary. Dr. Marks stated that medications for opioid use disorder decrease fatal and non-fatal overdoses. She added that structural barriers must also be decreased that prevent people from accessing the system and care.

Dr. Marks stated currently, they are partnering with 96 distinct treatment programs and providers at over 170 unique sites. This includes 10 KORE funded bridge clinics that provide screening, treatment, peer support, overdose education, and naloxone distribution. She stated they partner with the Kentucky Primary Care Association to increase the treatment capacity of federally qualified health centers. They, along with the Hazelden Betty Ford Foundation have built a sustainable model of treatment in a primary care setting.

Dr. Marks stated KORE serves as a last resort for individuals who are uninsured or underinsured and are in need of residential care. She stated KORE partners with over 23 methadone programs to also serve as a payer of last resort for those uninsured or underinsured. She added that KORE's partnership with the Department for Community Based Services (DCBS) has allowed them to expand their child welfare initiative programs. She stated KORE has partnered closely with the Department of Corrections and the Office of Drug Control Policy to begin medications for opioid use disorder in prison settings, and to fund re-entry coordinators.

Dr. Marks spoke about recovery supports that allow people to remain in remission long-term. These recovery supports range from supporting the recovery housing initiatives, to strengthening transformational employment initiatives, to expanding the number of mutual aid groups that support all paths to recovery. Dr. Marks stated in order to do this KORE has engaged with a wide variety of partners. For example, KORE's strategic initiative for transformational employment has allowed them to partner with the Kentucky Chamber of Commerce and dozens of businesses to create recovery friendly environments.

Dr. Marks stated KORE funds numerous recovery housing expansion initiatives to create an environment where individuals with all paths to recovery can have a safe recovery-friendly environment to live in. She stated KORE also operates access to recovery programs that pay for those non-reimbursable services that often-times make a significant difference.

Dr. Marks stated there are 12,550 individuals that have been served by KORE-funded recovery support services. There have been 2,932 people served across six recovery community centers and two additional centers will be opening soon. There have been 2,241 individuals that have received recovery housing, 2,973 people received employment services, and 1,343 have been served by the Access to Recovery Program.

In conclusion, Dr. Marks stated the KORE motto is "together we are stronger than opioids." She added that in the near future there are plans for KORE to expand and include 22 additional partners.

In response to a question asked by Chairman Alvarado concerning barrier reduction, Dr. Brenzel stated they would like to see individuals get out of the justice system and into treatment, therefore they are looking for partnerships for decriminalization, diversion programs, and the funding of drug courts. He added that they are working with Medicaid on a waiver that will allow for the providing of services prior to incarceration release.

Dr. Brenzel also suggested increasing and enforcing parody protections to ensure that third party payers recognize and reimburse for both behavioral health and substance use disorder services. He added that Kentucky was in the forefront of parody legislation, but it is imperative to make sure it includes substance use disorder, and that payers do not use preauthorization processes to block services. Dr. Brenzel stated he would also like the consideration of removing some preauthorizations. He added that some states have considered this step at least on the initial admission for an individual. Dr. Brenzel also stated he would like to see continued flexibility around telehealth use, as well as the co-prescribing of Narcan.

In response to a question asked by Chairman Alvarado, Dr. Brenzel stated the overdose death numbers provided are very close to real-time numbers, although they are not 100 percent completed. He stated he believes the trend is going back towards pre-COVID-19 baseline numbers.

Substance Use Treatment Programs and Therapeutics Discussion - Provider Perspective

Tiffany Cole Hall, Chief Operating Officer Volunteers of America Mid-States spoke to the Task Force on Volunteers of America's substance use disorder and re-entry services. She stated that VOA delivers integrated and evidence-based services, adding that VOA knows that comprehensive services are needed for life-changing recovery and re-entry for individuals and families.

Ms. Hall stated that VOA's services include assessment, family therapy, comprehensive case management, re-entry support, customized services for pregnant and parenting women and their children, veteran's services, a full continuum of care, transitional housing, and clinical services and peer support.

Ms. Hall stated that Kentucky incarcerates women two times more than the national average. The VOA Freedom House and re-entry program for pregnant and parenting women was started in 1993 and helps moms to overcome substance use disorder and keeps families together. A vital outcome is keeping more women out of the criminal justice system and transitioning women from the corrections system back into the community. Other measurable outcomes include delivering healthy babies and keeping children out of foster care. Ms. Hall added that this program recently was approved for conducting withdrawal management and partial hospitalization services. She also stated relationships

with these women and families are maintained for at least three years as that is the timeframe likely for relapse and for possible abuse or neglect of a child.

Ms. Hall stated that VOA is uniquely qualified to partner with DCBS to provide early assessment and intervention that addresses substance use disorder and safely keeps families together. She added a pilot program was proposed in 2021 in two high needs counties: Clay and Hardin County. This pilot program would involve embedding a therapist in social worker offices to try to prevent the removal of a child from their home.

Ms. Hall stated the Halfway Back Men's Program is a comprehensive residential substance use disorder treatment program for men exiting the Kentucky Department of Corrections. The program allows men to engage in an individualized case plan that promotes greater accountability and ownership for living a healthy lifestyle. The program utilizes integrated clinical and peer support services. Residents of this program are expected to participate in individual and group counseling, life skills training, GED education, and employment readiness assessment and training. The program also provides re-entry support for men re-entering the workforce.

Ms. Hall stated currently there are a total of 50 beds in the Halfway Back Men's Program. As of March 2, 2020, there were 36 of those beds filled. As of today, there are 16 beds filled, which represents a two-year low, and has been trending consistently lower even before the Covid-19 crisis. Because of this, Ms. Hall stated VOA is struggling with what to do with this program as VOA cannot continue to operate at one-fourth capacity in the men's re-entry program. She added that the Department of Corrections has a need for proven, comprehensive re-entry services and VOA provides that. The current issue is that they need to immediately and fully utilize VOA's re-entry beds or eliminate the re-entry beds so they can be repurposed for other individuals in need of treatment for a substance use disorder.

In response to a question asked by Co-Chair Webber, Ms. Hall stated she is unsure of what actions need to be taken by the task force and the General Assembly to be able to assist VOA in filling the beds. She added awareness and efforts to try to collaboratively solve the issue is a great step in the right direction.

In response to a question asked by Co-Chair Webber, Ms. Hall stated there is an open line of communication between VOA and DOC, and some great conversations have been had about how to address the issue. She added she is not sure that the conversations are being had with the correct people who have the ability to actually implement change.

In response to a question asked by Representative Willner, Ms. Hall stated it is possible that there are too many recovery beds available, but that is hard to determine. She also added that it is hard to determine if the actual need of these individuals are being met as well.

Senator Raque Adams suggested observing if community partnerships are being utilized to the best and fullest extent. She added that one objective of the task force should be to link partners together to achieve the common goal of helping the individuals in need. She also suggested a state-wide needs assessment be conducted.

Substance Use Treatment Programs and Therapeutics Discussion - Provider Perspective

Chad Grant, Senior Vice President Grant Consulting Group introduced Alex Waldron, Chief Strategy Officer Pear Therapeutics BIO and Yuri Maricich, Chief Medical Officer and Head of Department Pear Therapeutics BIO spoke about Pear Therapeutics and the prescription of digital therapeutics for the treatment of diseases. Mr. Maricich explained prescription digital therapeutics (PDTs) and what they are. He stated that traditional medication is referred to as small molecules. He stated injectables which are used or injected like insulin are referred to as biologics. Mr. Maricich added that there are cell and gene therapies as well. He stated that Pear Therapeutics thinks of digital therapeutics as a fourth class of treatment. Pear Therapeutics is one of the leaders in this technology, but there are a number of other organizations that are developing this class of treatment, where there is software working either alone or with standard medications to treat diseases.

Mr. Maricich stated what sets PDTs apart from all of the other health and wellness applications is that they deliver evidence-based and scientifically backed mechanisms of action to the software. He added that these therapeutics are ran through clinical trials like any traditional medication. The manufacturing and clinical data is submitted to the Federal Drug Administration (FDA) on both safety and effectiveness. If the FDA agrees and approves these products, then they have a label just like a medication.

Mr. Maricich stated that Pear PDTs follow the traditional therapeutics model for medication. There is a product that claims to treat the disease, and in this instance, software with effectiveness claims to treat the disease. An individual is then diagnosed by a physician and the product is prescribed. Payment is then administered and reimbursements via a pharmacy or medical benefits can sometimes occur. Fulfillment of the prescription occurs via a specialty pharmacy or patient service center. The patient then uses the product according to the indications for use and lastly, the patient follows up with a physician.

Mr. Maricich stated reSET and reSET-O are both prescription digital therapeutics for patients with substance use disorder or opioid use disorder. ReSET is derived from the content of the Therapeutic Education System (TES), developed by Lisa Marsch, PhD at Dartmouth's Geisel School of Medicine. The TES was developed in response to the National Institutes of Health (NIH) solicitation for projects to digitize evidence-based behavioral therapies. It is an interactive, web-based program rooted in the evidence-based community reinforcement approach to behavior therapy. ReSET delivers TES content via

a mobile app, rather than a desktop computer. ReSET's digital delivery method is designed to increase engagement and retention and improve patient access to treatment.

Mr. Maricich stated that both reSET and reSET- O have two components. He stated when the patient is given the prescription, they then go to their application store on their device, download the software treatment and receive an access code. There are three different mechanisms of action. The first is addiction specific behavioral cognitive therapy which moves a patient from actively using the substance to eventual discontinuation of the use. Fluency training is then utilized that assess the individual's proficiency and reinforces onset mastery. Contingency management is also utilized which delivers positive rewards and reinforcements for patients when they do not use the substance and also when they engage in treatment. All of the assessment information is then collected and shared with a clinician dashboard so members of the clinical care team can access this data and use it to reform their treatment.

Mr. Maricich stated that reSET has a 12-week prescription duration. He stated it is available for patients with substance use disorder and for treatment of the following: stimulants, alcohol plus another substance, marijuana, cocaine, and opioids (when not the primary substance of abuse.) ReSET is not indicated for patients who are on opioid replacement therapy, or abusing alcohol solely, or abusing opioids as their primary substance. Mr. Maricich stated ReSET delivers therapy based on the community reinforcement approach (CRA), an intensive form of validated neurobehavioral therapy for substance use disorder, along with contingency management and fluency training to enhance learning.

Mr. Maricich showed a chart that summarized one of the randomized clinical trials that evaluated reSET. In this study 399 patients with a substance use disorder received either treatment as usual (TAU) consisting of intensive face-to-face therapy or reduced TAU and reSET for 12 weeks. Patients provided urine samples twice per week to objectively monitor abstinence. Retention in treatment was also monitored. The results showed that patients who were randomized to the treatment as usual had a 17.6 percent rate of abstinence. When TAU was combined with reSET those numbers rose to 40.3 percent. He added that patients who have not been abstinent and are still using on their first day of treatment had a 3.2 percent rate of abstinence with TAU, and a 16.1 percent rate of abstinence with the combination of TAU and reSET. The clinical trial also showed that the retention in treatment for all patients was 63.2 percent in patients that utilized TAU alone, but 76.2 percent in patients that utilized TAU along with reSET.

Mr. Maricich stated the main difference between reSET and reSET- O is that reSET-O has some additional functionality to support using medications of opioid use disorder, particularly buprenorphine and Suboxone. It also has additional therapeutic models.

Mr. Maricich showed a chart that summarized another randomized clinical trial that evaluated reSET-O. In this trial, 170 patients were randomized to receive either TAU consisting of contingency management plus buprenorphine or TAU plus reSET – O. All patients received 30 minutes of face-to-face counseling every other week. Patients provided urine samples three times per week to objectively monitor abstinence. The retention rate with TAU was 66.4 percent, but the retention rate with TAU plus reSET – O is 82.4 percent.

Chairman Alvarado expressed his excitement for the ability to use a mobile device to attend therapy sessions needed to aide in addiction recovery. He added that the approval of the FDA for use of a PDT, as well as the proven scientific data that showcases the success of the use of a PDT is remarkable.

In response to a question asked by Chairman Alvarado, Mr. Maricich stated Pear Therapeutics is currently working with 12 states and the federal government to explore the coverage of the use of PDTs by Medicaid. He added that in several states Governors are also involved in these discussions. Mr. Maricich also stated that Centers for Medicare and Medicaid Services (CMS) has offered to provide states proactive guidance in terms of the fact that states can cover these products under their own state Medicaid plans.

Substance Use Treatment Programs and Therapeutics Discussion - Provider Perspective

Marc Wilson, Partner, Top Shelf Lobby spoke to the task force on the use of naloxone for addicted individuals. He stated naloxone is a drug that will immediately reverse the effects of opioids in case of an overdose. naloxone use has saved countless lives across the U.S. Mr. Wilson stated the goal is to identify those individuals that are at risk for overdose and ensure that naloxone is readily available to those individuals for a family member or friend to administer. He stated he believes greater access to naloxone should be a key part of the efforts in fighting the opioid epidemic.

Michelle D. Ford, Senior Director of State Government Affairs, Mid-Atlantic Region, Emergent BioSolutions spoke about Emergent BioSolutions and naloxone co-prescribing. Ms. Ford stated Emergent BioSolutions is a public health threat company that works on any number of things from an anthrax vaccine to naloxone nasal spray. Ms. Ford recognized Representative Bentley who has worked closely with Emergent on co-prescribing policy initiatives.

Ms. Ford stated that the Kentucky General Assembly has aided in addressing the number of opioids that can and are prescribed. In-spite of that legislation there is still a high number of opioids being prescribed. She stated in 2018, Kentucky providers wrote 79.5 opioid prescriptions for every 100 persons compared to the average U.S. rate of 51.4 prescriptions. Despite widespread devastation caused by America's opioid epidemic, an investigation by National Public Radio (NPR) found that doctors and other health care

providers still prescribe highly addictive pain medications at rates widely considered unsafe. Critics say the practice exposes tens of millions of patients each year to unnecessary risk of addiction, overdose, and death. It also floods communities with vast quantities of opioid medications that go unused, building up a deadly reservoir of drugs in home medicine cabinets that often wind up being abused.

Ms. Ford addressed the standing order and prescription volume in Kentucky. She stated that the standing order referenced is any order that allows for any person that goes into a pharmacy to ask for prescription naloxone, similar to the way they would ask for a flu shot, without having an individual prescription. In 2019, 248 prescriptions in Kentucky were standing order prescriptions for naloxone that were filled, and there were 65 in 2020. In 2019 there were 17,484 personal prescriptions of naloxone filled, and in 2020 there were 18,235 personal prescriptions filled.

A chart was presented that showcased Kentucky opioid mortality trends. The chart compared the use of all opioids, to prescription opioids, to heroin, and synthetic opioids from 1999 to 2018.

Ms. Ford stated most addicted individuals become addicted during their earliest days due to their legal prescription. She reiterated that for some people there is still a great need for opioids in different scenarios to aide with pain management. Ms. Ford referenced a continuum chart that showed different points at which a person could overdose, and several points at which they could utilize naloxone. Those points included the initial prescription of opioids, the utilization of a community based organization to obtain help, treatment, emergency room discharge, incarceration or entanglement with the Department of Corrections, a meeting with first responders and law enforcement, or the eventual use of illicit opioids.

Ms. Ford stated it was important to note that in Kentucky there is a very strong advocacy program for the distribution of naloxone. This program is funded by federal grant dollars as well as the University of Kentucky and other organizations that have put forth their efforts and their dollars in order to provide naloxone.

Ms. Ford gave an overview of the co-prescribing Naloxone landscape. She stated many stakeholders support integrating naloxone for at-risk opioid patients. Some of those stakeholders include SAMHSA, CMS, the Center for Disease Control and Prevention (CDC), the American Medical Association (AMA), the World Health Organization (WHO), the American Society of Addiction (ASAM), the American Heart Association (AHA), the National Association of Boards of Pharmacy, and the American Pharmacists Association (APhA), just to name a few.

Ms. Ford stated that state legislation and rules requiring co-prescribing on naloxone have expanded naloxone to high-risk opioid patients. She added that there is a growing

trend where states have implemented requirements to co-prescribe naloxone. To date, nine states have required co-prescribing naloxone with high-risk opioid prescriptions. Criteria that triggers a requirement for co-prescribing varies (mainly by level of morphine milligram equivalent (MME)), however, all states have seen significant adoption by physicians, and filled prescriptions by patients who are at increased risk of overdose.

Charts were provided that showed data which illustrated the spikes in naloxone distribution post implementation of those laws and regulations. Nine co-prescribing states show growth post implementation. Those states are Arizona, California, Florida, New Mexico, Ohio, Rhode Island, Virginia, Vermont, and Washington.

Ms. Ford stated in Utah the language on naloxone co-prescribing states that prescribers are encouraged to co-prescribe an opioid antagonist in those taking higher opioid dosages such as a dose greater than or equal to 50 MME per day or concurrent Benzodiazepine use. In California, the language reads that a prescriber shall offer a prescription of naloxone to patients with prior overdose, substance abuse, doses in excess of 90 MME per day/or concomitant Benzodiazepine. In New Mexico, the language reads that a physician shall co-prescribe opioid antagonist with any opioid prescription of more than five days.

In response to a question asked by Chairman Alvarado, Ms. Ford stated that because a majority of funding for naloxone comes from federal dollars, there is some concern about how long that funding stream will last. She encouraged the General Assembly to study where funding sources outside of the federal government could be made available for continued naloxone prescription use.

Substance Use Treatment Programs and Therapeutics Discussion - Provider Perspective

Dr. Nick Casale, Associate Director, Medical Outcomes and Value Global Medical Affairs and Safety Indivior Treatment Services, Inc gave an overview of Sublocade, which is their current marketed product used for opioid use disorder. He stated Sublocade has been on the market for approximately two years, however, there has been an increase in Sublocade utilization over the past year. Sublocade is an extended release injection of buprenorphine. It is the first medication assisted treatment product that is delivered via the subcutaneous route.

Dr. Casale stated the indicated use of Sublocade is for moderate to severe opioid use disorder. Before Sublocade is prescribed, the patient must have some experience with buprenorphine products. He added that there is a warning on Sublocade due to if the product were to be injected in the vein it could form an occlusion that could be fatal to the patient. Because of this, there is a limited distribution program that ensures that this medication is never dispensed directly to a patient. It is shipped by one of their specialty pharmacies in the patient's name to the physician's office where their DEA registration is

on file. Once it is delivered to the site, the physician or another health-care professional would administer the subcutaneous injection in their office.

Dr. Casale stated the rationale for developing this product was that they wanted to develop a buprenorphine contained product that delivers a sustained concentration of buprenorphine that has a positive correlation to opioid use disorder symptoms such as the symptoms of withdrawal and opioid blockade. Dr. Casale found that one nanogram per milliliter is needed of sustained buprenorphine concentration to keep patients out of the signs and symptoms of opioid withdrawal. He added that all buprenorphine products contain at least this amount for that reason.

Dr. Casale stated the half-life of Sublocade is 44 to 46 days, meaning it would take at least five half-lives for the drug to be cleared from the body. Because of this long half-life, it is delivered every month with no oral supplementation. Once the Sublocade is delivered the patient should be out of opioid withdrawal and in a state of blockade.

In response to a question asked by Representative Bentley, Dr. Casale stated if Sublocade is ordered though one of their specialty pharmacies, it would be considered as dispensed once it leaves the pharmacy because it would be sent in the patients name. He added that the other route of procurement for Sublocade is for a site to be enrolled in the Evaluation, Mitigation, and Strategy (EMS) program. That site, such as a physician's office, would have to get certified which would give them the ability to buy Sublocade in bulk. In that case, Sublocade would ship without a patient's name, so that site would be responsible for storing it and then dispensing it within the site's setting.

In response to a question asked by Representative Bentley, Dr. Casale stated that because of the risks of dispensing Sublocade and the fear of patients self-injecting the product, a framework was established to start a limited distribution process of Sublocade, thus the reason for specialty pharmacy dispensement.

In response to a question asked by Representative Bentley, Dr. Casale stated there have not yet been any reports of self-removal of the product. He added however, that it is not impossible and could be done.

With no further business to go, Chairman Alvarado adjourned the meeting at 4:56 P.M.