COUNTY OF HUNTERDON NEW JERSEY

HUMAN SERVICES ADVISORY COUNCIL

LOCAL ADVISORY COMMITTEE ON ALCOHOLISM & DRUG ABUSE
YOUTH SERVICES COMMISSION
MENTAL HEALTH BOARD

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REFERENCE:
- ☐ Council
- ☐ Mental Health
- ☐ Youth
- ☐ Disability Services
- ☒ Substance Use Disorder
- ☐ Transportation

Approved May 18, 2022

LOCAL ADVISORY COMMITTEE ON ALCOHOLISM AND DRUG ABUSE

Regular Meeting

Wednesday, March 16, 2022, 2:30 p.m.
Via Webex

MEMBERS PRESENT		STAFF	GUESTS/PACADA LIAISON
L. Smallwood	M. Logan	S. Becker	D. Pagaduan
D. Laclair	K. Schwartz	S. Nekola	F. Crisologo
J. Giotis		M. O'Reilly	C. Moore
		A. DeLuca	R. Denlinger
		M. Sweeney	
		R. Neiber	

I. CONVENE: OPEN PUBLIC MEETING STATEMENT:

"This meeting is being held in accordance with the provisions of the Open Public Meetings Act, N.J.S.A. 10:4-6 – 10:4-21. Notice of this meeting has been provided in the Hunterdon County Democrat and the Courier News. A public notice announcing this meeting has also been placed in the lobbies of the Hunterdon County Department of Human Services, the first floor of the Main Street County Complex, 71 Main Street Building #1, Flemington, NJ; the first floor of the Route 12 County Complex, Building #3, 314 State Route 12, Flemington, NJ and County Clerk's Office."

The regular meeting of LACADA was opened at 2:30 p.m. with the reading of the Open Public Meetings statement. Introductions were made.

Introductions were made by all participants.

S. Becker stated she is with the Department of Human Services as the Assistant Mental Health Administrator and Drug & Alcohol Director.

A. DeLuca stated she is with the Department of Human Services as a Program Development Specialist; County Alliance Coordinator.

J. Giotis stated he is an educator in Raritan Township, Hunterdon County.

F. Crisologo stated he is a captain with the Hunterdon County Prosecutor's Office.

A. Hicks stated she is a Recovery Advocate from the Open Door Recovery Center which is a division of Prevention Resources, Inc.

I. Hamm stated she is Community Health Manager with Hikma Pharmaceuticals USA Inc.

K. L. McKown is the program coordinator for the Open Door Recovery Center which a division of Prevention Resources, Inc.

K. Schwartz stated he is a part of the recovery community and supports Operation Helping Hands and is a peer recovery coach at Open Door Recovery Center.

L. Smallwood stated she is representing the recovery community.

M. O'Reilly stated she is the Human Services Administrator for Hunterdon County.

V. Peters stated she is a Family Support Advocate with the Sharing the Hope Family Support Center, as well as apart of Prevention Resources, Inc.

Y. Pepin stated she is a director with Government Alliances at Community Health, a division of Hikma Pharmaceuticals USA Inc.

D. Laclair stated she is a Case Manager for the Hunterdon County STAR Program; the Support Team for Addiction Recovery.

M. Logan stated she is a Lebanon Borough resident and community member.

J. Cassano stated she is a job developer with the Greater Raritan Workforce Development Board.

II. MINUTES:

J. Giotis made a motion and L. Smallwood seconded to approve the minutes of January 19, 2022. All were in favor. The motion passed.

III. REPORTS:

A. County Update: M. O'Reilly informed the group that the utility moratorium for shutoffs has ended. The Department of Community Affairs announced a Low-Income Household Water Assistance Program (LIHWAP) that can be used for water and sewer arrears. The eligibility requirements can be located on the DCA website. She will add this information to the Chat Box. The application can be found online and anyone requiring any assistance can either call 2-1-1 or can call 1-800-510-3102 to be referred to a local agency to help apply for that assistance.

The Tri-County Care Management Organization has an RFP opportunity. S. Becker forwarded the information and details out earlier. A maximum total of $68,678.46 is available to fund one or more projects. Funding is to be used for expansion or creation of resources available to tri-county youth experiencing emotional, behavioral, developmental, intellectual, and substance use needs, and their families. All types of projects that result in the creation or expansion of community-based resources that meet cited multi-source needs data will be considered.

Information had been shared by the Department of Children & Families regarding vaccines and booster shots that are available through the New Jersey Department of Health. There was information in an email to contact the Department of Health for any pop-up clinics. M. O'Reilly will provide the information in an email.

B. Municipal Alliance Program: A. DeLuca conveyed the grant application had been submitted to GCADA on February 28, 2022 and an email went out to the county coordinators from GCADA that the Counsel Review Team will be holding their meetings on May 17, 2022 and June 21, 2022. She is awaiting to hear back what date Hunterdon County had been assigned to in order to be made aware if the grant has been approved and they will be able to be accepting funds.

A. DeLuca reported the municipal alliances are doing really well. Central Hunterdon has completed all of their programs except one which is Campfire for Kids. This program just began today and will be completed at East Amwell. A. DeLuca conveyed she received positive feedback from that alliance, i.e. the programs have been going well.

Del Val is in the process of a budget modification right now. A majority of their programming is complete, but they did have one line item that had a $1,000.00 that they felt would be a better fit to additional programs to an already existing line item. Del Val is going to move funds from their Prevention Education from middle school to Don't Get Vaped In to add some additional classes. This budget modification is for this fiscal year which means it is only available through the remainder of this school year.

North Hunterdon has been doing well with their programming and has been spending down their dollars. Bill have been trickling in from them along from the other alliances.

She noted she had recently spoke with Wendy Sidebottom from Prevention Resources, Inc. inquiring how South Hunterdon has been doing with their programming. W. Sidebottom stated they are in the process of Footprints for Life at Lambertville. It started on February 28, 2022 and it is running weekly until April 4, 2022. One of the counselors from South Hunterdon has worked with Prevention Resources, Inc. to schedule programming for grades 7 to 12 for the middle schools and high school. They will be doing programming on April 13, 2022 for vaping, alcohol and mental health. Lastly, A. DeLuca spoke with South Hunterdon's counselor who runs the Peer Assistance and Leadership Program (PAL). She provided fantastic feedback. She said the group will be meeting on Monday and they are working on International SEL-based science and activities.

A. DeLuca stated Voorhees High School's programming is also going well and at their last meeting on March 3, 2022, a counselor from High Bridge stated her programming would be finished very soon. Voorhees has also began submitting bills too.

Overall, the municipal alliance program has been running very well and A. DeLuca is very proud of their successes, efforts, and hard work.

C. PACADA Update: S. Becker advised that PACADA will be meeting tomorrow, March 17, 2022. They will be having a presentation on the Maternal Wrap-Around Program, which is a program dedicated to women who are pregnant and/or postpartum diagnosed with any substance use disorder. S. Becker conveyed the agencies are either working virtually, fully

operational or utilizing a hybrid model. Staffing issues are still concerns for many agencies due to COVID. Everyone is hiring at the moment.

D. HSAC Update: M. O'Reilly stated that at the February 23, 2022 HSAC meeting, the Tri-County CMO presented on their services, as well as announced they have funding available through the RFP process.

M. O'Reilly conveyed the HSAC group is looking deeper into their committees by streamlining the processes and ensure the members are aware of each committee and what they are responsible for at the last meeting.

IV. UNFINISHED BUSINESS: No Report.

V. NEW BUSINESS:

A. Yashira Pepin/Imani Hamm – Kloxxado Presentation – S. Becker introduced the guests, Y. Pepin and I. Hamm who will be presenting on Kloxxado Nasal Spray manufactured by Hikma Pharmaceuticals USA, Inc. Y. Pepin began by thanking the group for having their team and then introduced I. Hamm as the Community Health Manager and is local to New Jersey. Y. Pepin stated she is based in Massachusetts and has family in New Jersey, as well as she likes to spend time in New York City.

Hikma Pharmaceuticals USA Inc. is one of the largest generics supplier of medicines critical to public health. They offer over 200 medicines that are manufactured in the United States and employ about 1900 employees. Their headquarters are located in Berkeley Heights, NJ and the company has three manufacturing and Research & Development sites in the United States. Kloxxado is manufactured in Columbus, OH and they produce Naloxone vials in Cherry Hill, NJ. The company has a rich history of making MAT medications in the generic space. Hikma only has three branded products with Kloxxado as their second branded product. Y. Pepin conveyed the company had been very instrumental in the response to COVID because they have a really robust injectable line of medicines. She reported that due to the shortage of Naloxone vials produced by Pfizer Pharmaceutical last year, Hikma donated 50,000 vials for free.

Kloxxado is an 8 Mg Naloxone spray. The mechanism for the medicine is the same as Narcan. They use the same manufacturer as who Narcan uses. It is double the strength as Narcan and has the same amount of liquid.

Y. Pepin reported the number of deaths related to overdoses from synthetic opioids continue to rise since 1999. The deaths were very much contributed to commonly prescribed opioids and heroin. Beginning in 2013, more particularly in 2015, there is a switch from commonly prescribed opioids and heroin to other synthetic opioids, specifically to what is known now as illicitly manufactured fentanyl. The deaths recorded in 2018 started to see about 50% of a mixture not only with illicitly manufactured fentanyl but with cocaine-involved and Benzodiazepine-involved substances. A quarter of the cases include antidepressants and Psychostimulant. S. Becker concurred Hunterdon County is also experiencing the same increase in deaths.

A. Hicks asked for clarification in language about the deaths involving non-opioid substances; if they were a cause of death or they were just taking these substances alongside of taking the opioids. Y. Pepin feels it may have been found in the toxicology reporting and will inquire

with the medical advisor.

Y. Pepin continued on explaining the demonstration of the potency and lethality of heroin as of compared to fentanyl and to carfentanil. What was found in the past with heroin overdoses, sometimes individuals would have up to 1 to 3 hours to be revived and now with fentanyl along with illicitly manufactured fentanyl, the overdose can happen within minutes. This will put the individual in a very difficult situation where they will be facing very dire circumstances. This will lead to a set of even more negative consequences. Minutes matter when it comes to overdose. Permanent brain damage can occur within four minutes of oxygen deprivation. She conveyed sometimes when people are in this moment of crisis, they are finding that people are really concerned quite appropriately with ensuring that people are alive. Obviously, recovery and treatment cannot be found if a person is not alive. Sometimes there isn't enough conversation about how people are coming back and their quality of life from coming back. This is why they really want to make sure that as conversations occur between stakeholders, people with lived through experiences and people in the treatment community, as well as all other stakeholders that they are talking about bringing people back as fast as possible with as little as negative health consequences as possible. This is one of the biggest reasonings for using Kloxxado. Theoretically, the hope of the double strength of Kloxxado will help to bring the person back sooner and hopefully, less health consequences.

Y. Pepin informed that through an Avetian et al study which was held in 2016 within 7 states and published in 2018, out of 261 reversal attempts, 34% of overdose reversals used 2 or more doses of Narcan. The good thing about this study was it also looked at the adverse events of administering those doses. No unexpected or life-threatening events were reported in 4 to 16 mg doses of Narcan Nasal Spray in one 2016 survey of community distribution groups. Y. Pepin will provide the presentation to the group.

Y. Pepin continued to cover another study that had taken place in 2021. It was a MORE Study (Manuscript in Preparation) and looked at 125 reversal attempts. This study finds out of the 125 reversals, 48% required two or more Narcan doses and 30% required three or more Narcan doses. This study was not only quantitative; it was also qualitative. 90% of respondents reported being worried that having one box (2 sprays) of 4 mg naloxone nasal spray would not be enough. These respondents called into a voicemail and provided their testimonials about what it was like to be a bystander in that reversal attempt. Y. Pepin shared a slide that provided participants testimonials reflecting their preferences for an 8 mg spray. Very compelling. Discussion ensued regarding recidivism and how many doses as it correlates to the potency of the drug in use; has the market providing said drug change in potency. Y. Pepin will advise with a scientific advisor. M. O'Reilly suggested the OORP team through the Prosecutor's Office may have data. S. Becker added that data is not tracked. Y. Pepin advised she may have data on how beneficial the medicine is in terms of saving a life vs. how cost effective it is.

Kloxxado is Naloxone and has the same warnings and precautions as all FDA approved Naloxone products. If someone is opioid-dependent, they may experience opioid withdrawal. The issue is it is unknown who will experience opioid withdrawal because it is highly subjective to the person, what they took, when they took it, their history of abuse, their genetics and all sorts of individual characteristics.

Kloxxado (8 mg) is twice as strong as Narcan (4 mg) and is more cost effective. There had not been any head-to-head comparisons between Narcan and Kloxxado. There is VA guidance

that is called Guidance for Use for Naloxone Rescue from the Department of Veteran Affairs. It is the closest documentation from a federal agency that tries to draw a distinction between the two. She will forward this information.

Y. Pepin reiterated that Kloxxado is an 8 mg nasal Naloxone spray. It is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression for adult and pediatric patients. Warning and precautions are the same as any other Naloxone product approved by the FDA. Adverse events are tracked across Kloxxado's two PL studies. She pointed out Dr. Patrice Harris, Head of the American Medical Association's Opioid Task Force, stating, "The FDA is making sure the overdose-reversing drug is potent enough to counteract the increasingly lethal and illicitly manufactured fentanyl". There is the support from the AMA for Kloxxado early on and in keeping with the other federal agencies support for higher dose Naloxone.

2 PK studies were used to compare Kloxxado and 47 healthy volunteers compared to what was the standard of care at that time which was IV Naloxone and IM Naloxone. Y. Pepin covered and explained a slide that provided specific information related to Plasma Naloxone Peaks at 15 minutes and 30 minutes. Kloxxado can be used for adults and the pediatric population. S. Becker asked if there were any specific information related to pediatrics.

Y. Pepin stated the indication and important safety information of Kloxxado; the warnings and precautions are the risk of recurrent respiratory and central nervous system depression. Seek emergency assistance immediately after administration of the first dose and keep the patient under continued surveillance. The duration of action of most opioids may exceed that of Kloxxado, resulting in a return of respiratory and/or central nervous system depression after initial improvement in symptoms. The risk of limited efficacy with partial agonists or mixed agonist/antagonists; reversal of respiratory depression by partial agonist/antagonists may be incomplete.

Larger or repeat doses of naloxone hydrochloride may be required. Use in patients who are opioid dependent may precipitate opioid withdrawal characterized by body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, etc.

In two pharmacokinetic studies, a total of 47 healthy adult volunteers were exposed to a single dose of KLOXXADO, one spray in one nostril. Adverse reactions were reported in two subjects for each of the following: abdominal pain, asthenia, dizziness, headache, nasal discomfort, and presyncope. Signs of nasal inflammation and nasal congestion were observed, and serious adverse reactions reported: none.

The following most frequently reported events (in decreasing frequency) have been identified primarily during post-approval use of naloxone hydrochloride: withdrawal syndrome, vomiting, non-responsiveness to stimuli, drug ineffective, agitation, somnolence, and loss of consciousness.

Naloxone may precipitate opioid withdrawal in the pregnant woman and fetus. Careful monitoring is needed until the fetus and mother are stabilized.

In situations where the primary concern is for infants at risk for opioid overdose, consider the availability of alternate naloxone-containing products.

For more information, please see the full Prescribing Information and Patient Information, which can be found on dailymed.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit https://www.fda.gov/medwatch.com or call 1-800-FDA-1088. Distributed by: Hikma Specialty USA Inc., Berkeley Heights, NJ 07922.

Y. Pepin thanked the group and stated her, and her team will be a continued resource pertaining to the presentation on Kloxxado. S. Becker thanked the team for their time and education.

The status on Hope One is they are trying to get out more since the weather is going to be more promising and the Prosecutor's Office Helping Hands are awaiting on their van. More information to follow.

Additionally, the IDRC program will coordinating with Gloucester County and will be partnering with Somerset County.

A motion was made and seconded by membership. The motion passed and there being no further business. The meeting was adjourned at 3:46 p.m. The next meeting of LACADA is scheduled for Wednesday, May 18, 2022, at 2:30 pm via Webex.