Statewide Drug Policy Advisory Council

Public Meeting Book

Via Go-to-meeting

October 20, 2020
8:30AM-12:30PM

Statewide Drug Policy Advisory Council Meeting

October 20, 2020
8:30 am to 12:30 pm

GoToMeeting Information
Meeting link: https://global.gotomeeting.com/join/868127213
Dial-in number: 1-866-899-4679
Access code: 868-127-213

AGENDA

Time	Item	Topic	Topic Facilitator / Presenter
8:30–8:50 am	1	Welcome/Introductions/Opening Remarks	Scott A. Rivkees, MD State Surgeon General
	2	Approval of September 8, 2020 meeting minutes	DPAC
8:50–9:10 am	3	Preventing overdose deaths in hospitals	Mary Mayhew CEO, Florida Hospital Association
9:10–9:30 am	4	Prescription digital therapies	Yuri Maricich MD, MBA CMO, Pear Therapeutics
9:30–9:50 am	5	ODMAP	Annie White Assistant Special Agent in Charge Office of Statewide Intelligence FDLE
9:50–10:10 am	6	Recent Trends in Fatal and Non-fatal Overdoses	Jared Jashinsky, PhD Epidemiologist & Project Manager DOH
10:10 am–12:00 pm	7	Review and Approve 2020 DPAC Annual Report	DPAC
12:00–12:15 pm	8	Public Comment	
12:15–12:30 pm	9	Next steps and future meeting date Motion to Adjourn	Scott A. Rivkees, MD State Surgeon General

Statewide Drug Policy Advisory Council
Meeting Minutes

September 8, 2020
8:30 AM - 12:30 PM

GoToMeeting Information Meeting link:
https://global.gotomeeting.com/join/789412261
Dial: United States (Toll Free): 1-866-899-4679
Access Code: 789-412-261

Due to COVID-19, the Statewide Drug Policy Advisory Council meeting was held virtually via GoToMeeting. A recording of the meeting can be found here: :
https://ww10.doh.state.fl.us/pub/dpac/DPAC-meeting-September2020.m4v

Attendees:
Scott A. Rivkees, State Surgeon General, Chair
Maggie Agerton, for Mark Inch (Department of Corrections)
Lt. Jason Britt, for Terry Rhodes (Department of Highway Safety and Motor Vehicles)
Jeffrey Cece, for Chad Poppell (Department of Children and Family Services)
MAJ Nate Dinger (Department of Military Affairs)
Nathan Dunn, Staff Liaison (Florida Department of Health)
Mark Fontaine (Florida Behavioral Health Association)
Dotti Groover-Skipper (HeartDance Foundation)
Rachel Kamoutsas for Ashley Moody (Attorney General)
Beth Labasky for Peggy Sapp (Informed Families)
Doug Leonardo (Chrysalis Health)
Walter Liebrich (Executive Office of the Governor)
Tracy Shelby, for Simone Marstiller (Department of Juvenile Justice)
Roaya Tyson (Gracepoint)
Nichole Wilder, for Richard Corcoran (Department of Education)
Annie White for Rick Swearingen (Department of Law Enforcement Commissioner)

Guests and staff:
Katie Black (Florida Department of Health)
Michelle Harkness (Florida Department of Health)
Holly Wheeler
Cynthia Henderson

1. Welcome/Introductions/Opening Remarks:

Nathan Dunn, MSA, Strategic Projects Manager, DOH, opened the meeting and introduced Scott A. Rivkees, MD, Chair, State Surgeon General for opening remarks. Dr. Rivkees welcomed everyone and expressed his appreciation for everyone's dedication to DPAC. Dr. Rivkees talked about the status of COVID-19 in

Florida:

- First case reported March 1st in Florida
- July- 18% positivity rate (11,000 hospitalized)
- Today- under 5% positivity rate, 3300 hospitalized
- We continue to monitor the situation – encouraged everyone to wear a mask, wash hands, practice social distancing, and avoid crowds
- 80% of deaths in Florida are people over 65 years old
- Will continue to track impact of COVID-19 on opioid overdoses and mental health

Business

2. **Review and Approval of Meeting Minutes from July 21, 2020**
   Dotti Groover-Skipper indicated she would like the minutes to reflect that she is no longer with the Salvation Army. The minutes were approved with this one edit.

3. **Discuss Recommendations in the 2019 DPAC Annual Report-**
   Dr. Rivkees reminded everyone that the DPAC Annual Report is due to the Governor's Office in December. Nathan Dunn explained organization of report and track changes he had done. Mark Fontaine suggested recommendations should be in an organized chart/table.

   The following group discussion was held regarding the Annual Report:

   23 recommendations are a lot – do we want to reduce the number of recommendations? Are there key issues that should be addressed?

   Doug Leonardo– reconstituting Office of Drug Control (ODCP)– this is not in there, most likely because Governor had said he was going to reinstate this office; not sure where that landed – Doug feels this should be in the report as it is important to convene other agencies. Dotti Groover-Skipper agrees; we should continue to make this recommendation; this should be implemented. Mark Fontaine– supports the recommendation as well and suggested some of the other recommendations in report would fall under the Office of Drug Control. Mr. Dunn suggested using wording on p. 51 of Statewide Opioid Task Force recommendation report. Where does this recommendation fit in the report? Mark Fontaine suggested it should stand alone – the first recommendation, as it is top priority.

   Recommendation #1 (Public Awareness Campaign):
   MAJ Nate Dinger - concerned with reducing number of recommendations. He stated that with the huge impact of COVID-19, reducing the recommendations this year may reduce the options for the legislature to support recommendations.

   Mark Fontaine – indicated we will be lucky to hold on to the funding we have since state budget has been significantly impacted – we need to be aware of our reality.

   MAJ Nate Dinger- funds for prevention efforts are usually the first to be diverted elsewhere – if we give up on prevention, this may be a big problem down the road.

   Jeff Cece – block grant – requires spending 20% on primary prevention – there's flexibility with some federal funds.

   Mark Fontaine– asked if we are still in need of a public awareness campaign.

   MAJ Nate Dinger- stated public awareness campaign is needed due to stigma; many people don't report to their physician; people need to see messages repeatedly.

Mark Fontaine- public awareness campaign should focus on stigma – Nate Dinger and Jeff Cece agree with this.

Jeff Cece– Group should look into evaluation and research on results of stigma campaign.
Do people exposed to these campaigns reduce their use or seek treatment more? Mr. Fontaine mentioned that once we start talking about addiction as a health condition and opening door to medication assisted treatment (MAT), stigma can be reduced.

Beth Labasky– supports these statements.
ACTION: MAJ Nate Dinger – agreed to write-up this piece for the draft report – stated he's in training for next two weeks but will have this done by beginning of October; he will take some of the content from Jeff Cece on p. 22 and incorporate any relevant info into his write-up.

Recommendation #2 (Prevention Efforts):
MAJ Nate Dinger- obtaining support of coalitions would be great – they are covering large areas with few resources; he believes this recommendation should remain.

Mark Fontaine- thinks we should maintain previous funding and not expand. MAJ Dinger suggested putting "increase/maintain."

Doug Leonardo- stated the group should not be concerned with factors out of its control (such as money availability). The group should not hold back on recommendations because of what others might do; the group should make the recommendations that they feel are needed.

There was a discussion about coalitions.
ACTION: The general consensus was to expand definition of #1 and combine #1 and #2 to make a single recommendation. If metrics can be tied in to show how these recommendations can be effective, they will have much more likelihood of being supported.

Recommendation #3 (Prevention-Youth):
MAJ Nate Dinger- This recommendation goes hand in hand with DOE; strategies should align with community needs.

Mark Fontaine- Schools have resources to do this work because legislature has given $100 million to schools to deliver 5 hours of mental health training to students. MAJ Dinger mentioned his program is working on an online course designed to satisfy the 5 hours.

Nichole Wilder- substance abuse is included as a topic area under mental health, but there is no specific rule to have a substance abuse curriculum. Each school district can create their own or use whatever they see fit to meet the requirements. The curriculum is not required to be evidence-based. She suggested maybe revising language to make it more concise and focus on evidence-based/evidence-informed curriculum.
ACTION: Ms. Wilder will revise this recommendation.

Recommendation #4 (E-cigarette Prevention Strategy):
Mark Fontaine- SB810 went to the Governor last week – many things in this recommendation are being covered under this bill – not sure if Governor is going to sign the bill.
MAJ Nate Dinger- If SB810 is passed, many of these components/items under this recommendation will have been met.
Dr. Rivkees- mentioned the vaping age was raised to age 21 – so this is covered under Federal regulation.
ACTION: If Governor signs the bill, this recommendation will be deleted from the Annual Report.

Recommendation #5 (DOH Initiative-SBIRT-Evidence-based Practices):
Mark Fontaine- this recommendation should be kept in annual report. This should be revised to clarify

action.
ACTION: Mr. Fontaine agreed to revise this recommendation.

Recommendation #6 (Expanding Naloxone Availability):
Mark Fontaine- suggested that there could be one recommendation containing everything related to Naloxone instead of having several separate items for Naloxone.
ACTION: Jeff Cece- will reflect on recommendations #6-11 to determine whether these should be revised and combined into one section, with the exception of #9, which needs to be moved before #12.

Recommendation #7 (Syringe Exchange Programs):
There was a discussion whether this recommendation should remain or be removed.
Jeff Cece– sees a benefit of leaving it in and feels that it is gaining traction.
Dotti Groover-Skipper– Agrees with leaving it in.
ACTION: It was concluded that Recommendations 6,7,8, and 10 will be left in place. Mr. Cece may provide additional info.

Recommendation #9 (Warm Hand-off Programs):
This recommendation should be moved before #12.
Florida Hospital Association (FHA)-18 Emergency Departments in Florida have warm hand-off procedure.
Mark Fontaine- Suggested AHCA may be able to survey hospitals to see if they have warm hand-off procedures. This would create a baseline.
Nathan Dunn- will look into having a presentation by FHA on this issue.
ACTION: Mr. Fontaine will provide updates/supporting info and the recommendation will be kept in report.

Recommendation #11 (CHDs and FQHCs distributing Naloxone):
Mark Fontaine-asked about HEROS program and CHDs
Nathan Dunn- HEROS program distributes Naloxone to first responders
Mark Fontaine-asked if CHDs are handing out Naloxone at this time?
ACTION: Mr. Dunn stated he will check into whether CHDs are distributing Naloxone.

Recommendation #12 (Programs for Addiction Medicine Specialty):
Mark Fontaine asked if it is known how many physicians in Florida have a specialty in addiction medicine. He suggested maybe Florida Society of Addiction Medicine (FSAM) might know.
ACTION: Mr. Dunn stated he would reach out to FSAM.

Recommendation #13 (Parity):
Mark Fontaine-stated we do not have definite information about whether Florida is in line with the parity rule.
ACTION: This recommendation will remain in the report. Mr. Fontaine will provide updates/other information for the draft report.

Recommendation #14 (Prior Authorization for MAT):
Discussion about reaching out to AHCA to determine what prior authorization process is in place for MAT at this time. And on the commercial side, reach out to Florida Association of Health Plans.
ACTION: Reach out to AHCA and the Florida Association of Health Plans

Recommendation #15 (AHCA Secretary and OIG Commissioner added to DPAC):
This recommendation will remain in the report.
Rachel Kamoutsas- suggested there may need to be legislation to add them to the Council.

Recommendation #16 (Recovery Oriented System of Care - ROSC):
Mark Fontaine-suggested the recommendation remain as there has been great progress on this issue.
Jeff Cece-suggested maybe combining content (ROSCs may be good partners to implement stigma-reduction campaigns).

MAJ Nate Dinger- stated there are two messages (youth and adult); this should remain in treatment section.
ACTION: This recommendation will remain in report.

Recommendation #17 (Individuals with lived experience/peers):
Mark Fontaine-stated legislation has been signed by Governor; there are eight charges that are not counted when applying to be a peer; this legislation has not been implemented.
ACTION: Mr. Fontaine will re-word this in light of legislation and make suggestions for moving forward.

Recommendation #18 (Awareness of Stimulant Use):
Jeff Cece- stated that he did research on contingency management with community reinforcement approach (stimulant use disorders). There are interventions that have already been developed so this piece can be removed. Regarding increasing awareness, this alone isn't going to reduce substance use.
Mark Fontaine – agreed with Mr. Cece and thinks recommendation should be rewritten. He stated the recommendation should include policy change to allow use of contingency management in Florida and promote community reinforcement approach.
Jeff Cece-suggested there should be a presentation to the Council on the community reinforcement approach.
ACTION: Nathan Dunn stated this recommendation will be set aside for now and will be re-visited after the presentation. This recommendation will be deleted from the 2020 report.

Recommendation #19 (Behavioral Health Workforce):
Mark Fontaine- data indicates there will be a lack of psychiatrists in Florida and there is the continued challenge of getting peers and getting medical professionals to work in the field. One thing that is helping with regard to workforce is the use of telehealth. Workforce challenges continue to exist.
Doug Leonardo- there's no financial incentive to get into the profession. Increasing use of telehealth in and of itself is not going to solve the issue.
Roaya Tyson - agreed with Mr. Leonardo.
Tracy Shelby- asked if anyone knew what the average salary is for masters-level clinicians; members did not have that data readily available.
ACTION: Mark Fontaine will review this recommendation and see if he can revise it to make it more precise. Based on his research, the recommendation will either be rewritten or deleted.

Recommendation A (Community Reinforcement Approach Presentation):
This is not a recommendation for the report, but it is more an internal recommendation for DPAC. The presentation should be on the DPAC agenda.
Supporting information under this recommendation- Nathan Dunn and Jeff Cece stated this could be moved to "Summary of Findings."
ACTION: Mark Fontaine suggested the recommendation be rewritten to reflect need for more training. Jeff Cece stated he is ok with re-writing the recommendation in this manner.

Recommendation B (AHCA-Prior Authorization):
Mark Fontaine and Jeff Cece agreed that this recommendation and recommendation #14 seem duplicative.
ACTION: Mr. Fontaine agreed to look at both of these recommendations and combine them.

Discussion around COVID-19 changes regarding access to care (i.e. telehealth, prior authorization, etc.). Mark Fontaine asked whether there should be a recommendation around continuing these innovations post COVID.
Doug Leonardo-stated there is a white paper listing services being allowed; it was created to in order to have the exceptions become more permanent post COVID.
Mark Fontaine-asked about making recommendations to the Federal government but it was agreed that the report needs to contain recommendations appropriate to the state of Florida. Mark will send information for "Summary of Findings" regarding Federal information.

Recommendation #20 (Safe Medication Storage and Disposal):
Discussion about whether this recommendation should stay in report. Jeff Cece stated there has been a lot of movement on this one; if removed, there would be nothing under this topic. Beth Labasky agreed it should remain and possibly be reworded.
Recommendation will remain in report.
Mark Fontaine asked if this should be placed in the prevention section instead.
Nathan Dunn asked if the group wanted to put this under prevention and eliminate this topic for now.
Annie White stated most recommendations under this topic are at a Federal level; she will take a look and get back to Mr. Dunn with any state-level recommendations.
ACTION: This recommendation will move under prevention and this section will be removed at this time.

Recommendation #21 (Medical Examiner Data Systems):
Nathan Dunn suggested this recommendation can be marked completed.
ACTION: It was agreed that it will be listed as "Complete."

Recommendation #22 (Statewide Dashboard of Substance Abuse Data):
Nathan Dunn asked whether this recommendation can be marked complete. Mark Fontaine indicated this is not completed yet.
ACTION: Mr. Dunn will circle back and ask for any additional information that may be added to this recommendation.

Recommendation #23 (ODMAP Access):
MAJ Nate Dinger stated that he knows they are continuing to expand.
ACTION: MAJ Dinger will get an update to Nathan Dunn and this recommendation will remain in the Annual Report.

End of meeting general discussion:
Tracy Shelby suggested combining Naloxone recommendations.
Mark Fontaine stated a summary of recommendations should be in the report.
Nathan Dunn confirmed that there will be a summary of recommendations.

4. **Discuss Recommendations in "Findings and Recommendations of the Statewide Task Force on Opioid Abuse"-**
   Nathan Dunn stated that the Statewide Opioid Task Force recommendations were taken into consideration while reviewing the DPAC recommendations.

5. **Discuss draft 2020 DPAC Annual Report summary of findings and recommendations-**
   This was completed during the meeting in the course of reviewing the 2019 DPAC Annual Report recommendations.

6. **Public Comment-**
   No public comment was received.

7. **Closing and Future Meeting Date-**
   Dr. Rivkees thanked Council members and meeting attendees for their participation.

   Next meeting date: October 20, 2020

   Meeting adjourned at 12:20 p.m.

Pear Therapeutics: Redefining Medicine

Prescription Digital Therapeutics for the Treatment of Serious Disease

reSET® and reSET-O ®

PEAR THERAPEUTICS

Disclaimer

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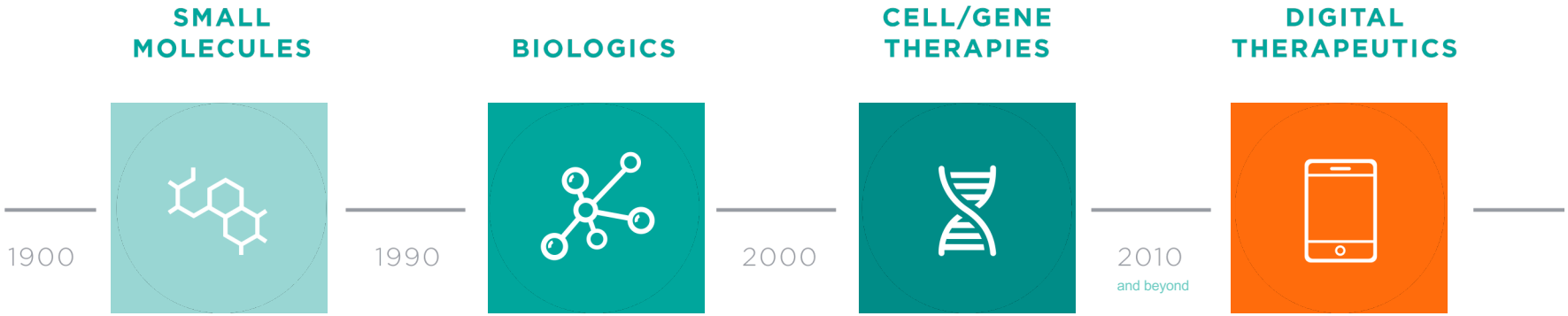
Agenda

Prescription Digital Therapeutics

- Pear Therapeutics
- SUD / OUD
- reSET and reSET-O

Prescription Digital Therapeutics (PDTs): a new therapeutic class that is being integrated into standard of care



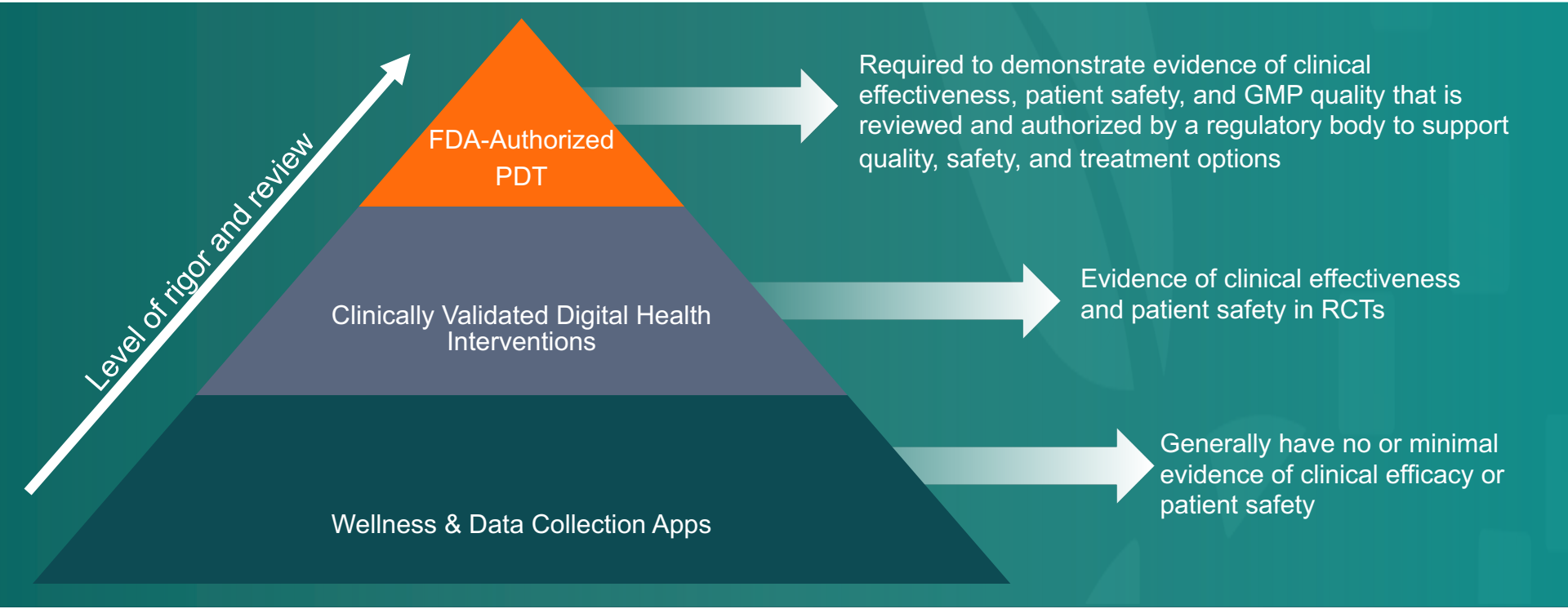
"Software as therapeutics" that treat serious diseases with high unmet medical need

PDTs meet stringent regulatory requirements related to:

- Safety and effectiveness of clinical data [1,2]
- Regulatory labeling[3]
- Payers to evaluate coverage based on traditional therapeutic coverage mechanisms

1. Campbell ANC, Nunes EV, Matthews AG, et al. Internet-delivered treatment for substance abuse: a multisite randomized controlled trial. Am J Psychiatry. 2014;171(6):683-690.
2. Christensen DR, Landes RD, Jackson L, et al. Adding an internet-delivered treatment to an efficacious treatment package for opioid dependence. J Consult Clin Psychol. 2014;82(6):964-972.
3. Federal Drug Administration permits marketing of mobile medical application for substance use disorder [press release]. FDA News Release; Site https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm576087.htm Published September 14, 2017. Accessed July 2019

What is a Prescription Digital Therapeutic (PDT)?



PDTs have efficacy and safety data in FDA authorized label

	Prescription Digital Therapeutics (PDTs)	Traditional Wellness Apps
Deliver disease-specific, evidence-based treatment via mobile devices	✓	✗
FDA-regulated software as a medical device (SaMD)	✓	✗
Evaluated and clinically-validated for safety and efficacy	✓	✗
Receive FDA-marketing authorization	✓	✗
Intended to be used as adjunct to standard outpatient treatment	✓	✗
Label describes indications and intended use, supporting appropriate clinical use	✓	✗

PDT Landscape Gaining Momentum

Digital Landscape Developments

GROWING RECOGNITION

- The FDA, AMA, and WHO have all established working groups or committees to develop critical digital health capabilities & expertise[1]

REGULATORY ADAPTATION

The FDA is:

- Issuing guidance clarifying medical software provisions of legislation
- Developing a new approach to digital health oversight (FDA Pre-Certification.)
- Building FDA's bench strength and expertise in digital health[2]

INFRASTRUCTURE

Current Procedural Terminology (CPT) codes are being reviewed by the AMA's **Digital Medicine Payment Advisory Group** to **enable reimbursement** that reflects the **increasing amount of provider time** spent engaging with technology to **enhance and improve patient care**[3]

1. World Health Organization News Release. WHO is establishing technical advisory group and roster of experts on digital health. Published 2019. Website: https://www.who.int/news-room/detail/10-05-2019-who-is-establishing-technical-advisory-group-and-roster-of-experts-on-digital-health. Accessed July 2019
2. AMA News Release. Henrey, Tanya Albert. 2019 CPT codes offer new paths to payment for digital medicine. Published October 17, 2018. Website: https://www.ama-assn.org/practice-management/cpt/2019-cpt-codes-offer-new-paths-payment-digital-medicine. Accessed 2019
3. Federal Drug Administration. Precertification (Pre-Cert) Pilot Program: Frequently Asked Questions. Updated July 2019. Website https://www.fda.gov/medical-devices/digital-health-software-precertification-pre-cert-program/precertification-pre-cert-pilot-program-frequently-asked-questions. Accessed July 2019

Agenda

- Prescription Digital Therapeutics

Pear Therapeutics

- SUD / OUD
- reSET and reSET-O

Pear is partnering for healthcare transformation

Partnering for Innovation

PROVIDER LEADERSHIP
Novel approach to patient care

CONNECTIVITY TO PATIENTS
Track patient engagement to treatment and highlight areas of need through Clinician Dashboard

PATIENT ACCESS & ENGAGEMENT
Support patients through novel treatment option with 24/7 access

Clinically Meaningful Outcomes

PATIENT OUTCOMES
Deliver reliable and clinically-validated therapeutics

EFFICACY & SAFETY
Focused on developing PDTs with proven efficacy and safety through RCTs.

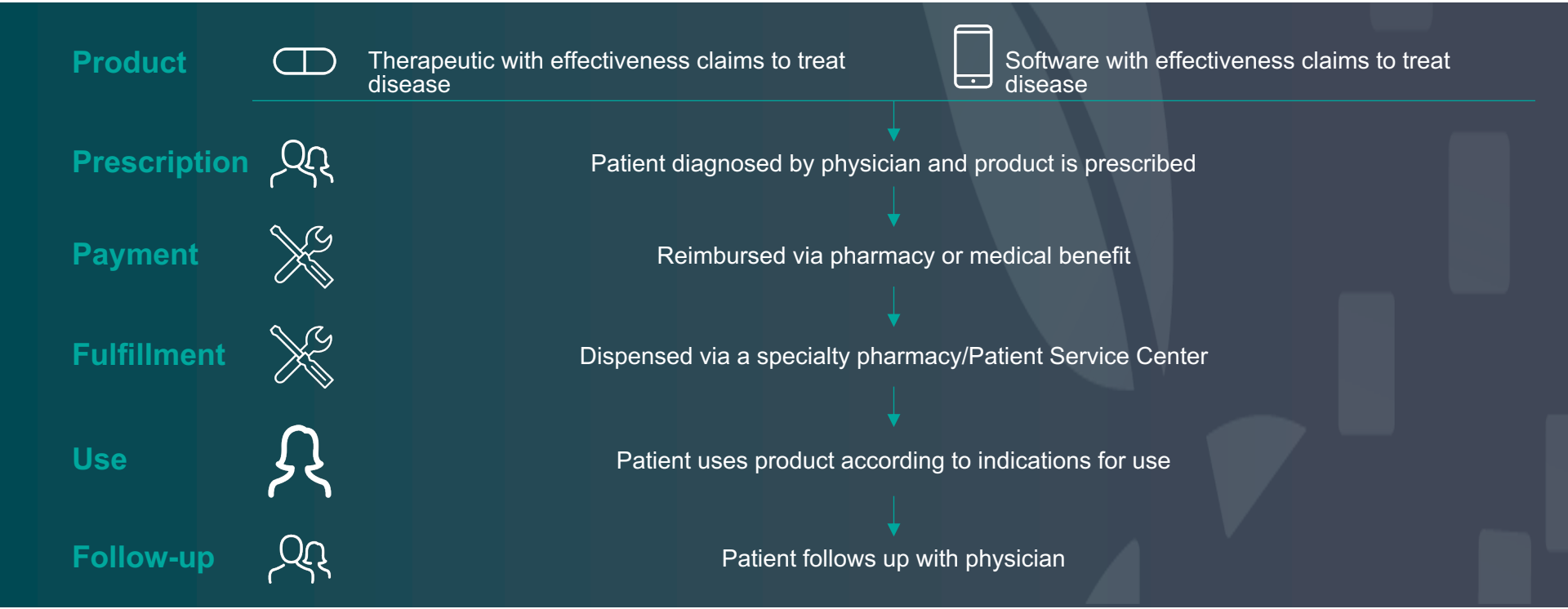
DATA DRIVING CLINICAL INSIGHT
Track patient cravings, triggers, severity and drug use in real-time through the Clinician Dashboard

Attaining Value-Based Care

COST SAVINGS
May decrease healthcare cost savings, for example, ED visit frequency and excess non-OUD treatment costs for patients with OUD

PATIENT ENGAGEMENT
May decrease patient no-shows and multiple bookings, while increasing patient adherence and compliance

Pear PDTs Follow the Traditional Therapeutics Model



Agenda

- Prescription Digital Therapeutics
- Pear Therapeutics

SUD / OUD

- reSET and reSET-O

Technology's potential impact on the on-going public healthcare crisis of SUD/OUD

$500B
impact of OUD annually in US[1]

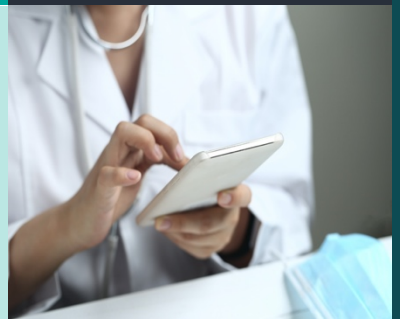
81%
of US population own smart phones[3]

10 hrs
of average time per day on smart phone[4]

21.6M
Americans with SUD/OUD

CURRENT BARRIERS

- Access to care
- Patient stigma
- Patient drop-out

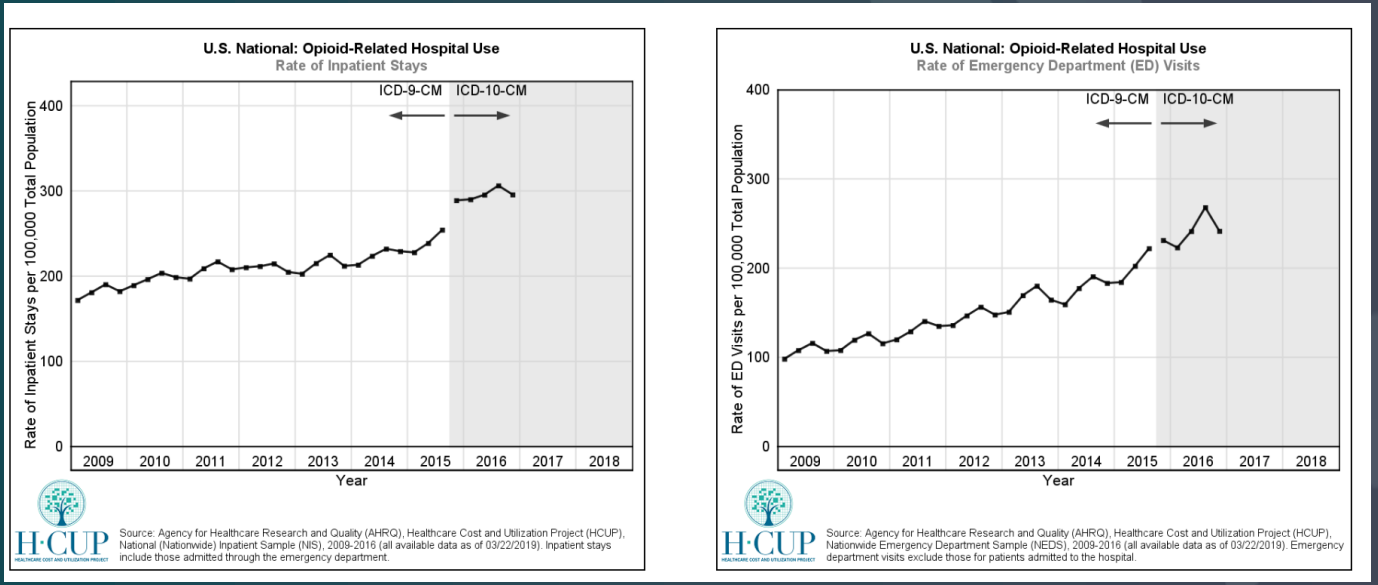


115
People die every day from opioid overdose[2]

Only
4.1M
people receive treatment each year[5]

1. Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-48, HHS Publication No. (SMA) 14-4863. Hedegaard H, Chen L-H, Warner M. Drug-Poisoning Deaths Involving Heroin: United States, 2000–2013.; 2015.
2. http://www.cdc.gov/vitalsigns/heroin/index.html
3. https://www.pewinternet.org/fact-sheet/mobile/
4. https://www-m.cnn.com/2016/06/30/health/americans-screen-time-nielsen/index.html?r=https%3A%2F%2Fr.search.yahoo.com%2F_ylt%3DA0geJaat1lFdVuwAbHFx.9w4%3B_ylu%3DX3oDMTBydWNmY2MwBGNvbG8DYmYxBHBvcwM0BHZ0aWQDBHNlYwNzcg--%2FRV%3D2%2FRE%3D1565673262%2FRO%3D10%2FRU%3Dhttps%253a%252f%252fwww.cnn.com%252f2016%252f06%252f30%252fhealth%252famericans-screen-time-nielsen%252findex.html%2FRK%3D2%2FRS%3DlOlEDwl6PKLz_12NDb7hmq1fKrc-
5. https://www.samhsa.gov

Opioid use drives high cost inpatient hospital stays & ED visits



Source: Healthcare Cost and Utilization Project
https://www.hcup-us.ahrq.gov/faststats/OpioidUseServlet?radio-3=on&location1=US&characteristic1=01&setting1=IP&location2=US&characteristic2=01&setting2=ED&expansionInfoState=hide&dataTablesState=hide&definitionsState=hide&exportState=hide

Agenda

- Prescription Digital Therapeutics
- Pear Therapeutics
- SUD / OUD

reSET and reSET-O

reSET® and reSET-O® were developed to address challenges with SUD / OUD treatment

reSET® is derived from the content of the Therapeutic Education System (TES), developed by Lisa Marsch, PhD, at Dartmouth's Geisel School of Medicine

- TES was developed in response to NIH solicitation for projects to digitize evidence-based behavioral therapies
- TES is an interactive, web-based program rooted in the evidence-based Community Reinforcement Approach to behavior therapy[1]
- 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

Improve Patient Access To Treatment

1. Bickel et al. Exp Clin Psychopharmacol. 2008;16(2):132-143.

Engage patients and clinicians to treat Substance Use Disorder

reSET®

INTERVENTION

Cognitive Behavioral Therapy (CBT) Modules

Fluency Training

Contingency Management

Craving & Trigger Assessment

PATIENT

+

reSET®

INSIGHT

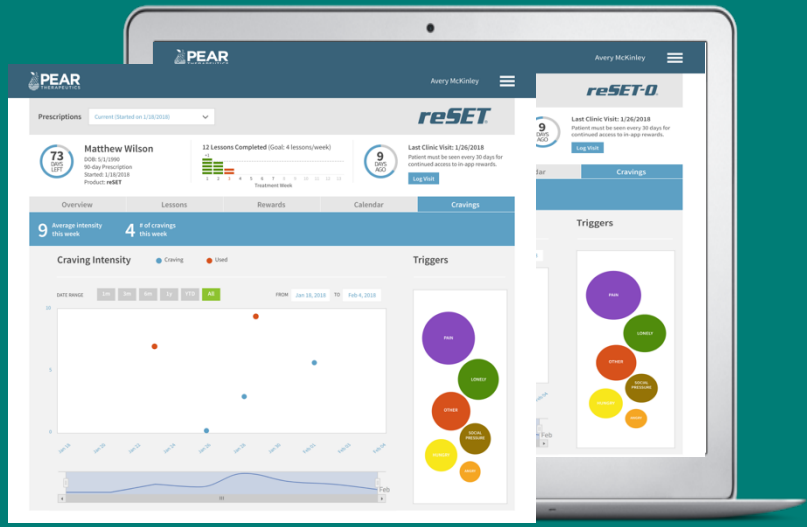
Abstinence and Appointments

CBT Module Use

Fluency Training

Contingency Management

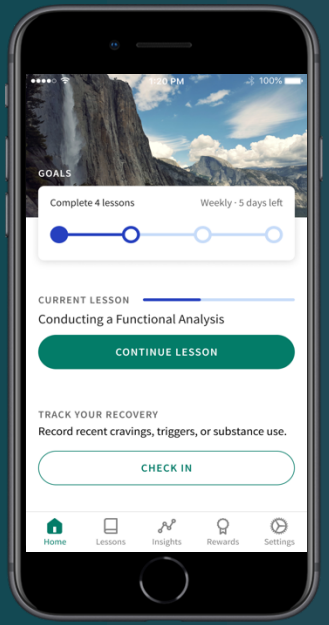
Cravings and Triggers



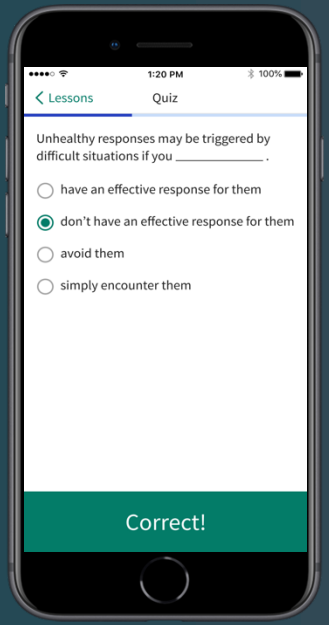
CLINICIAN

Implementing therapeutic techniques designed to maximize clinical effectiveness

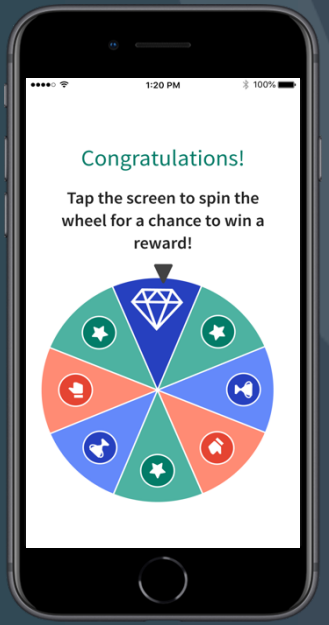
Cognitive Behavioral Therapy (CBT) Lessons



Fluency Training



Contingency Management



Craving & Trigger Assessment

reSET®: Revolutionary paradigm to treat Substance Use Disorder

INDICATION(S)

- reSET® is intended to provide cognitive behavioral therapy, as an adjunct to a contingency management system, for patients18 years of age and older, enrolled in outpatient treatment under the supervision of a clinician
- 12-week prescription duration
- Patient population: Patients with SUD, under treatment for the following:
  - Stimulants, Alcohol + another substance, Marijuana, Cocaine, Opioids (when not primary substance of abuse)
- Not indicated for patients who are on opioid replacement therapy, or abusing alcohol solely, or abusing opioids as their primary substance

MECHANISM OF ACTION

Delivers therapy based on the community reinforcement approach (CRA), an intensive form of validated neurobehavioral therapy for SUD, along with contingency management and fluency training to enhance learning.

PRODUCT DESCRIPTION

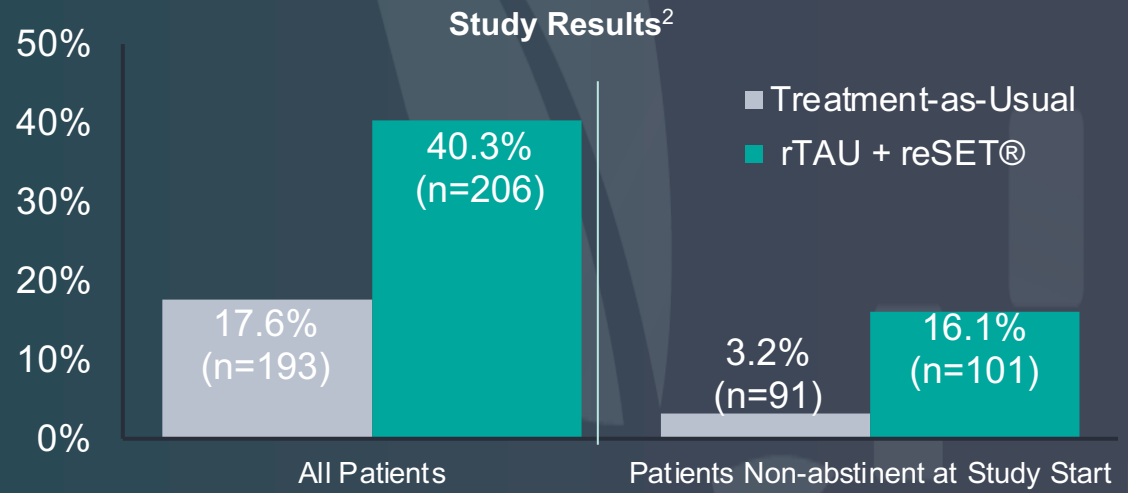
- Based on the Therapeutic Education System (TES)
- Comprised of 62 interactive modules: 32 core modules and 30 supplemental modules
- Core modules focus on key CRA concepts, building skills to support behavior change and prevent relapse
- Supplemental modules provide more in-depth information on specific topics such as relationship skills or living with Hepatitis C
- Each module can be completed in approximately 10-20 minutes

1. American Journal of Psychiatry. 2014. 171(6):683-690.
2. Pear Internal data and Pear regulatory submission. DEN160018
3. Campbell et al., American Journal of Psychiatry. 2014. 171(6):683-690.
4. Chaple et al. 2016. The Prison Journal. 96(3):485-508.
5. DEN 160018 FDA Decision Summary.

reSET Clinical Data | Pivotal Trial Summary

PIVOTAL TRIAL OVERVIEW

- 399 patients with SUD (alcohol, cannabis, cocaine, stimulants) received either:
  - Treatment-as-Usual **(TAU)**, consisting of intensive face-to-face therapy
  - Reduced TAU and reSET (**rTAU+ reSET®**) for 12 weeks[1]
- Patients provided urine samples twice per week to objectively monitor abstinence
- Co-primary study endpoints
  - Abstinence in weeks 9-12
  - Retention in treatment

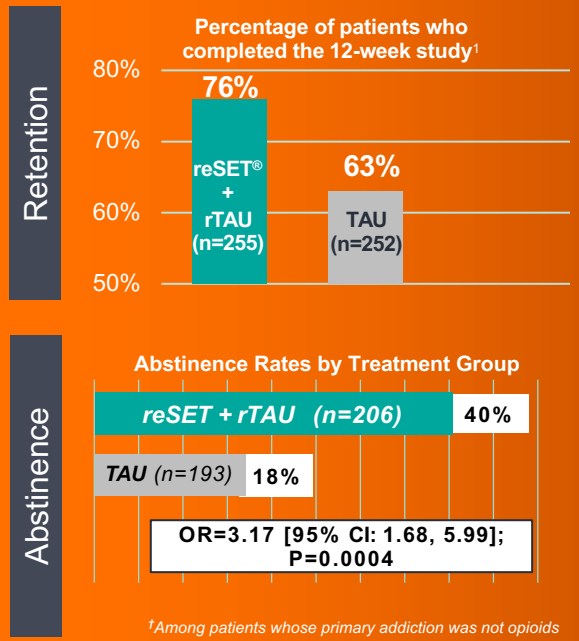


Outcomes	rTAU+reSET®	TAU	P-value
Abstinence: all patients	40.3%	17.6%	0.0004
Abstinence: non-abstinent at study start	16.1%	3.2%	0.0013
Retention in treatment: all patients	76.2%	63.2%	0.0042

1. American Journal of Psychiatry. 2014. 171(6):683-690.
2. Pear Internal data and Pear regulatory submission. DEN160018

reSET | Additional Clinical Data Highlights

HIGHLIGHTS	CLINICAL OUTCOMES SUMMARY
Abstinence	▪ Among patients whose primary addiction was not opioids, adding reSET® to outpatient therapy more than doubled abstinence rates (40% vs. 18%)
Retention	▪ Among all patients, adding reSET® to outpatient therapy improved rates of retention (76% vs. 63%) ▪ Patients who adhered to reSET® module completion in the first six weeks of the trial were 7x more likely to complete treatment than those who did not
Treatment Attendance	▪ Clinical trial data revealed a positive correlation between module completion and appointment attendance[1]
Safety	▪ reSET® did not demonstrate a significant difference in unanticipated adverse events[1]
Module Completion	▪ Average Core Modules Completed: 38[2] (of 48) ▪ Number of reSET® modules completed correlated with abstinence (R^2=0.21, p<.001 with n=206)[2]



1. Pear Internal data and Pear regulatory submission. DEN160018
2. Luderer HF, Campbell ANC, Nunes EV, Maricich YA. A Digital Therapeutic for SUD, reSET®, Demonstrates a Correlation Between Dose and Treatment Outcomes. Poster presented at: 29th Annual Meeting of the American Academy of Addiction Psychiatry; December 6-9, 2018; San Diego, CA.

reSET-O®: Revolutionary paradigm to treat Opioid Use Disorder

INDICATION(S)

- reSET-O® is intended to increase retention of patients with opioid use disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician.
- 12-week prescription duration
- Indicated as a prescription-only digital therapeutic

MECHANISM OF ACTION

- Delivers addiction-specific form of CBT, fluency training, and contingency management for opioid use disorder (OUD)

PRODUCT DESCRIPTION

- Based on the Therapeutic Education System (TES)
- Comprised of 67 interactive modules: 31 core modules and 36 supplemental modules
- Core modules focus on key CRA concepts, building skills to support behavior change and prevent relapse
- Supplemental modules provide more in-depth information on specific topics such as relationship skills or living with hepatitis
- Each module is approx. 10-20 minutes
- Voluntary buprenorphine check-in feature to support buprenorphine use

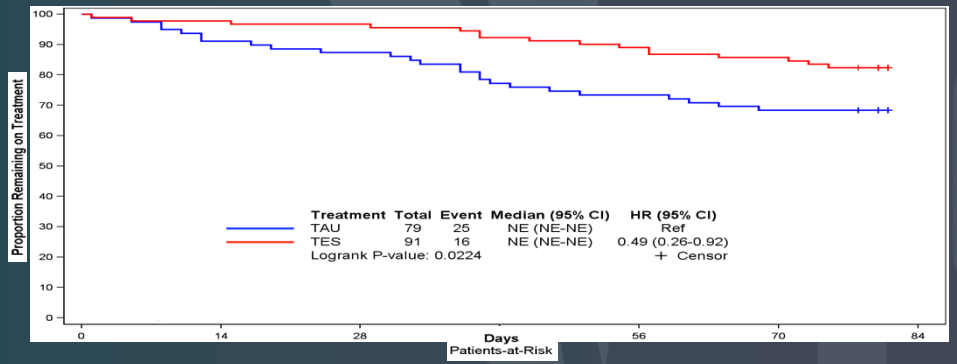
1. American Journal of Psychiatry. 2014. 171(6):683-690.
2. Pear Internal data and Pear regulatory submission. DEN160018
3. Campbell et al., American Journal of Psychiatry. 2014. 171(6):683-690.
4. Chaple et al. 2016. The Prison Journal. 96(3):485-508.
5. DEN 160018 FDA Decision Summary.

reSET-O Clinical Data | Pivotal Trial Summary

PIVOTAL TRIAL OVERVIEW

- 170 patients were randomized to receive either:
  - Treatment-as-Usual **(TAU)**, consisting of Contingency Management + buprenorphine[1] or
  - **TAU + reSET-O®** (academic name Therapeutic Education System, or TES) + Contingency Management + buprenorphine
- All patients received 30 mins. of face-to-face counseling every other week.
- Patients provided urine samples 3x per week to objectively monitor abstinence.
- Co-primary endpoint analysis[2]
  - Negative urine drug screens in weeks 9-12
  - Retention in treatment

STUDY RESULTS[1]



	TAU + reSET-O®	TAU	P-value
Retention (All)	82.4%	68.4%	0.0067

1. Christensen DR, Landes RD, Jackson L, et al. Adding an internet-delivered treatment to an efficacious treatment package for opioid dependence. J Consult Clin Psychol. 2014;82(6):964-972. doi:10.1037/a0037496., and Pear regulatory submission. DEN160018hcf, and reSET-O Clinician Directions for Use. Boston, MA: Pear Therapeutics, Inc; 2019.
2. Pear regulatory submission. DEN160018hcf

reSET-O | Additional Clinical Data Highlights[1]

HIGHLIGHTS	CLINICAL OUTCOMES SUMMARY
Retention	▪ Adding reSET-O® to outpatient treatment using buprenorphine **increased retention of patients with OUD almost 15%**
Safety	▪ The observed adverse events (AE) were of type and frequency as anticipated in a large population of patients with OUD, or associated with buprenorphine pharmacotherapy, particularly during the induction phase. ▪ The AEs observed were not adjudicated to be device related. ▪ reSET-O® vs TAU did not demonstrate any significant safety differences between the cohorts

1. Christensen DR, Landes RD, Jackson L, et al. Adding an internet-delivered treatment to an efficacious treatment package for opioid dependence. J Consult Clin Psychol. 2014;82(6):964-972. doi:10.1037/a0037496., and Pear regulatory submission. DEN160018hcf, and reSET-O Clinician Directions for Use. Boston, MA: Pear Therapeutics, Inc; 2019.

reSET®

Indications for Use

reSET is intended to provide cognitive behavioral therapy, as an adjunct to a contingency management system, for patients 18 years of age and older who are currently enrolled in outpatient treatment under the supervision of a clinician. reSET is indicated as a 12-week (90 days) prescription-only treatment for patients with substance use disorder (SUD), who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or who do not abuse opioids as their primary substance of abuse.

It is intended to:

- Increase abstinence from a patient's substances of abuse during treatment, and
- Increase retention in the outpatient treatment program.

Important Safety Information

Warnings: reSET is intended for patients whose primary language is English and who have access to an Android/iOS tablet or smartphone. reSET is intended only for patients who own a smartphone and are familiar with use of smartphone apps (applications).

Clinicians should not use reSET to communicate with their patients about emergency medical issues. Patients should be clearly instructed not to use reSET to communicate to their clinician any urgent or emergent information. reSET is not to be used for emergencies. In case of an emergency, patients should dial 911 or go to the nearest emergency room.

reSET is not intended to be used as a stand-alone therapy for substance use disorder (SUD) and does not replace care by a licensed medical practitioner. reSET does not represent a substitution for a patient's medication. Patients should continue to take their medications as directed by their physician or medical provider.

The long-term benefit of treatment with reSET on abstinence has not been evaluated in studies lasting beyond 12 weeks in the Substance Use Disorder (SUD) population. The ability of reSET to prevent potential relapse after treatment discontinuation has not been studied.

This presentation does not include all the information needed to use reSET safely and effectively. Please see full Directions for Use for complete Important Safety Information.

reSET-O®

Indications for Use:

reSET-O is intended to increase retention of patients with opioid use disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician. reSET-O is indicated as a prescription-only digital therapeutic.

Important Safety Information

Warnings: reSET-O is intended for patients whose primary language is English and who have access to an Android/iOS tablet or smartphone. reSET-O is intended only for patients who own a smartphone and are familiar with use of smartphone apps (applications).

Clinicians should not use reSET-O to communicate with their patients about emergency medical issues. Patients should be clearly instructed not to use reSET-O to communicate to their clinician any urgent or emergent information. In case of an emergency, patients should dial 911 or go to the nearest emergency room.

reSET-O is not intended to be used as a stand-alone therapy for Opioid Use Disorder (OUD). reSET-O does not replace care by a licensed medical practitioner. reSET-O does not represent a substitution for a patient's medication. Patients should continue to take their medications as directed by their healthcare provider. The ability of reSET-O to prevent potential relapse after therapy discontinuation has not been studied.

This presentation does not include all the information needed to use reSET-O safely and effectively. Please see full Directions for Use for complete Important Safety Information.

References

1. reSET® Clinician Directions for Use. Boston, MA and San Francisco, CA. Pear Therapeutics; 2019.
2. reSET-O® Clinician Directions for Use. Boston, MA and San Francisco, CA. Pear Therapeutics; 2019.

Overdose Detection Mapping Application Program (ODMAP)

What is ODMAP?

- ODMAP is a free, Web-based, mobile-friendly software platform to support reporting of suspected fatal and nonfatal overdoses. The Washington/Baltimore High Intensity Drug Trafficking Area (HIDTA) launched ODMAP in 2017.
- The goal of ODMAP is to provide near real-time data to public safety and public health agencies, enabling them to mobilize responses to overdoses as quickly as practically possible. ODMAP displays overdose data within and across jurisdictions to help agencies identify spikes and clusters.

Why Was It created?

- More than 630,000 people died from an overdose between 1999 and 2016, and we currently see overdose death tolls of 115 Americans every day (Beeson, 2018).
- In 2016, 63,600 overdose deaths were reported across the country, a dramatic rise from the 52,000 deaths in 2015 (Beeson, 2018)
- Despite these dramatic statistics, the country lacked a consistent methodology to track overdoses, which limits our ability to understand and mobilize against the crisis. To address this problem in January 2017, the Washington/Baltimore High Intensity Drug Trafficking Area (HIDTA) program developed the Overdose Detection Mapping Application (ODMAP).

Who Can Input Overdose Data Into ODMAP?

ODMAP capabilities include access for two types of users: Level I and Level II.

- Level I users are primarily defined as law enforcement or fire/EMS providers. These users provide on scene reports of real-time overdoses.
- Level II users are most often leadership from public health and safety, or data analysts. Level II access requires special permission for login credentials to access the central database and map which captures the approximate locations of the overdoses as reported by the Level I user.

Level One & How It Works

For each known or suspected overdose incident, an authorized user must report four pieces of information to the level one area of ODMAP:

- Date and time of the incident
- Location of the incident or first encounter
- Whether the overdose was fatal or non-fatal
- Whether a first responder administered naloxone to the victim, and if so, how much

Level One & How It Works

Other types of information may be reported in level one by authorized users but is not required. The optional permissible categories of information include age of victim, gender of victim, suspected drug involved, additional drugs involved, if the victim was one of multiple victims, if the victim was taken to the hospital, if the incident involved a motor vehicle, and case number

ENTER LOCATION

- (•) Use My Devices Location
- ( ) Use An Address

Address (include State, City & Zipcode)

Ex: 123 Anyroad, Anyplace, CA 12345

- ( ) Use Coordinates

Latitude

Ex: 35.048230

Longitude

Ex: 176.0985405

CASE INFORMATION

Case Number

Age

Gender

Select

Primary Suspected Drug

Select

Victim Was Taken to the Hospital

Select

Additional Suspected Drug

Alcohol
Benzodiazepine
Cocaine
Crack
Fentanyl

Part of Multiple Overdose Victim Incident

Select

Motor Vehicle Involved

Select

Naloxone Administered By

Select

NON-FATAL OVERDOSES

Naloxone Administration Unknown

Naloxone Not Administered

Single Dose (2mg IN or 0.4mg IV) Naloxone Administered

Multiple Doses (>2mg IN or >0.4mg IV) Naloxone Administered

FATAL OVERDOSES

Naloxone Administration Unknown

Naloxone Not Administered

Single Dose (2mg IN or 0.4mg IV) Naloxone Administered

Multiple Doses (>2mg IN or >0.4mg IV) Naloxone Administered

Duplicate Entry Notification

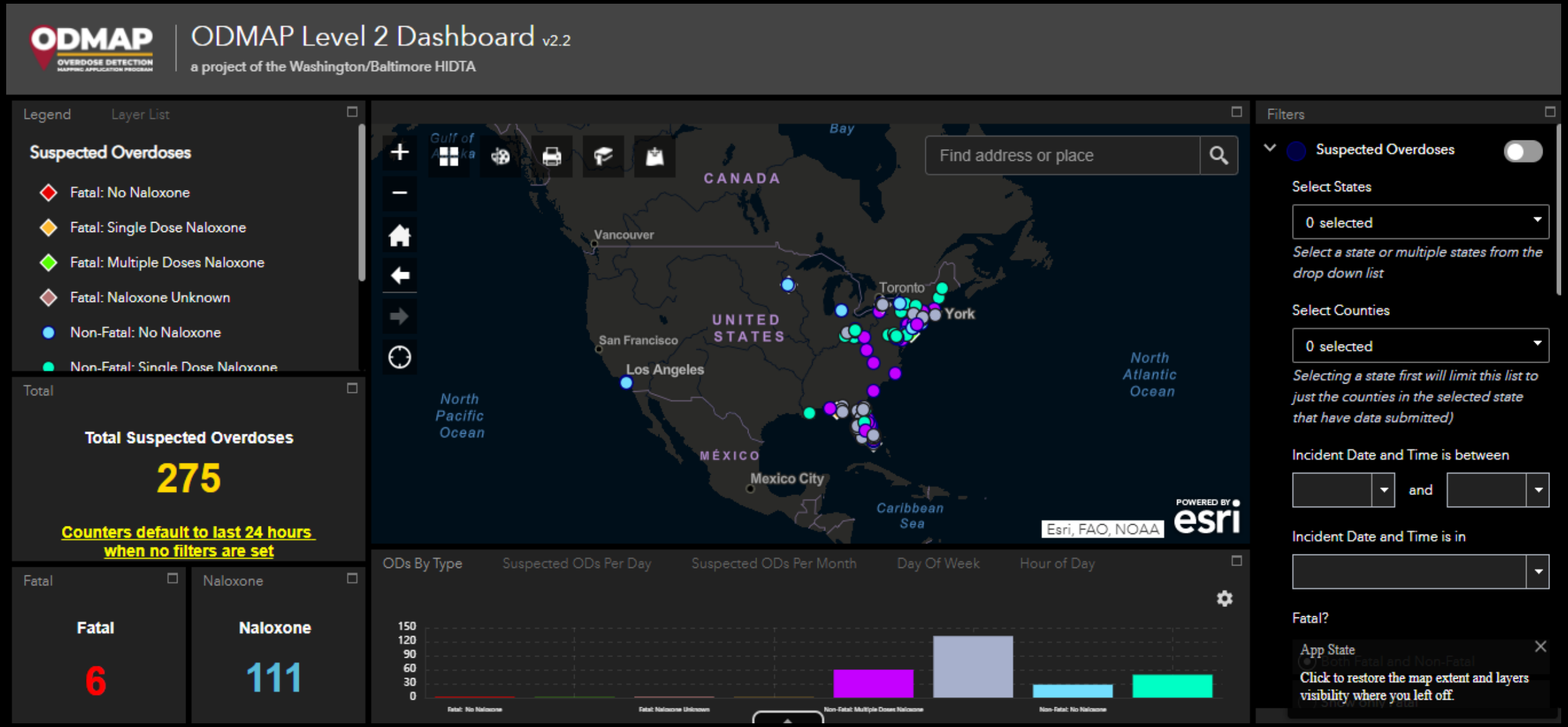
Once a user clicks on the box verifying the point is the correct one, the system will check for any existing overdoses that are within 285 feet and 1 hour of the overdose they are attempting to save

If there are any matches (the system matches on ALL records, not just the ones the user has submitted), it will return a warning message with the contact info from the other user(s) and asks if they want to still submit the point.

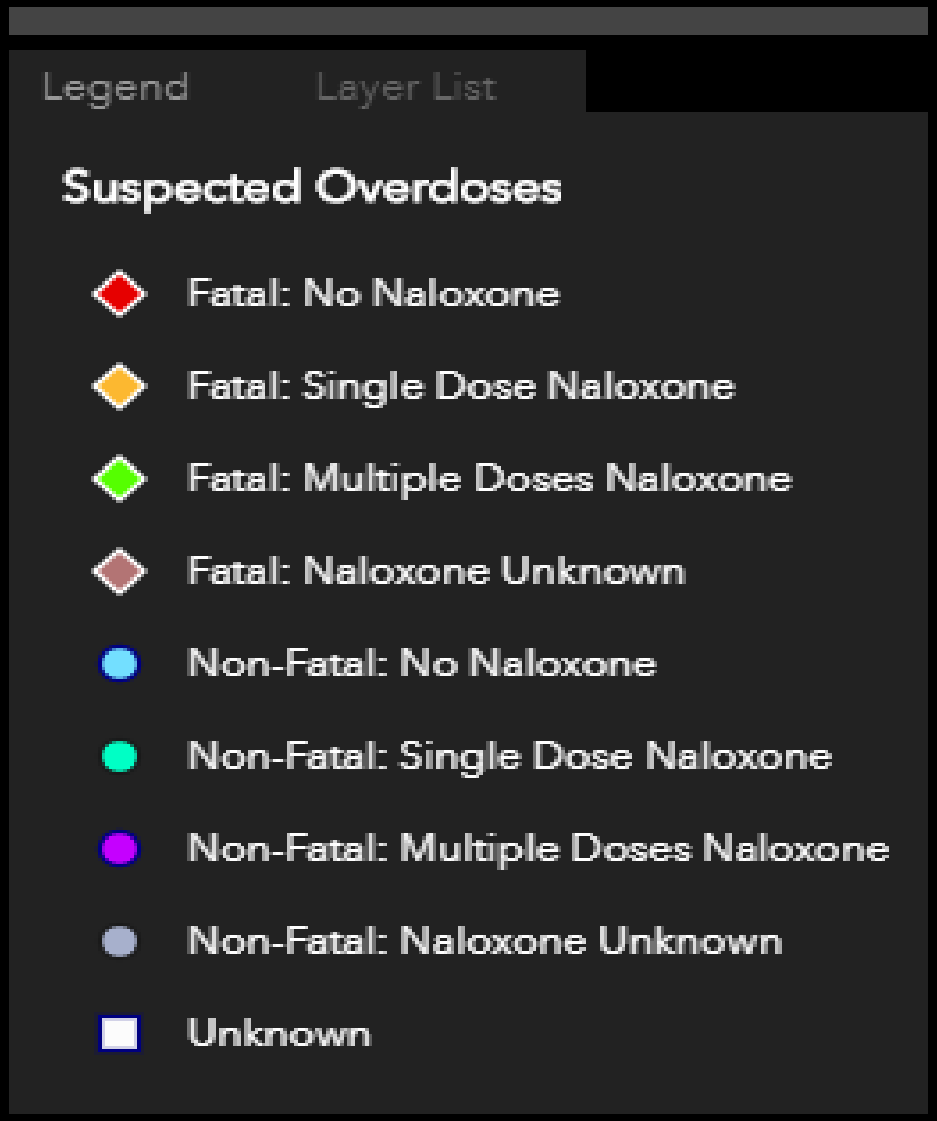
Spike Alerts

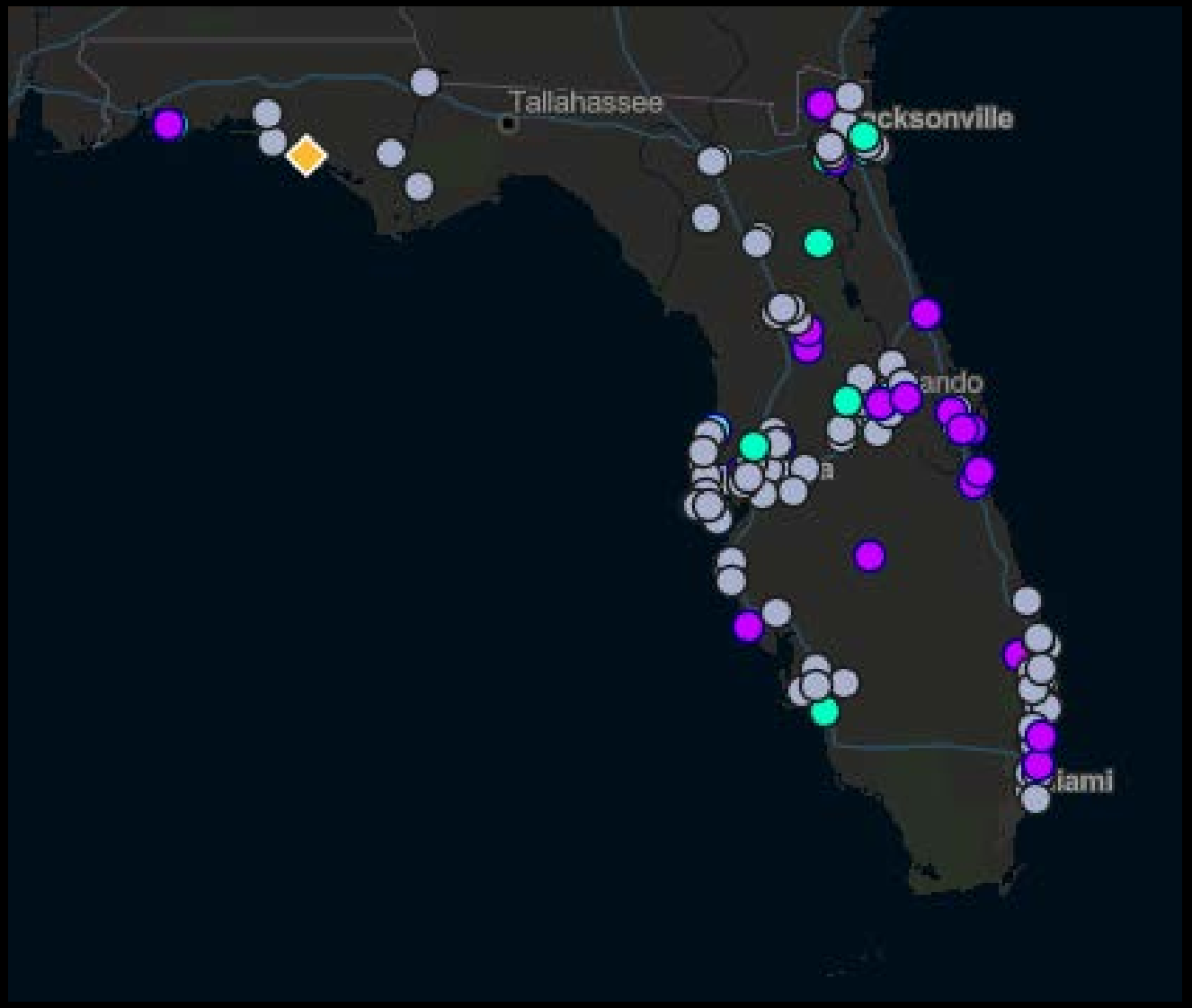
Spike alerts can be set-up to notify an agency by email, if the total overdoses in an area exceeds a pre-determined threshold within a 24-hour period. Spike alerts can be established for an agency's own county, as well as nearby or neighboring counties. By establishing spike alerts for nearby counties, the program can serve as an early warning feature; if a spike in overdoses occurs in a neighboring area, officials can anticipate a spike in their area and prepare.

Level Two and How It Works



Level Two and How It Works





Select States

0 selected

Select a state or multiple states from the drop down list

Select Counties

0 selected

Selecting a state first will limit this list to just the counties in the selected state that have data submitted)

Incident Date and Time is between

and

Incident Date and Time is in

Fatal?

- (•) Both Fatal and Non-Fatal
- ( ) Show only Fatal
- ( ) Show only Non-Fatal

Naloxone Administered?

- (•) Show All Naloxone Incident Types
- ( ) Yes
- ( ) No
- ( ) Unknown

Select ZIP Codes

0 selected

Primary Suspected Drug is any of

0 selected

Please note primary suspected drug is an optional field and is not always entered in Level 1. Suspected drugs are based on field reports and not on official toxicology.

Select Agencies

0 selected

Select Police Districts

0 selected

Available in Limited Areas Only

Is Multiple Victim Scene?

- (•) Show Multiple and Single Victim Inci...
- ( ) Yes
- ( ) No

Day Of Week is any of

- [ ] SUN
- [ ] MON
- [ ] TUE
- [ ] WED
- [ ] THUR
- [ ] FRI
- [ ] SAT

Days of the Week are based on UTC time not on your local time

Hour Of Day is any of

0 selected

Hour of Day is based on UTC timezone and not your local timezone

Benefit to Law Enforcement

- Most American jurisdictions do not share data among law enforcement, fire departments, and emergency medical services, and even fewer do so in real time. ODMAP eliminates this data-sharing shortfall by centralizing all agencies' data relating to overdoses within one platform.
- Departments can identify hotspots and assign resources based on map data. The map has a built-in spike alert notification system and data analytics, to help law enforcement identify trends over designated time periods.
- Law enforcement agencies can also view overdose information from neighboring jurisdictions, which might share a drug supply source.
- ODMAP gives public health, police, and others involved in the opioid response important information about a forthcoming overdose spike that they wouldn't have without this cross-jurisdictional comparison.

How Is ODMAP Data Protected?

ODMAP data is considered controlled unclassified information (CUI) and is released only to authorized personnel who have a need and a right to know in the performance of public safety and public health functions. ODMAP does not collect personally identifiable information (PII) or personal health information (PHI).

Assistant Special Agent in Charge Annie White
Florida Department of Law Enforcement
Office of Statewide Intelligence
Phone: 850-410-7456

Department of Health

Recent Trends in Fatal Overdoses

Jared Jashinsky, PhD

10/20/2020

Drug Policy Advisory Council Meeting

Presenter

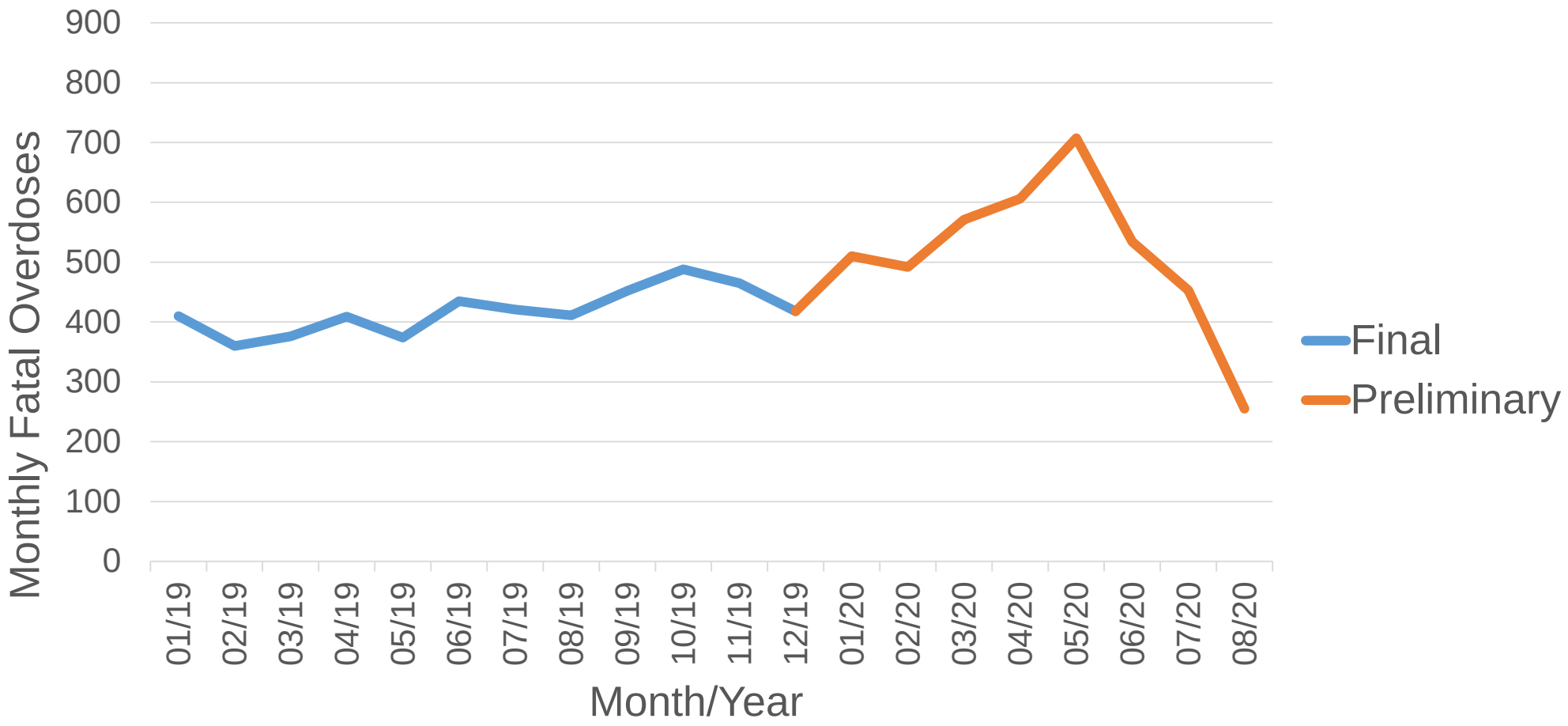
Jared Jashinsky, PhD, MPH

- Epidemiologist & Project Manager
- Bureau of Emergency Medical Oversight
- Florida Drug Overdose Surveillance and Epidemiology Team (FL-DOSE)
  - Funded by the Centers for Disease Control and Prevention's Overdose Data to Action Grant (OD2A)

Florida Fatal Overdose Trends

- Florida Department of Health (DOH) Bureau of Vital Statistics tracks all Florida deaths via ICD-10 coding
- Cases with ICD-10 codes related to drug overdoses are counted in DOH's surveillance systems
- Recent data released by DOH Bureau of Vital Statistics are incomplete

Fatal Overdoses in Florida Vital Statistics



Florida Fatal Overdose Trends

Date	Sept 1st	Oct 1st	Growth
Jan-20	499		
Feb-20	477		
Mar-20	560		
Apr-20	577		
May-20	643		
Jun-20	445		
Jul-20	233		

Monthly totals tracked beginning July 1, 2020

Florida Fatal Overdose Trends, Continued

Date	Sept 1st	Oct 1st	Growth
Jan-20	499	510	
Feb-20	477	492	
Mar-20	560	571	
Apr-20	577	606	
May-20	643	707	
Jun-20	445	534	
Jul-20	233	453	

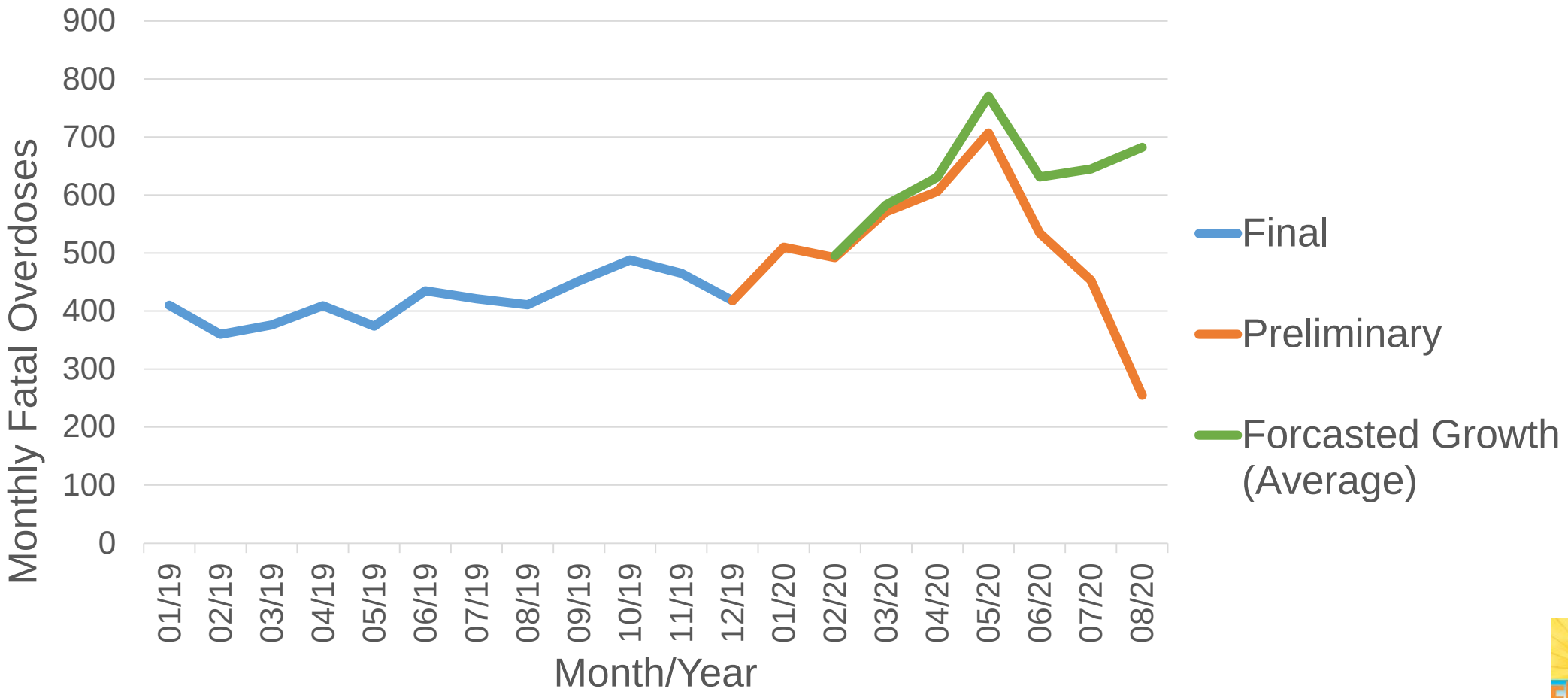
Monthly totals tracked beginning July 1, 2020

Florida Fatal Overdose Trends, Continued

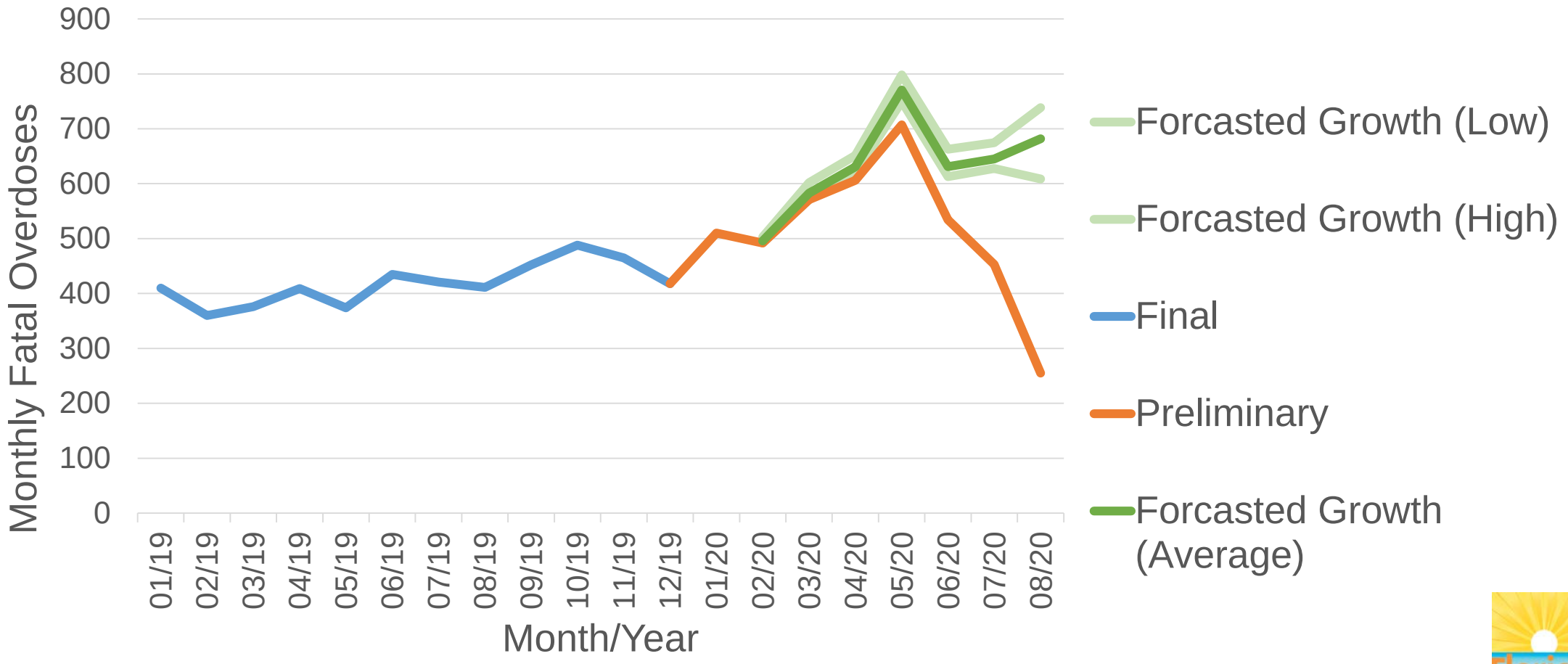
Date	Sept 1st	Oct 1st	Growth
Jan-20	499	510	2.2%
Feb-20	477	492	3.1%
Mar-20	560	571	2.0%
Apr-20	577	606	5.0%
May-20	643	707	10.0%
Jun-20	445	534	20.0%
Jul-20	233	453	94.4%

Historical % growth can be used to forecast where the preliminary data might land

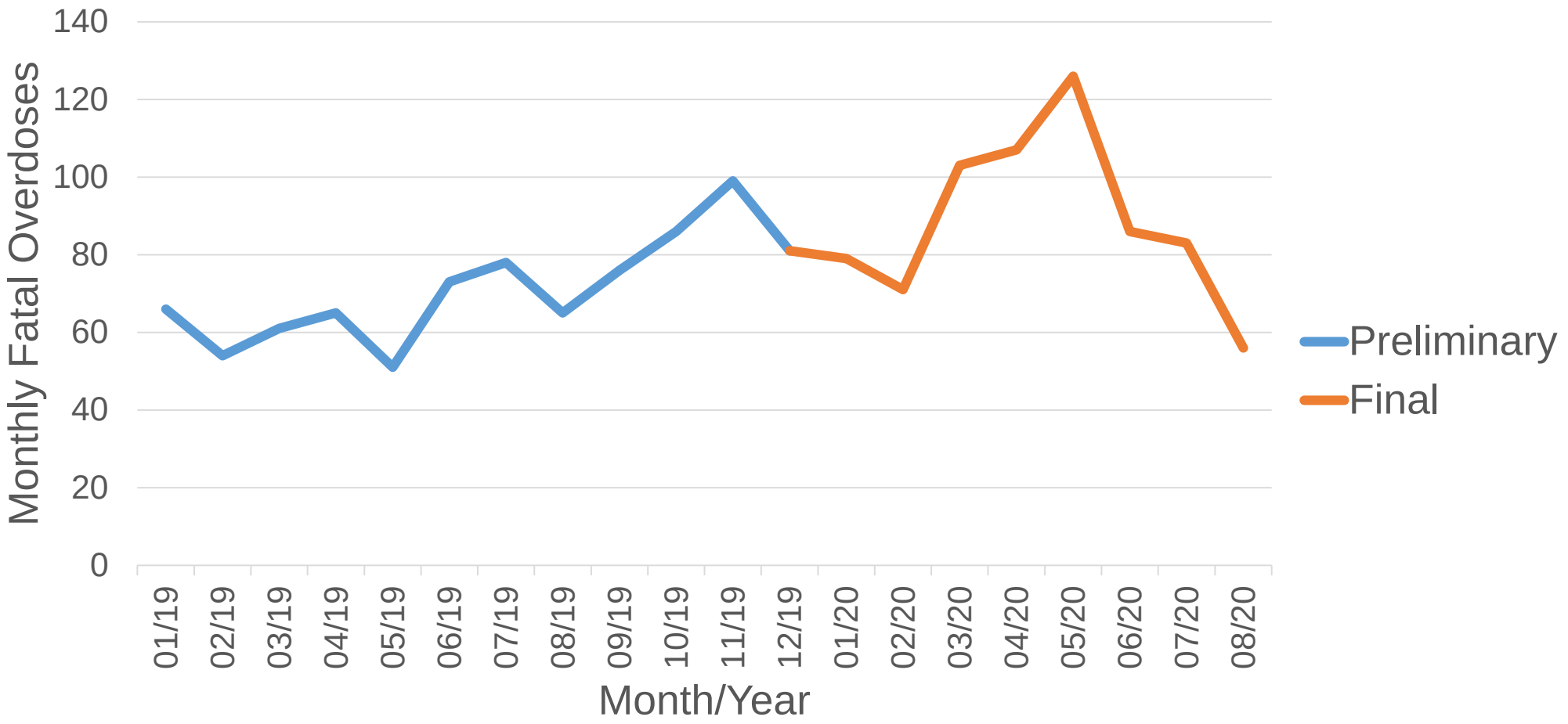
Fatal Overdoses in Florida Vital Statistics



Fatal Overdoses in Florida Vital Statistics, Continued



Fatal Overdoses in Women of Childbearing Age



Department of Health

Recent Trends in Fatal and Non-Fatal Overdoses

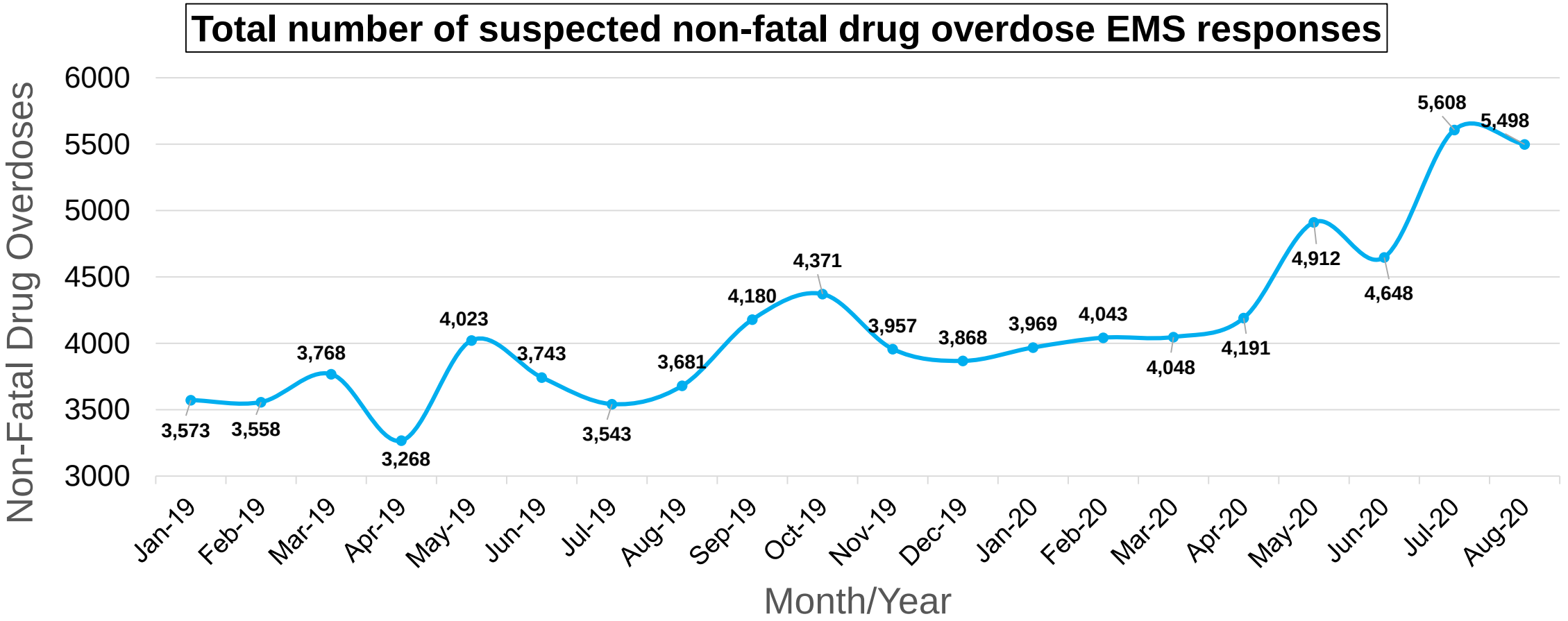
Author

Junwei Jiang, MPH
- Epidemiologist
- Bureau of Emergency Medical Oversight

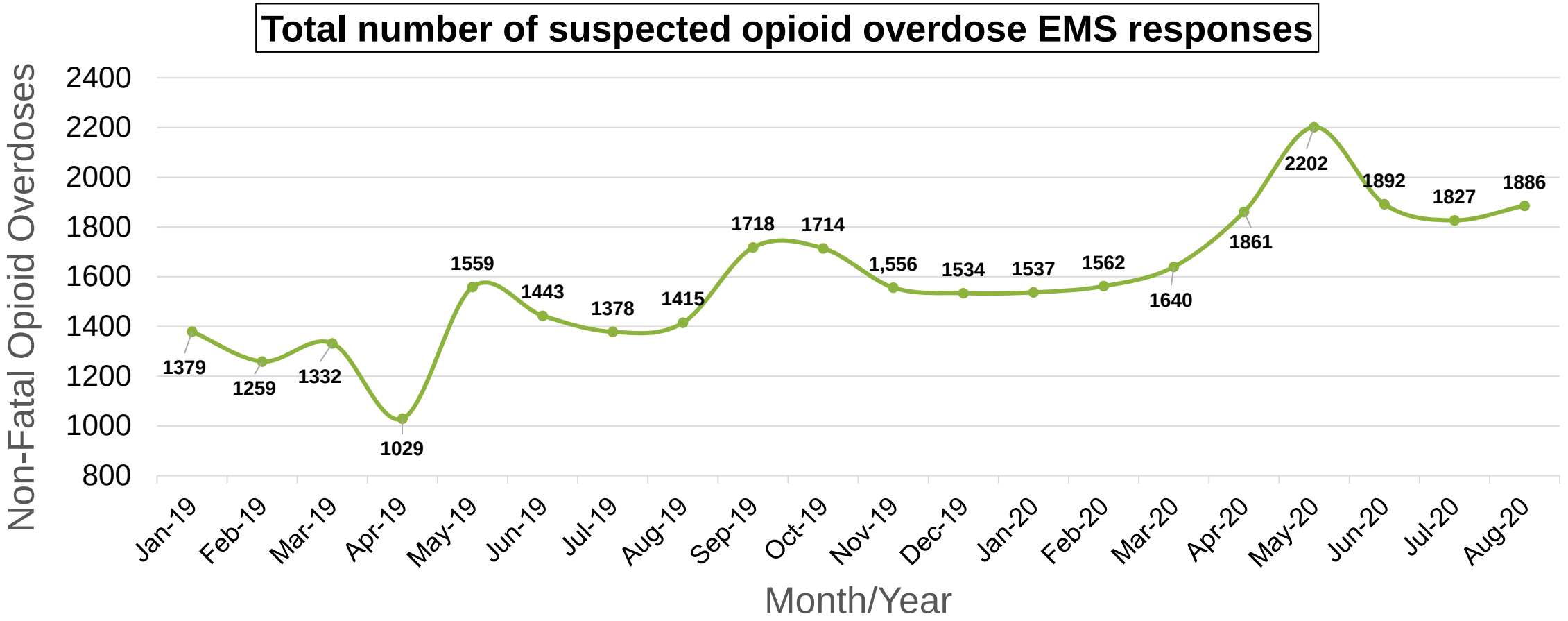
Emergency Medical Services Controlled Substance Overdose Report: Quarter 2

- Overdose data from licensed emergency medical services (EMS) through the Florida Emergency Medical Services Tracking and Reporting System (EMSTARS)
- EMS agencies participating in EMSTARS record medical diagnosis codes for all patients
- Patients with codes related to drug overdose are counted in the report

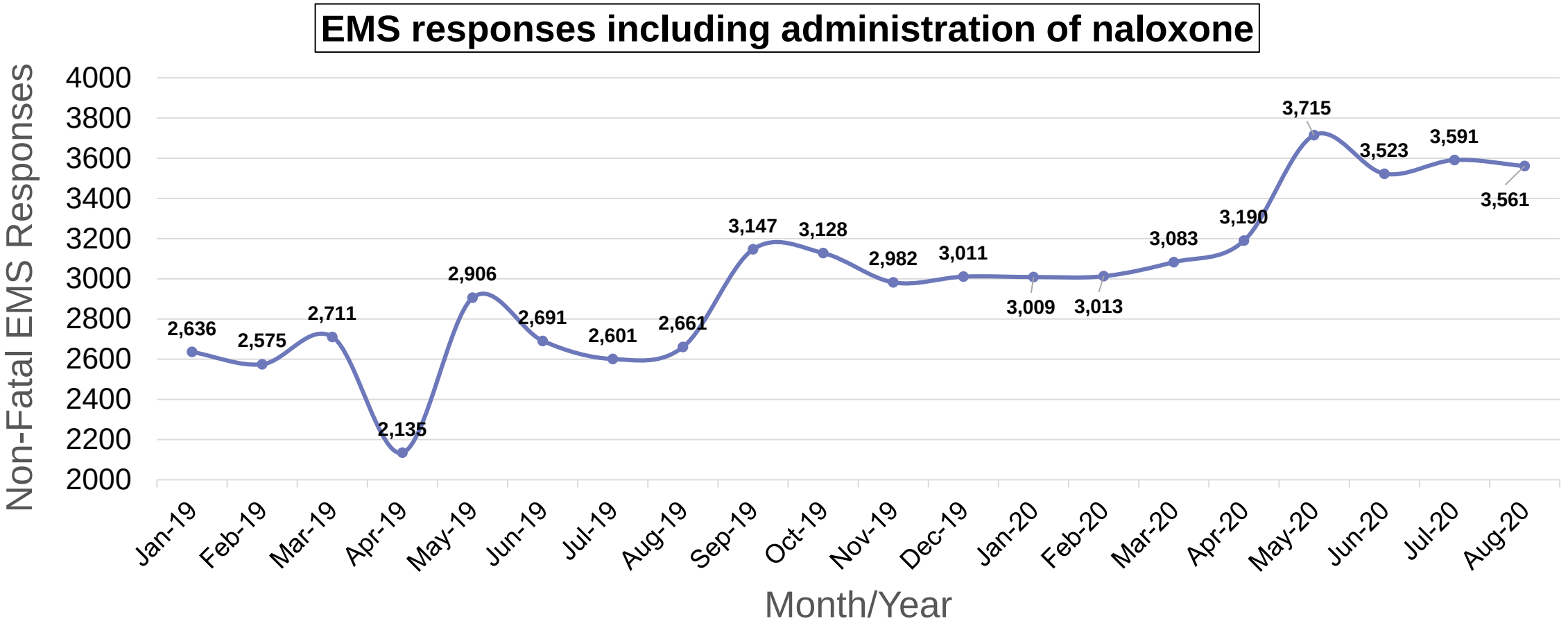
Trend – Non-Fatal Drug Overdoses



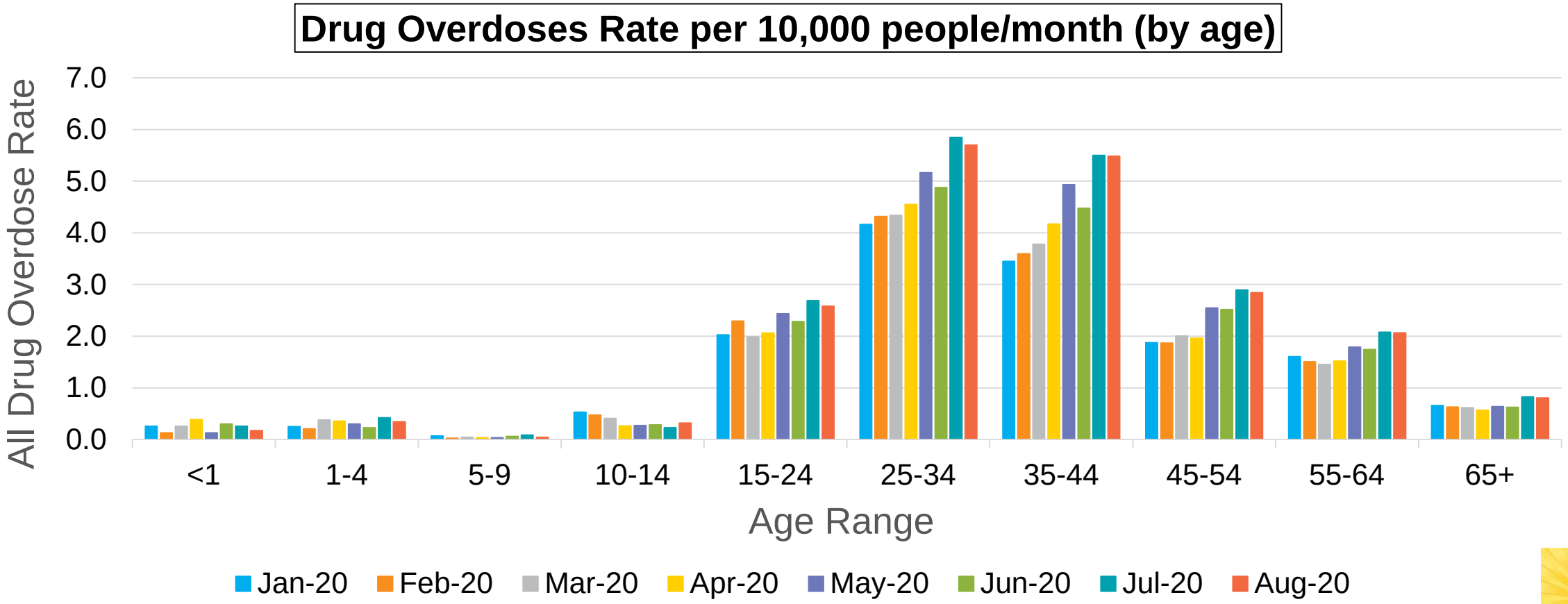
Trend – Non-Fatal Opioid Overdoses



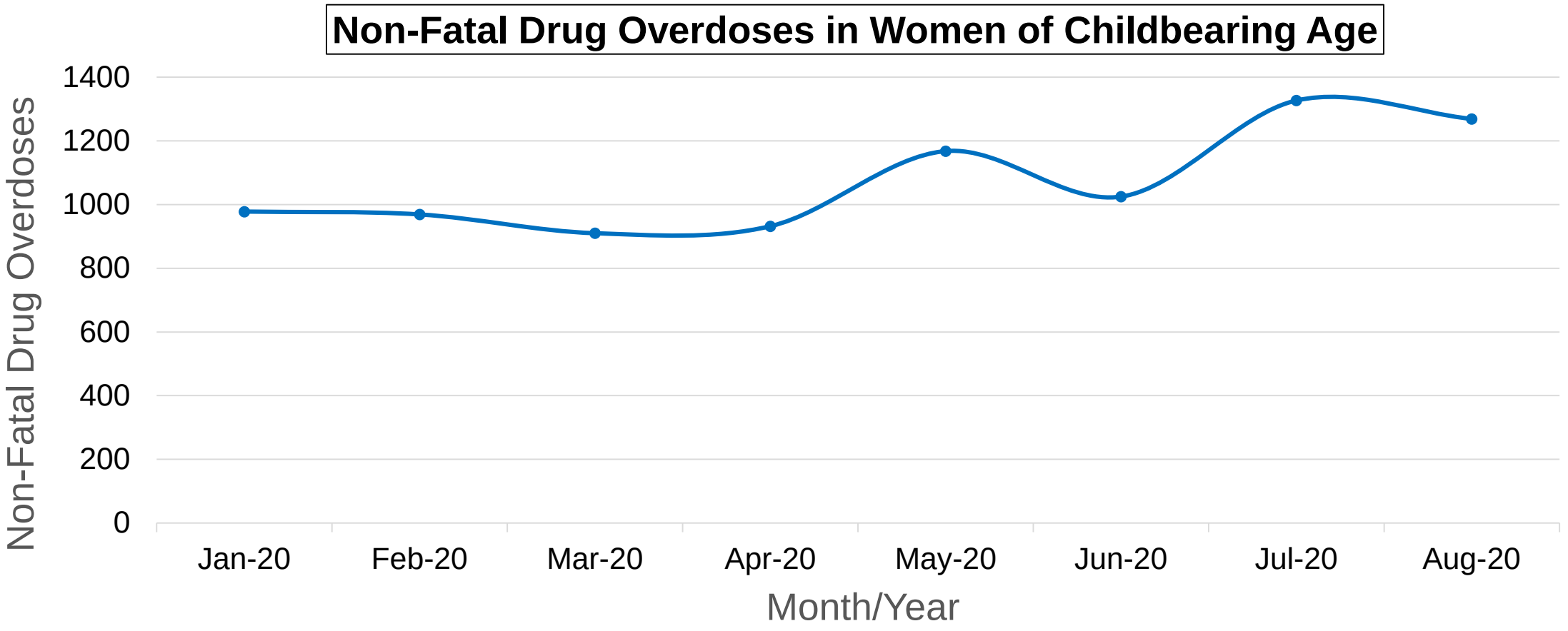
Trend – Naloxone Administration



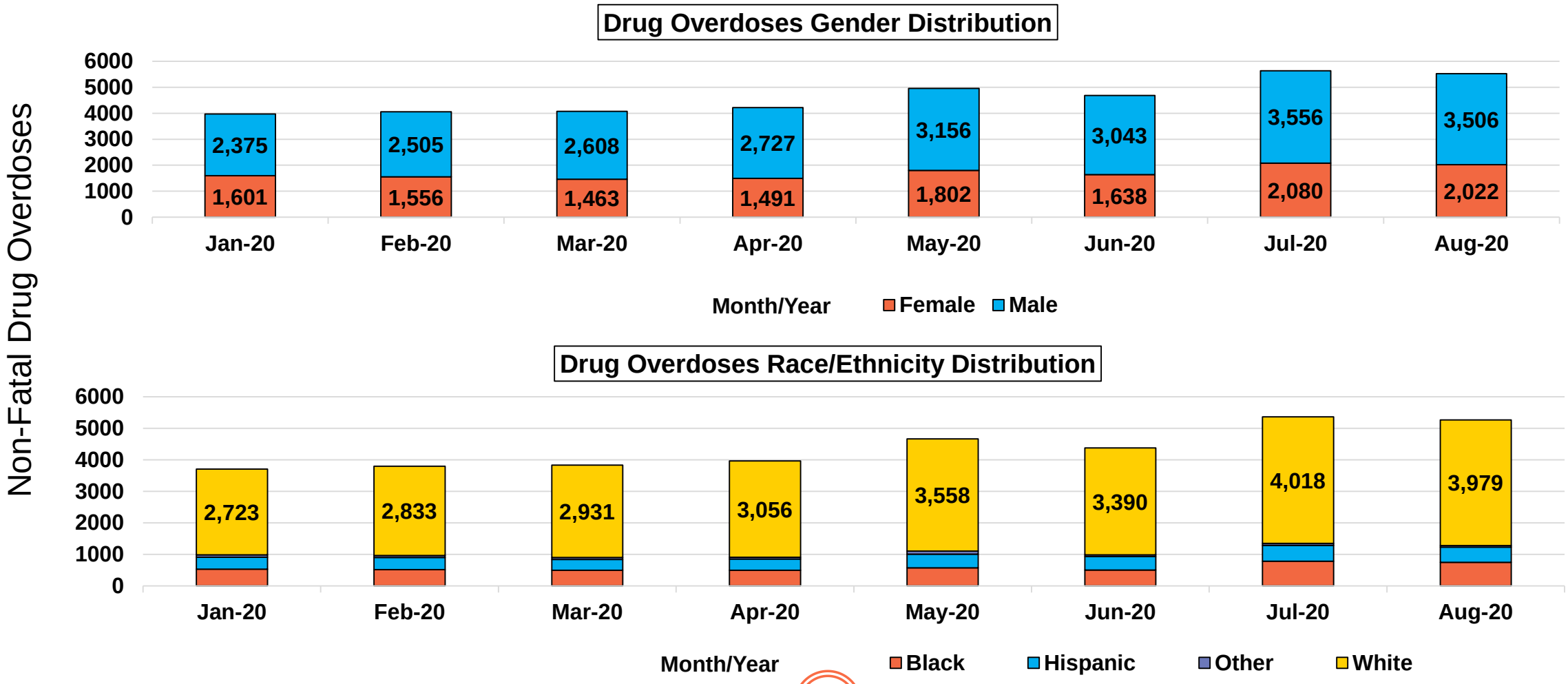
Drug Overdoses – Demographic Distribution



Drug Overdoses – Women of Childbearing Age



Drug Overdose – Demographic Distribution



Questions?

Contact Information

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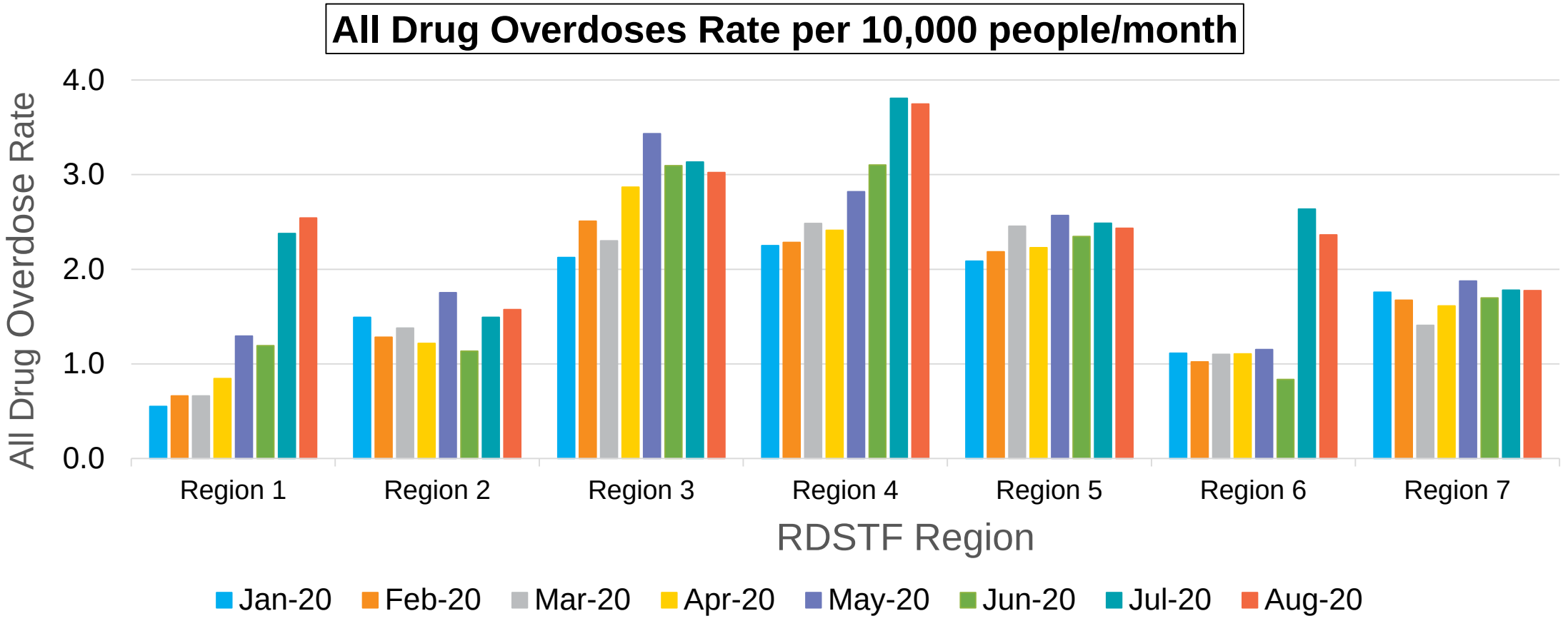
- Epidemiologist & Project Manager
- Email: Jared.Jashinsky@flhealth.gov

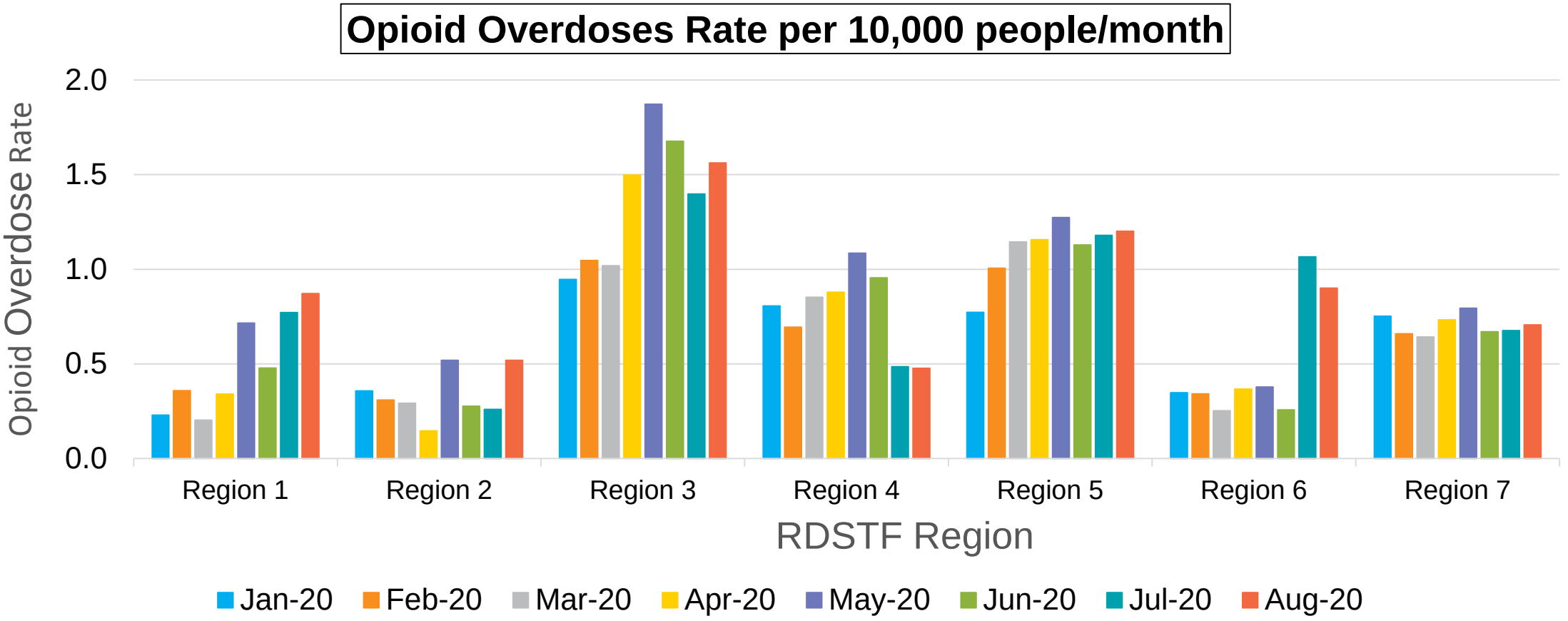
Junwei Jiang, MPH

- Epidemiologist
- Email: Junwei.Jiang@flhealth.gov

Drug Overdoses by Regions



Opioid Overdoses by Regions



Statewide Drug Policy Advisory Council
2020 Annual Report

To the Governor,

the President of the Senate,

and the Speaker of the
House of Representatives

December 1, 2020

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Statewide Drug Policy Advisory Council
Members and Designees

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  State Surgeon General

Florida Attorney General
- The Honorable Ashley Moody
- Rachel Kamoutsas
  Deputy General Counsel

Office of Planning and Budget
- Chris Spencer
  Policy Director
- Walter Liebrich
  Senior Analyst

Florida Department of Law Enforcement
- Rick Swearingen
  Commissioner
- Annie White
  Assistant Special Agent in Charge
  Office of Statewide Intelligence

Department of Children and Families
- Chad Poppell
  Secretary
- Jeffrey Cece, MS, CPM
  Office of Substance Abuse and Mental Health

Department of Corrections
- Mark Inch
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- Maggie Agerton
  Bureau Chief
  Substance Use Treatment Services

Department of Education
- Richard Corcoran
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- Nichole Wilder
  Director, Office of Healthy Schools

Florida Highway Safety and Motor Vehicles
- Terry Rhodes
  Executive Director
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  Director

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- Tracy Shelby PhD
  Director Mental Health and Substance Abuse Services

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- COL John L. Steele
  Director of Military Support,
  Florida National Guard

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- Vacant

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- Aaron Gerson
  Office of the State Courts Administrator

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  Heartdance Foundation, Inc.
- Doug Leonardo, LCSW
  Sr. VP Operations and Development
  Central and North
  Chrysalis Health
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- Kimberly K. Spence
  CEO Keaton Corrections
- Roaya Tyson
  COO Gracepoint
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  Executive Director
  Sunshine State Association of Christian Schools

Staff Liaison
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Acronyms Used in this Report

ACGME:	Accreditation Council for Graduate Medical Education
AHCA	Agency for Health Care Administration
API	Application Programming Interface
CAPT	Center for Application of Prevention Technologies
CDC	Centers for Disease Control and Prevention
CDP	Consumer Driven Product
CHD	County Health Department
CNPPA	Child Nicotine Poisoning Prevention Act
DCF	Department of Children and Families
DEA	Drug Enforcement Agency
DEN	Drug Epidemiology Network
DOE	Department of Educations
DOH	Department of Health
DTO	Drug Trafficking Organization
ED	Emergency Department
EMS	Emergency Medical Services
EMSTARS	EMS Tracking and Reporting System
FBHA	Florida Behavioral Health Association
FADAA	Florida Alcohol and Drug Abuse Association
FDA	Food and Drug Administration
FDC	Florida Department of Corrections
FDLE	Florida Department of Law Enforcement
FLHealthCHARTS	Florida Health Community Health Assessment Resource Tool Set
FPQC	Florida Perinatal Quality Collaborative
FQHC	Federally Qualified Health Center
FSAM	Florida Society of Addiction Medicine
FYSAS	Florida Youth Substance Abuse Survey
HEROS	Helping Emergency Responders Obtain Support

HIDTA	High Intensity Drug Trafficking Areas
HMO	Health Maintenance Organization
IDEA	Infectious Disease Elimination Act
MAT	Medication Assisted Therapy
MH	Mental Health
MHPAEA	Mental Health Parity and Addiction Equity Act
NAS	Neonatal Abstinence Syndrome
NIDA	National Institute on Drug Abuse
NSDUH	National Survey on Drug Use and Health
OD	Opioid Overdose
OD2A	Overdose Data to Action
ODMAP	Overdose Detection Mapping Application Program
ONDCP	Office of National Drug Control Policy
OUD	Opioid Use Disorder
PDMP	Prescription Drug Monitoring Program
PPO	Preferred Provider Organization
RCO	Recovery Community Organization
ROSC	Recovery Oriented System of Care
SAMHSA	Substance Abuse and Mental Health Services Administration
SAPT	Substance Abuse Prevention and Treatment
SBIRT	Screening, Brief Intervention and Referral to Treatment
SEOW	State Epidemiological Outcomes Workgroup
SEP	Syringe Exchange Program
SMMC	Statewide Medicaid Managed Care
SOR	State Opioid Response
STR	State Targeted Response
SUD	Substance Use Disorder

Message from the State Surgeon General Scott A. Rivkees, MD

Summary of 2020 Meetings
Statewide Drug Policy Advisory Council

As required by section 397.333(4)(b), Florida Statutes, Florida's Statewide Drug Policy Advisory Council's 2020 Annual Report analyzes the problem of substance abuse in the state and provides updates on recommendations to the Governor and Legislature for consideration.

On January 28, 2020 the Council heard a presentation regarding the Overdose Data to Action (OD2A) grant. In September 2019, the Florida Department of Health (DOH) state office and the Broward, Duval, and Palm Beach County Health Departments were awarded grant funding through the OD2A grant from the Centers for Disease Control and Prevention (CDC). This three-year grant provides $58.8 million for surveillance strategies to improve the collection and timely dissemination of actionable overdose data, and prevention strategies implemented at the local level that are informed by more timely data streams. The state also allocated funding to support five Florida Epidemic Intelligence Service (EIS) opioid fellows assigned to county health departments. There was also a presentation from DOH-Duval, one for the three counties that received OD2A funding. Duval had more than 550 opioid deaths in 2017. Duval is working with local partners like Drug Free Duval, Premier Biotech, LSF Health systems. The Council also received a legislative update on relevant bills. Some of the bills discussed included SB 298 Prior Authorization for Opioid Alternatives, HB 743 Nonopioid Alternatives, and HB 339 Drug Trafficking Offenses. Council members provided individual updates.

On April 21, 2020 the Council was scheduled to meet. However, due to COVID-19, this meeting was postponed.

On July 21, 2020 the Council heard a presentation on "Community Partnerships to Reduce Neonatal Abstinence Syndrome & Improve Maternal Recovery from Opioid Use Disorder." This focused on the work of the Maternal Opioid Recovery Efforts (MORE) initiative and the "Urgent Maternal Mortality Message." This work is important because drug-related deaths are now the leading cause of death to mothers during pregnancy or within one year afterwards in Florida. Ms. Reeves reported that 23 hospitals participate in the MORE initiative, which represents 35% of births in the state. The goal is to link these hospitals with community partners, as they all touch substance-affected mothers, infants, and families. There was a presentation on "Addressing Behavioral Health through Community Health Improvement Planning" which focused on community health improvement planning (CHIP) process, reviewing behavioral health activities addressed in CHIPs, and recognizing the impact of COVID-19 on health improvement planning. As of March 2020, 88% of Florida counties address behavioral health within their CHIPs. Common behavioral health themes in CHIPs include: Education/Awareness (substance use, opioid prescribing practices, trauma), Trainings (Mental Health First Aid, Naloxone administration), Access to behavioral health services (transportation, telehealth), and Screening/Care Coordination. There was also a presentation on "Florida Medicaid Coverage of Telemedicine & Telehealth." Florida Medicaid serves approximately 4 million of Florida's most vulnerable citizens, including children, pregnant women, the aged and the disabled. The Statewide Medicaid Managed Care (SMMC) program was implemented in 2013-2014 and updated in 2019-2020. The three components of the SMMC program are: Managed Medical Assistance (MMA) – acute care like doctor visits, etc., Long-Term Care (LTC) – care given in a nursing home or assisted living facility, and Dental. There are many benefits of telemedicine for patients. These include expanded access and after-hours care, remote monitoring and management for chronic conditions, reduced hospital readmissions, reduced waiting time to see a practitioner, reduced travel time and cost and better access to specialists. Additional benefits for those with behavioral health disorders, including SUD are that there is more expedient

access to specialists or other providers not otherwise available, for example crisis intervention, evaluation to determine diagnosis or treatment recommendation and medication management. There also was a presentation on the Overdose Data to Action (OD2A) grant. The grant supports awareness and education informed by media campaigns and community and school-based collaborations for prevention. In addition, the grant includes Florida's Drug Overdose Surveillance and Epidemiology (FL-DOSE) and supports increased Medication Assisted Treatment and community paramedicine for patient follow-up. The Council members shared individual updates and discussed the status of the 2020 Annual Report.

The Council members requested a meeting to focus fully on the 2020 Annual Report. On September 8, 2020, the Council met and reviewed the recommendations from the 2019 DPAC Annual Report. Members discussed which recommendations needed to be revised or deleted. There was also a discussion about new recommendations that may be added to the report. Several Council members were asked to make revisions and provide that information to DOH. The draft 2020 DPAC Annual Report will be edited to and a revised version will be provided to the Council members before the next meeting.

HOLD FOR SUMMARY of October 20, 2020 meeting

2020 Recommendations
Statewide Drug Policy Advisory Council

1. Establish the Florida Office of Drug Control.

2. State agencies and commercial health plans provided service delivery flexibilities to respond to the challenges related to the delivery of mental health and substance use disorder care during the COVID-19 pandemic. It is recommended that the state agencies, commercial health plans, and other private payors permanently adopt these flexibilities, specifically:
   - Waiving prior authorization requirements and services limits (frequency, duration and scope) for all behavioral health services (including targeted case management).
   - Maintaining payment parity for telehealth services by reimbursing services provided via telemedicine at the same rate as face-to-face encounters.
   - Expanding coverage of telehealth services to include telephone communications, only when rendered by licensed psychiatrists and other physicians, physician extenders, and licensed behavioral health practitioners.
   - Requiring managed care plans to waive limits on medically necessary services when additional services will maintain the health and safety of an enrollee diagnosed with COVID-19 or when it is necessary to maintain an enrollee safely in their home.
   - Using audio-only services when video capability is not available, and services can only be provided telephonically, which should be thoroughly documented.

3. Develop and implement a substance-use prevention strategy designed to reduce drug use among youth (ages 12-17). The strategy should focus on (1) the deployment of a unified anti-drug messaging campaign, (2) increase/maintain substance use prevention efforts by securing/sustaining front-end prevention funding, and (3) by expanding state partnerships with anti-drug coalitions, educational institutions, law enforcement, and other members of the 12 Community Sectors. Collectively, these efforts will enhance substance-use prevention efforts, allow for the unified employment of limited resources towards a common goal, and reduce the impact of substance use among youth by 10% and Marijuana use by 3%.

4. Implement a substance-use prevention strategy designed to reduce drug use among youth (ages 12-17). The program focuses on evidence-based and/or evidence-informed prevention strategies proven to reduce substance use, while also increasing youth resiliency, coping strategies, positive mental health, and responsible decision-making. DCF should lead, in collaboration with DOH and DOE, a statewide initiative designed to increase and coordinate prevention efforts across Florida through a partnership with coalitions, community substance use disorder (SUD) providers, school districts, faith-based groups, and business entities. The end goal is to better link existing prevention education programs with Florida's educators, and reduce substance use and abuse among Florida's youth.

5. Develop and implement a comprehensive e-cigarette/e-liquid prevention strategy designed to reduce vaping among youth (ages 11-17) and limit the negative health effects associated with e-cigarettes, e-liquids, and/or other vaping materials.

6. Screening, Brief Intervention, and Referral to Treatment (SBIRT) is a comprehensive, integrated, public health approach to the delivery of early intervention and treatment services for persons with substance use disorders, as well as those at-risk of developing those

disorders[1]. To evaluate what evidence-based practices are presently in use in Florida to identify problematic alcohol or drug behavior in the primary care setting and to promote the implementation of SBIRT in our state, the following is recommended:

- The Department of Health lead an initiative to review the extent SBIRT and/or other evidence-based practices are utilized in primary care settings across Florida to identify and intervene with patients showing symptoms of problematic alcohol and/or drug use
- AHCA should report to the legislature on the availability of Medicaid coverage for SBIRT, and if not available, what changes to the state's Medicaid plan, billing and coding practices would need to be modified or changed to implement SBIRT

7. When filling prescriptions for controlled substances, strongly encourage pharmacies to educate consumers on safe medication storage and disposal procedures. Establish a media campaign to educate consumers on reason for safe use, safe storage and safe disposal and the location of safe disposal boxes in each community.
8. Expanding naloxone availability among people who use drugs and their peers through hospital emergency departments and floor units (with little to no paperwork, and no separate trip to the pharmacy), EMS/Fire Rescue naloxone leave-behind programs, county health departments, and Federally Qualified Health Centers.
9. Encourage county commissions to establish Syringe Exchange Programs (SEP) to distribute naloxone to people who use drugs and prevent new cases of HIV and Hepatitis C.
10. Encourage the continued establishment of warm handoff programs from hospital Emergency Departments (Ed's) to community Opioid Use Disorder (OUD) treatment providers to address opioid overdoses; issue naloxone to overdose patients before they leave the ED; and have AHCA report on the extent warm hand-off protocols have been implemented in ED's across the state.
11. Expand additional fellowship and residency programs for physicians to obtain a specialty in addiction medicine with a goal of increasing physicians with an addiction medicine specialty.
12. Pass model legislation that will align Florida law with the federal Mental Health Parity and Addiction Equity Act (MHPAEA) and require all state health agencies, health plans and commercial insurance to report annually on the implementation of the parity act in Florida. The reports should be transparent and available to inform the public.
13. State health agencies, health plans and commercial insurers should remove prior authorization requirements for evidence-based Medication Assisted Treatment to allow for use of medications such as buprenorphine and naltrexone especially where such an action would assist pregnant, post-partum and neo-natal populations.
14. Promote legislation that adds the Secretary of AHCA and the Commissioner of the Office of Insurance Regulation as members to the Statewide Drug Policy Advisory Council.
15. Continue the statewide Recovery Oriented System of Care (ROSC) initiative designed to promote and enhance recovery efforts in Florida and support the continued development of recovery community organizations (RCOs) and a statewide RCO that helps link community initiatives.
16. Develop and implement a stigma reduction campaign designed to reduce the shame associated with substance use disorder and other mental illness/injuries. Messaging should increase the awareness of medically assisted treatment options, reduce the stigma associated with addiction, and inform the public of the many benefits that come with obtaining psychological and/or counseling services from a licensed professional.

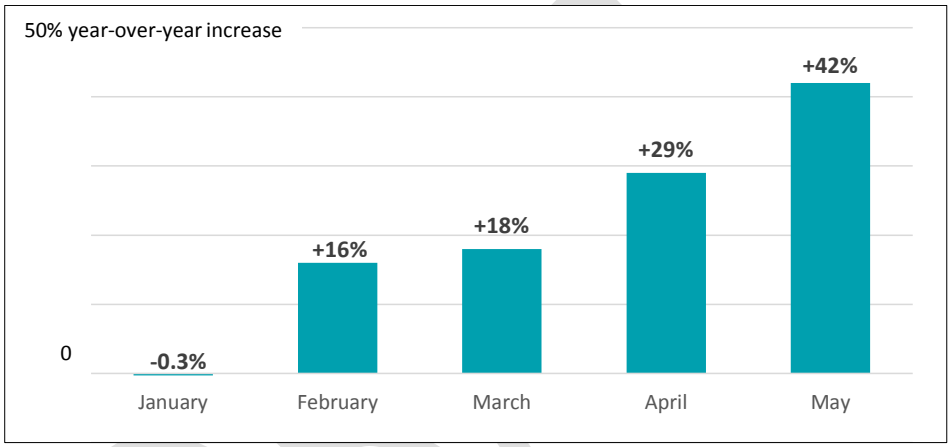
17. Evaluate the impact of SB 1120 on agency background screening requirements related to the eligibility of individuals with lived experience/peers attempting to enter the workforce; continue efforts to reduce the administrative burden of the background screening and exemption process; promote consistency among state agencies related to the background screening exemption process; ensure an individual with lived experience is part of the exemption review panel; and have AHCA, DCF, and Department of Corrections to provide an annual report on the number of individuals that applied for an exemption, actual timeframes for the process and number approved/disapproved with reasons why.
18. Create a statewide dashboard of substance abuse data measures that are readily available to policy makers and the public and can be used to monitor trends and identify emerging threats.
19. Encourage counties and municipalities to implement the ODMAP system in locations and agencies that do not participate in real-time overdose tracking. Through wider utilization, law enforcement and non-EMSTARS fire departments can track suspected overdose activity throughout all 67 counties. Agencies can utilize information obtained through ODMAP to identify high risk areas, equip personnel for increased overdose activity, and to warn neighboring agencies of sudden overdose activity within their counties and/or suspected transit routes.

Summary of Findings

Introduction

Florida and the nation face ongoing threats like the opioid epidemic while dealing with the new challenge of COVID-19 infections. Initial data is indicating that our communities are experiencing an increase in drug abuse during this time of COVID-19. Data from the Overdose Detection Mapping Application Program (ODMAP) indicates that nationally, drug overdoses in March 2020 increased 18 percent from ~~last~~ the previous year. In April 2020, the increase was 29 percent and in May 2020 the increase was 42 percent.[2]

Figure A. Overdoes rose up to 42% per month during the pandemic, compared to the same months in 2019



Note: Percent growth reference the 1,201 agencies reporting to ODMAP by January 2019.[3]

The Drugs Identified in Deceased Persons by Florida Medical Examiners 2018 Annual Report indicated that during 2018, there were 5,576 opioid-related deaths reported in Florida. This is 602 less than the previous year, which represents a 10 percent decrease. Regarding the percentage of surveyed Florida youth who vaped nicotine (e-cigarettes, vape pens, JUUL), in their lifetime and past 30 days, there has been a decrease among high school students among lifetime use from 17.4% (2019) to 15.6% (2020).[4] These continuing risks provide the need for ongoing collaboration at the local, state and national level.

Need for Services and Receipt of Services among the General Population

The National Survey on Drug Use and Health (NSDUH) provides important estimates of substance use, substance use disorders, and other mental illnesses at the national, state and sub-state levels. The NSDUH is an annual survey of the civilian, noninstitutionalized population ages 12 and older, using face-to-face, computer-assisted interviews. The NSDUH collects information from residents of households, persons in non-institutional group quarters (e.g., shelters, rooming/boarding houses, college dormitories, migratory worker camps and halfway houses), and civilians living on military bases. Persons *excluded* from the survey include persons with no fixed household address (e.g., homeless and/or transient persons not in shelters), active-duty military personnel, and residents of institutional group quarters, such as

correctional facilities, nursing homes, mental health institutions, and long-term hospitals. State- and sub-state level estimates are usually based on 2-year or 3-year averages to enhance precision. There is usually at least a 2-year lag between the date when the data are collected, and the state-level estimates are published.

According to the most recently published, Florida-specific estimates from the 2017-2018 NSDUH, approximately 4.3% of children ages 12-17 and 6.6% of adults ages 18 and older experienced a substance use disorder in the past year.[5] The majority of individuals with substance use disorders do not receive treatment, including approximately 92% of individuals with alcohol use disorders and 87% of individuals with an illicit drug use disorder.[6] Importantly, the vast majority (96%) of individuals classified by the NSDUH as needing, but not receiving, substance use treatment also report that they did not feel they needed it. Only about 1% felt they needed treatment and made an effort to get it.[7]

The State Epidemiological Outcomes Workgroup (SEOW)

Florida's State Epidemiological Outcomes Workgroup (SEOW) plays several roles in state, regional, and community drug-related morbidity and mortality surveillance. Membership (n = 18) consists of epidemiologists and individuals who are knowledgeable about substance use issues including prevention, intervention, and treatment. Participating entities include DCF, FDLE–Medical Examiners Commission, DOH, AHCA, and the Department of Education. In addition, the SEOW's composition includes a representative from each of the Drug Epidemiology Networks (DENs) that operate across the state of Florida. Through the Partnerships for Success grant, eight counties were selected for DEN development and implementation including Broward, Duval, Franklin, Hillsborough, Manatee, Palm Beach, Walton and Washington. Both the SEOW and individual DENs produce annual reports that are reviewed by DCF and incorporated into strategic initiatives as appropriate. ~~Additionally~~These reports indicate that~~,~~ fentanyl and fentanyl-analogs continue to drive overdoses, including deaths involving cocaine. Polydrug toxicity is still the most common pattern observed among deaths caused by drugs. Rural counties report an increase in heroin use and the emergence of fentanyl. An updated SEOW Report will be available at the end of November 2020 at the following location: https://www.myflfamilies.com/service-programs/samh/publications/.

Primary Prevention of Substance Use: Trends from the Florida Youth Substance Abuse Survey (FYSAS)

Substance use among youth in Florida continues to trend downward. Among middle and high school students in Florida, between 2008 and 2020, the prevalence of lifetime alcohol use decreased from 53 percent to 35 percent and the past-30-day prevalence of alcohol use decreased from 30 percent to 15 percent. Regarding binge drinking by students (in the past two weeks), the prevalence decreased from 15 percent to 7 percent. High schoolers are asked if they ever woke up after a night of drinking and did not remember the things they did or the places they went. Between 2014 and 2020, the lifetime prevalence of "blacking out" among high schoolers decreased from 19 percent to 14 percent.

Regarding marijuana use, the prevalence of lifetime and past 30-day marijuana use among middle and high school students is essentially flat between 2008 and 2020. Lifetime prevalence decreased from 21 percent to 20 percent, and past 30-day prevalence was approximately 11 percent in both 2008 and 2020. Looking more specifically at *vaping* marijuana, approximately 16 percent of middle and high school students reported vaping marijuana at least once in their lifetime~~s~~ in 2020, and approximately 7 percent did so in the past 30-days. Regarding the use of any illicit drug other than marijuana, the lifetime prevalence decreased from 21 percent to 14 percent between 2008 and 2020. The prevalence of the current (past 30-day) use of any illicit drugs other than marijuana decreased from 9 percent to 6 percent.[8]

Opioid Epidemic

The Drugs Identified in Deceased Persons by Florida Medical Examiners 2018 Annual Report indicated that there were 5,576 opioid-related deaths reported (which averages more than 15 deaths per day). This is 602 less than the previous year, which represents a 10 percent decrease. Overall, 6,701 individuals died with one or more prescription drugs in their system, which is a 3 percent decrease. The drugs were identified as either the cause of death or merely present in the decedent. These drugs may have also been mixed with illicit drugs and/or alcohol. The drugs that caused the most deaths were fentanyl (2,348), cocaine (1,644), benzodiazepines (1,136, including 664 alprazolam deaths), morphine (1,102), fentanyl analogs (874), ethyl alcohol (866) and heroin (806).[9]

Evidence-Based Responses to the State of Emergency Due to the Epidemic of Opioid-Related Deaths

DCF has taken the lead regarding the deployment of evidence-based resources to prevent opioid-related deaths. State and federal funds, including the Substance Abuse and Mental Health Services Administration's (SAMHSA) State Targeted Response (STR) Grant, State Opioid Response (SOR), and Substance Abuse Prevention and Treatment (SAPT) Block Grant, are directed at the most effective interventions. According to a model published in the *American Journal of Public Health* in 2018, the interventions that will reduce the greatest number of opioid overdose deaths over 5 to 10 years in the U.S. are identified in the table below.[10] All of these interventions were recommended by Florida's Drug Policy Advisory Council in previous Annual Reports. An update on each of them follows.

Figure B. Evidence-Based Interventions to Reduce Opioid Deaths Nationwide Over 5 to 10 Years[11]

Intervention	Estimated Number of Opioid Deaths Prevented Over 5 Years	Estimated Number of Opioid Deaths Prevented Over 10 Years
Expansion of Naloxone Availability	10,200	21,200
Expanded Access to Medication-Assisted Treatment	4,900	12,500
Expansion of Needle Exchange Programs	2,700	5,900
Reduced Prescribing for Acute Pain	1,900	8,000
Expansion of Prescription Drug Disposal Programs	300	2,400

Expansion of Naloxone Availability

Research indicates that naloxone distribution can reduce opioid overdose rates by as much as 11% to 46%.[12] It is conservatively estimated that one heroin overdose death is prevented for every 164 naloxone kits distributed.[13] Additionally, studies suggest that increasing health awareness through training programs that accompany naloxone distribution may reduce the use of opioids and increases users' desire to seek addiction treatment.[14] DCF initiated an Overdose Prevention Program in August 2016. The program has been funded through a variety of sources, including General Revenue, the SAPT Block Grant, the STR grant, and the SOR grant.

Organizations enrolled in the program distribute free, take-home naloxone kits directly to people who use drugs or are otherwise at risk of experiencing an overdose and to their loved ones who may witness an overdose. There are currently 149 organizations participating in the program, including substance use and mental health treatment facilities, hospital EDs, harm reduction programs, peer recovery organizations, homeless service providers, FQHCs and other community-based organizations. Since the start of the program, over 104,000 naloxone kits have been distributed from participating providers and over 5,000 overdose reversals have been reported. In order to take the fight against opioid deaths to the next level, DCF and DPAC endeavor to increase the number of hospital ED sites participating in the naloxone distribution program and the number of emergency medical services (EMS)/Fire naloxone leave-behind programs in operation. In FY 18-19, there were 10 ED sites participating in the program. In FY 19-20, 15 additional EDs were enrolled, bringing the current total to 25 EDs. In FY 18-19, there were only 5 EMS/Fire naloxone leave-behind programs in operation. In FY 19-20, an additional 5 programs were enrolled, bringing the current total up to 10 leave-behind programs.

In response to the nationwide opioid epidemic, funding has been made available through DOH for emergency opioid antagonists. DOH has established the Helping Emergency Responders Obtain Support (HEROS) Program for the purpose of acquiring emergency opioid antagonists for agencies that employ emergency responders. Between July 1, 2018 and June 30, 2020 HEROS provided approximately 305,095 doses of naloxone to approximately 291 agencies that employ licensed emergency responders. DOH has spent $9.7 Million or 97% of the $10,000,000 ($5,000,000 allocation each Fiscal Year) allocation. In addition, DOH has provided naloxone to agencies that employ licensed emergency responders located in 58 of Florida's 67 counties. Since July 1, 2020, DOH has accelerated the process to ship naloxone to Emergency Responder Agencies by establishing monthly rounds. The goal is to review applications during each round, determine successful applicants, and place orders for naloxone based on available funding and applicants meeting HEROS Program requirements the first week of the next month. The HEROS program will complete six Application Rounds between July 1, 2020 to December 31, 2020.

Expanded Access to Medication-Assisted Treatment (MAT)

Methadone and buprenorphine maintenance are effective ways to decrease the illicit use of opioids and reduce the risk of overdose. Research shows that the risk of fatal overdoses is at least cut in half when individuals are enrolled in agonist (methadone or buprenorphine) maintenance treatment for opioid dependence.[15] Expansion of access to MAT continues through DCF's State Opioid Response (SOR) grant, funded by SAMHSA through 2022 as described in the table below:

Figure C. Department of Children and Families - State Opioid Response (SOR) grant

Grant	Project Period	Annual Award Amounts
State Opioid Response (SOR) 1	9/30/2018 through 9/29/2020 No Cost Extension Approved	$76,186,527 (Year 1) $50,056,851 (Year 2)
State Opioid Response (SOR) 2	9/30/2020 through 9/29/2020	$100,170,437 (Year 1) $100,170,437 (Year 2)

Additionally, in 2017 there were only 65 authorized buprenorphine prescribers in DCF's network of publicly-funded treatment providers. Now there are 108 prescribers. For clients who have already completed opioid detoxification, long-acting injectable naltrexone (Vivitrol) is another U.S. Food and Drug Administration (FDA)-approved medication that helps prevent relapse. The number of Vivitrol prescribers in DCF's network quadrupled, increasing from only 11 prescribers in early 2017 up to 45 in 2020~~today~~. Under SOR 1, nearly 12,000 individuals received MAT (including 3,722 served with methadone, 5,523 served with buprenorphine, and 770 served with Vivitrol).

Expansion of Syringe Exchange Programs (SEPs)

Syringe exchange programs are front line public health interventions that effectively reduce the spread of HIV and hepatitis C by reducing the sharing, reuse, and circulation of syringes and injecting equipment.[16] Research shows that every dollar spent on syringe exchange programs saves at least three dollars in treatment costs averted.[17] Syringe exchange programs provide a range of comprehensive healthcare services including testing and counseling for various infectious diseases, overdose prevention, and vaccinations. Syringe exchange programs also facilitate recovery by linking people with substance use disorders to treatment services.[18] Florida's first legal syringe exchange program–called the IDEA Exchange–opened in Miami-Dade County on December 1, 2016. The program provides compassionate and nonjudgmental services and empowers people who use drugs to make healthier and safer choices regardless of whether they are ready to stop using drugs. From July 1, 2019 to June 30, 2020, 710 participants were served. During this time, 302 participants were tested for HIV and 264 participants were tested for hepatitis C. In addition, 71 participants entered drug counseling or treatment.[19]

Senate Bill 366 from 2019 permits county commissions to authorize the establishment of additional syringe exchange programs through county ordinances.[20] The law requires county commissioners to take several steps including enlisting the help of county health departments to provide ongoing advice and recommendations regarding program operation. For additional information please visit: http://www.floridahealth.gov/programs-and-services/idea/exchange.html.

Reduce Prescribing for Acute Pain

DCF, DOH, and a variety of community-based partners, including anti-drug coalitions throughout the state, have worked for many years on educational campaigns and initiatives designed to encourage safe prescribing practices and reduce the volume of unused opioids available for theft, diversion, and abuse. These efforts recently culminated with the enactment of new legislation (House Bill 21), which went into effect in Florida on July 1, 2018, that limits prescriptions for acute pain to a 3-day supply (with the potential for an extension up to a maximum of 7 days with additional documentation).[21] Preliminary research shows that the law substantially reduced opioid prescriptions. Six months after implementation of the law, the proportion of patients receiving opioid prescriptions for common outpatient surgical procedures decreased by 21%, and the average total opioid dose prescribed decreased by 64 Morphine Milligram Equivalents.[22] The proportion of patients receiving opioid prescriptions for longer than a 3-day supply decreased by 68%. The authors of this study concluded that, "The legislation should significantly decrease the amount of unused opioid pills potentially available for diversion and abuse."[23] Updates from the Department of Health also reflect decreases in the number of days' supply of controlled substances dispensed to patients and the Morphine Milligram Equivalents per prescription.[24]

Overdose Data to Action (OD2A) Grant

In September 2019, the Florida Department of Health (DOH) state office and the Broward, Duval, and Palm Beach County Health Departments were awarded grant funding through the Overdose Data to Action (OD2A) grant from the Centers for Disease Control and Prevention (CDC). This three-year grant provides $58.8 million for (A) surveillance strategies to improve the collection and timely dissemination of actionable overdose data, and (B) prevention strategies implemented at the local level that are informed by more timely data streams. During year 1 of the grant, the state health office allocated $2.2 million in mini-grants to 14 counties to assist local communities experiencing high impacts from the overdose epidemic. All 14 counties received funding to accomplish core surveillance and prevention activities of OD2A, including support for awareness campaigns to highlight the risks of opioid use disorder and enhancements to surveillance systems and data collection efforts to assist with monitoring overdose trends, understanding which populations are most at risk to prioritize resources, and evaluating ways to distribute resources. Five counties also received additional funding to implement evidence-based curriculums in public schools (Brevard, Manatee, Nassau, Pasco, and Sarasota) and two counties received additional funding to pilot community paramedicine projects to improve patient follow-up among individuals most at risk of overdosing (Clay and Marion). The state also allocated funding to support five Florida Epidemic Intelligence Service (EIS) opioid fellows assigned to county health departments.

Opioid, Maternal Health, and Neonatal Abstinence Syndrome Initiative (OMNI)

Florida was one of five states to be selected by the CDC and Association of State and Territorial Health Officers (ASTHO) for a site placement of a Maternal & Neonatal Opioid Prevention Coordinator to support the Opioid, Maternal Health, and Neonatal Abstinence Syndrome Initiative (OMNI). The coordinator's role was specifically designed to support the Maternal Opioid Recovery Effort (MORE) project by identifying and drawing together stakeholders in communities with high rates of NAS to help connect resources, identify system barriers, and share insights, gaps, and lessons learned with the broader Florida Neonatal Abstinence Syndrome (NAS) stakeholder group.

In response to the growing opioid crisis and the resulting increase in NAS, the Department of Health partnered with the Florida Perinatal Quality Collaborative (FPQC) at the University of South Florida, to implement the Maternal Opioid Recovery Effort (MORE) Initiative. The purpose of the initiative is to increase the number of pregnant women with Opioid Use Disorder (OUD) who receive treatment during pregnancy and maintain treatment after delivery. Florida's Pregnancy Associated Mortality Review committee released an Urgent Maternal Mortality Message this year, emphasizing that drug-related deaths are the leading cause of death to mothers during pregnancy or within one year afterwards in 2017, accounting for 1 in 4 of these deaths in Florida.

Hospitals face significant challenges addressing issues contributing to these high rates of maternal death, and there are several opportunities for improving interventions, including reducing the risk of overdose, reducing the impact/severity of NAS by getting women into treatment as early as possible, and addressing other system barriers, such as the availability of universal Screening, Brief Intervention, and Referral to Treatment (SBIRT) at each point of interaction with women with OUD. To be successful in each of these areas, it is essential to help hospitals connect with the system of care in their community in order to develop a cohesive approach to identification, referral, and treatment.

A shortage of MAT providers still presents barriers to care for women in communities throughout Florida. In ~~our~~ community visits, the shortage of MAT, behavioral health, and inpatient bed

services for pregnant and postpartum women was the single biggest challenge reported, with 15 out of 18 communities citing this as a barrier. Most counties also identified fragmented care, poor systems for referral, and outdated data systems as a barrier to care.

Although AHCA successfully removed the pre-authorization requirement for MAT, some communities are still having barriers with this as the policy change is not fully understood by payers or pharmacists. DOH will ~~also~~ work with AHCA to continue to educate pharmacists and payers about changes regarding MAT prescribing.

Finally, the majority of counties had concerns about the acceptability of treatment. Even when women were identified as needing treatment for OUD, they often refused treatment due to fear of repercussions, stigmas, and the overarching fear of losing custody of their infant. The initiative worked with women in recovery to develop a short video that can be used ~~for~~ encouraging women who ~~need~~ seek needed care. DOH is working with the DCF and Healthy Start to develop a framework and messaging for Plans of Safe Care (POSC) that will help improve POSCs across the state, improve reporting, and train providers on how to use motivational interviewing to engage women and encourage them to start the treatment and recovery process.[25]

Florida Prescription Drug Monitoring Program

The Florida Prescription Drug Monitoring Program (PDMP) provides data related to controlled substance prescriptions in the state. From July 1, 2018, to June 30, 2019, there were 29,935,352 controlled substance prescriptions dispensed to Florida patients, a 9.8 percent decline from the previous year. In addition, 4.95 million people in Florida were prescribed one or more controlled substances, a decrease of 10.3 percent. Alprazolam, oxycodone SA and hydrocodone SA were ranked the top three most commonly dispensed controlled substances for the fourth year in a row, together representing 37.4 percent of the total controlled substances dispensed from July 1, 2018, to June 30, 2019. Drugs with the largest year-to-year decreases in dispensing were hydrocodone SA (-19.7 percent), tramadol SA (-13.1 percent) and phentermine (-13.1 percent).[26]

Behavioral Health Workforce

Florida is experiencing a shortage of health care professionals to meet the growing needs of our state. For behavioral health professionals, the shortage is reaching near critical levels. Supply and demand for behavioral health practitioners are affected by factors including: population growth, aging of Florida's population, expansion of insurance coverage, changes in health care reimbursement, retirement, attrition, reduction in stigma to seek care, the opioid epidemic, low reimbursement rates, and geographic location of the health care workforce. While need grows, the workforce remains static at best. Meanwhile, Florida's aging population (65 and older) is expected to exceed any other age group by 2030 causing a dynamic shift in future behavioral health care needs. A recent addition to the behavioral health workforce has been the utilization of peers with lived experience, however, many of these individuals are unable to work due to background screening requirements and the bureaucratic burden of seeking an exemption. In addition, the medical workforce with a specialty in addiction medicine is inadequate to meet the growing need.[27]

Florida Statewide Task Force on Opioid Abuse

The Drug Policy Advisory Council wishes to thank the Florida Statewide Task Force on Opioid Abuse for the recommendations contained in their 2020 report. The Task Force report was extensive and multifaceted, and it identified a variety of promising interventions. The Task Force also highlighted a set of priority recommendations, and the Drug Policy Advisory Council would like to echo and amplify the Task Force's call to increase access to medication-assisted

treatment and associated psychosocial support services, including peer-based recovery support services and naloxone distribution. Research reviewed and summarized by this Council shows that this approach is most effective way to reduce opioid-related deaths. The Task Force is also commended for highlighting the importance of screening and brief interventions, warm-handoffs, mobile medication teams, telehealth, inmate reentry planning, improved data sharing, and school-based prevention programs, among other worthy suggestions which complement the conclusions of this Council. Additional information is available at this location: https://DoseofRealityFL.com.

Law Enforcement Perspective

Florida law enforcement remains engaged in the current effort to reduce the availability of heroin, fentanyl and fentanyl analogs and other substances contributing to opioid involved overdose and overdose deaths. Efforts to reduce deaths involving specific opioids (heroin and fentanyl analogs) appear to be trending slowly in a positive direction, based on indicators used to gauge illicit drug activities and the drug abuse environment.

According to the *Drugs Identified in Deceased Persons by Florida Medical Examiners* 2019 Interim Report, opioid involved deaths increased by 2 percent over the same period (January through June) in 2018; opioid-caused deaths also increased (6%). Deaths involving heroin, fentanyl and fentanyl analogs also increased. The most significant increase were deaths involving fentanyl which increased 26 percent; and deaths caused by fentanyl increased 28 percent. Decreases were seen within the prescription opioid category; deaths caused by hydrocodone decreased 1 percent and deaths caused by oxycodone decreased by 16 percent.

A comparison of FDLE laboratory submissions between the 2018 and 2019 revealed increases in heroin, fentanyl, morphine and buprenorphine. Prescription opioids, hydrocodone, hydromorphone and oxycodone decreased. Consistent with the trend noted in last year's data, were increased laboratory submissions of methamphetamine. Increases, in both the occurrence of methamphetamine in the deceased, and in the cause of death in the deceased were also noted in the interim report of the Florida Medical Examiners.

In September 2019, Florida was one of eight states named among the recipients of grant funding from the Bureau of Justice Assistance. The grant proposal outlined an initiative to expand the use of Naloxone (Narcan) by law enforcement responders who are first on the scene of a suspected opioid overdose. The proposal also outlined a plan to share overdose data from law enforcement and Emergency Medical Services (EMS) in Florida with community health and mental health services in an effort to mitigate opioid overdose deaths in Florida through overdose follow-up activities. As a result of the collaborative project, suspected overdose surveillance data is available in near real-time, supporting public safety and public health efforts to mobilize an immediate response to a sudden increase, or spike in overdose events. In July 2020, FDLE was awarded approximately $2.2 million in federal grant funds through the Community Oriented Policing Services (COPS) Program to augment investigations related to the distribution of illicit opioids including heroin, fentanyl, Carfentanil and other fentanyl derivatives; as well as the illegal distribution of diverted prescription opioids. Both of these grant funded opportunities will assist law enforcement in creating inroads for collaboration with the public health sector (prevention/treatment) as well as curbing the availability of opioids (supply reduction).

While the opioid crisis continues, the availability of other illicit drugs also impacts the state to varying degrees across regions. In particular, methamphetamine is gaining a foothold in many areas of the state. This is not the home-brew methamphetamine that has long been an issue in certain regions. The availability of a manufactured methamphetamine from super labs south of the United States/Mexico border has increased substantially over the past few years. This availability has become more widespread across the state and is not merely a regional problem.

The geographical size and diverse population of Florida has resulted in diverse drug problems across the state.

Two important national issues in 2019/2020 relative to the impact the supply and as a result, the price of some illicit drugs. First, conditions at the border; with increased security and scrutiny, the volume of drugs successfully making it across the border may be reduced, at least until cartels make adaptations to counter actions by border security agents. A reduced supply can often result in higher drug prices for the consumer. Second, the Coronavirus lockdown may also impact the ability to move contraband (drugs/drug proceeds) in either direction across the border. Both of these issues may provide opportunities for enhanced interdiction activities. Progress continues in combatting illegal drug activities throughout Florida. The opioid issue continues to be the priority problem. However, impacts of widespread use of many other dangerous drugs will require vigilance from the law enforcement community, in partnership with other stakeholder communities.

Statewide Drug Policy Advisory Council
Completed Recommendations from Previous Annual Reports

1. Modernize medical examiner data systems to reduce the wait time to obtain and produce invaluable drug-related death information.

DOH, Bureau of Vital Statistics is seeking to improve the timeliness and quality of drug overdose information on death records and the transfer of this information between systems. Florida will develop a pilot between two Medical Examiners (ME) districts for the collection and transfer of relevant drug information from the toxicology lab (University of Florida), to the Medical Examiners Case Management Systems (CMS) and then transfer data to DOH, Bureau of Vital Statistics Electronic Death Registration system (EDR) system. Then the data will go to the Medical Examiner Commission and the National Center for Health Statistics (NCHS). The goal of this effort is to concentrate on improving the time it takes for the data to get back to the CMS and have the data uploaded electronically through an Application Programming Interface (API), thereby saving considerable time from using paper/fax/pdf reports and the ME's re-keying data into the CMS.

2020 Recommendations

1. Establish the Florida Office of Drug Control.

The Drug Policy Advisory Council supports Governor Ron DeSantis' decision to reestablish the Florida Office of Drug Control. The legislature should re-establish the Office in statute and provide the required resources to employ a Director and support staff to implement the work of the Florida Office of Drug Control.

Due to the fact that addiction tears at the fiber of communities across the state, it is imperative that various levels of government at the federal, state, county, and local level work together with non-governmental entities and stakeholders to address this problem. A multidisciplinary approach is necessary to address this priority and to ensure the correct balance between awareness, prevention, treatment, law enforcement, legislative priorities, and policy.

Creation of a state Office of Drug Control is a proven strategy that results in a coordinated effort across all statewide entities to promote drug control strategies, support interdiction efforts, and provide leadership in ensuring prevention, treatment, and recovery supports are appropriately coordinated and funded. The Director and staff serve under the jurisdiction of the Governor and are responsible for all matters related to the research, coordination, and execution of programs related to alcohol and drug control. Typical duties of such an office include:

- Development and implementation of a strategic plan to reduce the prevalence of alcohol and substance use and abuse in Florida.
- Annually submit to the Governor, President of the Senate and Speaker of the House of Representatives a report on the effectiveness of state policies and coordinated state efforts to address alcohol and substance abuse and addiction; the effectiveness of illegal drug interdiction efforts; the promotion of healthy, drug free communities; and the progress of executive agencies in implementing initiatives outlined in the strategic plan.
- Review existing research on effective intervention, prevention, treatment, and recovery strategies and use this information to promote substantive policy.
- Monitor data trends related to use, abuse, supply, drug crimes, overdoses, prevention, treatment, and recovery.
- Manage a statewide dashboard of alcohol and substance use data that is readily available to policy makers and the public and can be used to forecast trends and threats.
- Issue policy recommendations to executive branch agencies that will result in greater coordination and collaboration related to resource utilization and service linkage.
- Coordinate media and other public information campaigns to: inform on the dangers of alcohol and substance abuse; promote healthy drug free living; respond to emergencies such as the opioid/overdose epidemic; promote prevention; and highlight the benefits of treatment and recovery support services

The Office of National Drug Control Policy (ONDCP) is a model for this type of initiative. By Congressional authorization the Office each year shall set forth a comprehensive plan for the year to reduce illicit drug use and the consequences of such use by promoting prevention, early intervention, treatment, and recovery support for individuals with substance abuse disorders.

2. State agencies and commercial health plans provided service delivery flexibilities to respond to the challenges related to the delivery of mental health and substance use disorder care during the COVID-19 pandemic. It is recommended that the state agencies, commercial health plans, and other private payors permanently adopt these flexibilities, specifically:

- **Waiving prior authorization requirements and services limits (frequency, duration and scope) for all behavioral health services (including targeted case management).**
- **Maintaining payment parity for telehealth services by reimbursing services provided via telemedicine at the same rate as face-to-face encounters.**
- **Expanding coverage of telehealth services to include telephone communications, only when rendered by licensed psychiatrists and other physicians, physician extenders, and licensed behavioral health practitioners.**
- **Requiring managed care plans to waive limits on medically necessary services when additional services will maintain the health and safety of an enrollee diagnosed with COVID-19 or when it is necessary to maintain an enrollee safely in their home.**
- **Using audio-only services when video capability is not available, and services can only be provided telephonically, which should be thoroughly documented.**

These flexibilities resulted in continued care, addressed transportation concerns, and allowed access to care that was not ~~access not~~ previously available. The pandemic has been traumatic and has impacted our collective sense of well-being.[28] This trauma will be long lasting for children, adults, and families~~,~~ and medical providers are also experiencing a significant~~an~~ increase in ~~the numbers of~~ individuals seeking care and a higher acuity in ~~the~~patients ~~individuals~~ presenting for treatment that will continue well beyond the emergency period. These individuals requir~~eing~~ their managed care plans to waive limits on medically necessary services when ~~additional~~ these treatments/ ~~-~~services will maintain the health and safety of an enrollee diagnosed with COVID-19, or when it is necessary to maintain an enrollee safely in their home.

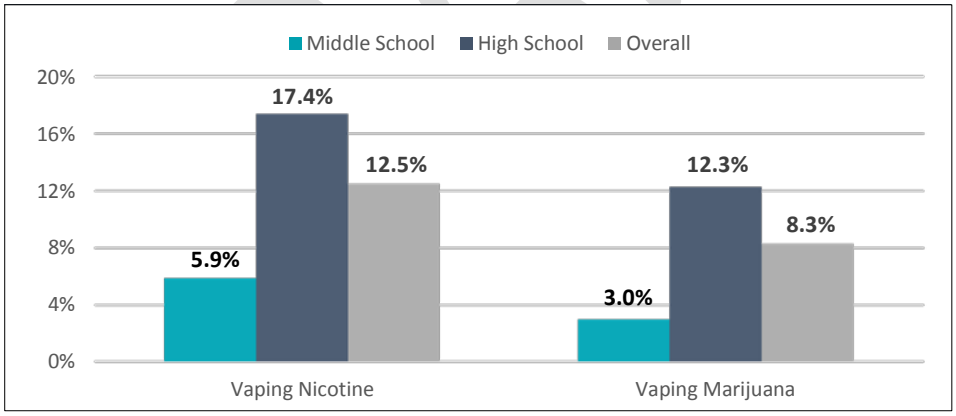
The COVID-19 pandemic has had a significant impact on the delivery of mental health and substance use disorder prevention, treatment, and recovery services across Florida and the country, challenging traditional delivery systems. Assisting this effort was the innovation and waiver of rules authorized by federal and state agencies and commercial health plans to allow flexibilities related to telehealth and audio-only telephonic services. Without these flexibilities, access to services would have been significantly diminished due to social distancing restraints, availability of transportation, and stay in place orders and quarantine requirements. Community mental health and substance use disorder service providers report the flexibilities allowed providers to continue serving clients during a period of increased anxiety, depression, psychosis, and substance abuse directly related to the isolation and economic uncertainty of the COVID-19 pandemic.

Prevention

3. Develop and implement a substance-use prevention strategy designed to reduce drug use among youth (ages 12-17). The strategy should focus on (1) the deployment of a unified anti-drug messaging campaign, (2) increase/maintain substance use prevention efforts by securing/sustaining front-end prevention funding, and (3) by expanding state partnerships with anti-drug coalitions, educational institutions, law enforcement, and other members of the 12 Community Sectors. Collectively, these efforts will enhance substance-use prevention efforts, allow for the unified employment of limited resources towards a common goal, and reduce the impact of substance use among youth by 10% and Marijuana use by 3%.

~~(1)~~ In many ways, Florida has made significant gains in preventing substance use among youth. According to the 2019 Florida Youth Substance Abuse Survey (FYSAS) high school students reported a 22.2% reduction in their past 30-Day alcohol use, 12.9% reduction in tobacco use, and 1% reduction in marijuana use as compared to 2004.[29] Despite these gains, new trends demonstrate the need for concern. According to the 2019 "Monitoring the Future" (MTF) survey, 25.4% of 12th graders have used some form of e-cigarette to consume liquid nicotine within the past 30 days. The MTF further outlined a 4.2% increase in the vaping of marijuana and a 5.6% increase in the vaping of nicotine.[30] The 2019 FYSAS also noted that 17.4% of Florida's high school students vape nicotine and another 12.3% vape marijuana.[31]

Figure D
Past 30-Day E-Cigarette/E-Liquid Use (2019 FYSAS)



Recognizing vaping as an enduring and significant problem, the Food and Drug Administration (FDA) expanded their anti-vaping/e-cigarette prevention campaign. The campaign, entitled "The Real Cost," is the FDA's ongoing effort to protect youth from the dangers associated with e-cigarettes. The FDA uses a science-based approach to educate young people on the dangers of e-cigarettes and hopes to reach 10 million students nationally. To deploy their message, the FDA employs television ads, online videos, websites, social media, and printed materials distributed throughout the United States at no cost to the end user.[32] With the use of a multifaceted drug prevention campaign, Florida can reduce and/or delay the use of alcohol,

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e-cigarettes, tobacco, and/or other recreational drugs by youth ages 12-17. To maximize impact, community partners such as the Florida Department of Children and Families (DCF), Florida Department of Education (FDOE), Florida National Guard Counterdrug Program, and other anti-drug organizations should be engaged in the process.

~~(2)~~ Preventing drug use before it starts is a fundamental tenet of a comprehensive approach to drug control. The science of prevention has evolved and significantly improved. Decades of research shows that prevention is most effective when carried out over the long-term with repeated evidence-based interventions.[33] Additional prevention strategies which have proved successful include the deployment of anti-drug awareness campaigns, expansion of drug take-back events, and the strengthening of anti-drug coalitions across Florida. To accomplish this, Florida should continue to support its anti-drug coalitions by maintaining or expanding grant opportunities similar to DCF's Prevention Partnership grants, Substance Abuse and Mental Health Services Administration (SAMHSA) grants, and the Office of National Drug Control Policy (ONDCP) grants.[34, 35, 36] Funds obtained through these sources are used to implement evidence-based prevention programs, local prevention messaging campaigns, and to expand prescription drug take-back events.

~~(3)~~ These intervention initiatives conducted in conjunction with a large-scale, multi-agency prevention campaign would potentially have a significant impact to the community. Partner organizations and community stakeholders would utilize their already existing social media platforms, websites, and other media outlets to dispatch substance-use prevention messages. As a result, these messages would be more widely available throughout the state and at minimal cost to the taxpayer. Statistical analysis continues to demonstrate that combining multiple evidence-based approaches in a comprehensive prevention program is more effective than a single activity alone. Moreover, these early investments pay large dividends in substantially reduced treatment and criminal justice costs, saving taxpayer dollars while reducing the number of young people whose lives are tragically affected by early substance abuse.[37] By ensuring prevention funding is continually available, local communities will consistently provide substance use prevention efforts through-out Florida. These funds will allow for the better integration of the 12 Community Sectors, which in turn, will improve a greater understanding of addiction, reduce the impact of stigma, and allow for the unified deployment of limited resources towards a healthier community.

4. Implement a substance-use prevention strategy designed to reduce drug use among youth (ages 12-17). The program focuses on evidence-based and/or evidence-informed prevention strategies proven to reduce substance use, while also increasing youth resiliency, coping strategies, positive mental health, and responsible decision-making. DCF should lead, in collaboration with DOH and DOE, a statewide initiative designed to increase and coordinate prevention efforts across Florida through a partnership with coalitions, community substance use disorder (SUD) providers, school districts, faith-based groups, and business entities. The end goal is to better link existing prevention education programs with Florida's educators, and reduce substance use and abuse among Florida's youth.

In Florida, over 660,000 adults and 181,000 children live with a serious mental illness.[38] The initial onset of many of these mental health and/or substance use disorders typically occurs during childhood or adolescence. This information provides state and local leadership an opportunity to address these issues prior to an individual reaching a crisis state. Communities can do this by implementing evidence-based practices designed to treat mental health issues early and prevent substance use among youth.

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Florida's communities are geographically and culturally unique. Therefore, all evidence-based practices must be flexible and adaptable to the needs of specific populations. These practices must contain a core prevention foundation that remains uniform across the state and provides guidance to administrators on acceptable changes or adaptations in methods of delivery. This process would ensure fidelity and provide measurable, repeatable, and effective outcomes. Collaboration between evidence-based administrators, researchers, and developers would be mandatory. To facilitate this process, Substance Abuse and Mental Health Services (SAMHSA) has established an evidence-based practice online resource center. The SAMHSA resource center contains a collection of evidence-based resources for a broad range of audiences. These resources include substance use prevention plans, treatment improvement protocols, toolkits, resource guides, clinical practice guidelines, and other science-based resources.[39]

Governor DeSantis identified quality mental and emotional health and substance use and abuse education as high priorities for Florida's Legislature. For decades, Comprehensive Health Education has included mental and emotional health and substance use and abuse as part of required instruction through section 1003.42 (2)(n), Florida Statutes, but did not include an instructional time requirement or the assurance mechanisms to support and verify instruction.

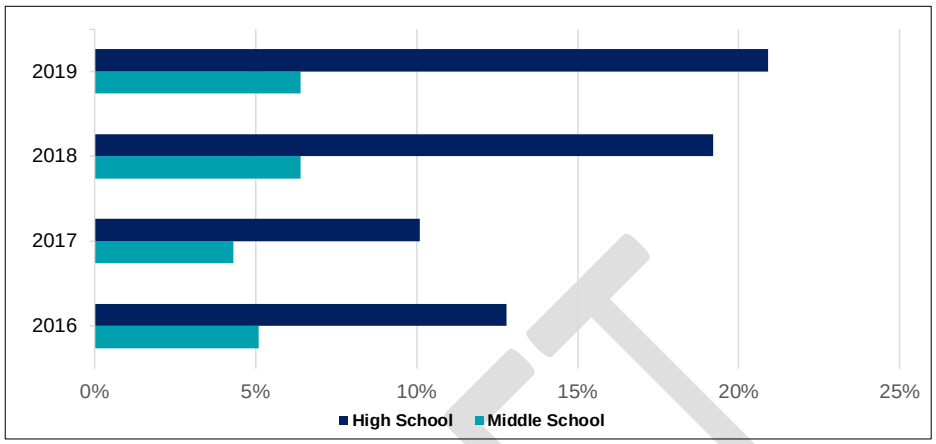
In an effort to ensure Florida students receive this critical education requirement, the FDOE established Administrative Code (AC) 6A-1.094121 (Mental and Emotional Health Education) and AC 6A-1.094122 (Substance Use and Abuse Health Education).[40, 41] AC 6A-1.094121 was approved by the State Board of Education on July 17, 2019 and requires that all students (Grades 6-12) receive a minimum of five hours of mental and emotional health education. The Board also approved AC 6A-1.094122 on August 21, 2019, requiring all Florida school districts to provide annual substance use and abuse education to students (Grades K-12). The selected course content must advance with each grade level through developmentally appropriate instruction and skill building. Decisions about which course(s) to use are determined at the school district level. These rules are in effect for the 2020-2021 school year.

With the deployment of an evidence-based and/or evidence-informed prevention strategy, Florida has the opportunity to reduce substance use among youth. Prevention programs such as these are proven to reduce drug use, while also increasing youth resiliency, enhancing their mental health, and providing students with sound protective factors that will aide them in making critical decisions.

5. Develop and implement a comprehensive e-cigarette/e-liquid prevention strategy designed to reduce vaping among youth (ages 11-17) and limit the negative health effects associated with e-cigarettes, e-liquids, and/or other vaping materials.

There has been a 52.3% increase in the use of e-cigarettes/e-liquids by Florida's youth (ages 11-17) since 2015.[42] According to the Centers for Disease Control and Prevention (CDC), this health emergency is a national epidemic. The CDC's research confirms that in 2019 more than one in four (27.5%) high school students and one in ten (10.5%) middle school students reported that they used e-cigarettes/e-liquids within the past 30 days.[43] The continued rise in e-cigarette use is likely due to unregulated advertising methods, a wide range of flavored vaping products, and an extremely high nicotine content. Many of these devises come in shapes designed to mimic the look of markers, highlighters, USB flash drives, etc., making them very easy to conceal.

Figure E. Florida Youth Substance Abuse Survey Past 30 Day Vaping Trend



Source: https://www.myflfamilies.com/service-programs/samh/prevention/fysas/2019/docs/FYSAS%202019%20(Final).pdf

Additionally, 8,269 children (ages 6 or less) were accidentally poisoned by consuming e-liquids during the period of 2012-2017.[44] Most, 92.5% of these children were exposed by ingesting e-liquids.[45] The Food and Drug Administration (FDA) believes these children consumed liquid nicotine because of the child-friendly packaging, cartoon placement, and diverse flavoring options.[46] The Child Nicotine Poisoning Prevention Act (CNPPA) of 2015 requires all e-liquids sold, manufactured, and/or distributed to be packaged in child resistant containers.[47] The CNPPA has helped reduce e-liquid exposures; however, the poisoning rate remains high as compared to 2012. In fact, new trends suggest that some youth populations are now deliberately drinking e-liquids and/or eating/chewing e-liquid pods/cartridges to gain access to the nicotine.[48]

In 2016, the FDA published a rule that extends its regulatory authority to all tobacco products. This regulation includes e-cigarettes, e-liquids, hookahs, cigars, and pipe tobacco. Prior to this regulation, these products were sold without any review of their ingredients, manufacturing processes, or their potential dangers.[49] Additionally, the ruling ensures e-cigarettes/e-liquids are not sold to minors and not available for purchase in vending machines that are accessible by youth. Since 2016, the FDA has sent 735 warning letters and issued 159 fines to Florida businesses for violating FDA's 2016 e-cigarette/e-liquid regulation.[50] Given FDA's limited time and resources, it should be assumed that additional violations would have been identified if other agencies were given the authority to conduct compliancy inspections. On December 20, 2019, the President signed legislation amending the Federal Food, Drug, and Cosmetic Act, and raising the federal minimum age for sale of tobacco products from 18 to 21 years. This legislation (known as "Tobacco 21" or "T21") is effective immediately, and it is now illegal for a retailer to sell any tobacco product—including cigarettes, cigars, and e-cigarettes—to anyone under 21. The new federal minimum age of sale applies to all retail establishments and persons with no exceptions. The Federal Food, Drug and Cosmetic Act does not require that states pass laws to raise their sales age to 21, but it does require states to demonstrate that their retailers are complying with the law. If not, the state eventually risks losing some portion of their federal

substance abuse grant funding. [51, 52] Florida has not established e-cigarette/e-liquid advertising laws that prohibit youth targeting or ban the sale of flavored vaping products popular among Florida's children. Tobacco companies, prior to the 1998 "Master Settlement Agreement," commonly used marketing practices designed to target youth, while encouraging them to experiment with cigarettes, chewing tobacco, and other items containing nicotine. These practices included the use of cartoon advertisements, brand name endorsements, outdoor signage, billboards, public transit ads, and free tobacco company merchandise/samples. Many of these same advertising methods have been retooled by vaping companies and are now being employed to target youth.[53] Electronic cigarette retailers in the state of Florida are not required to obtain a Tobacco Retail License to sell or manufacture e-cigarettes and/or e-liquids.[54] This precludes Florida's ability to inspect and/or regulate e-cigarette/e-liquid manufacturing processes and retail establishments where these products are sold. On January 2, 2020, the President of the United States announced a nation-wide ban of flavored pod-based vape cartridges, excluding tobacco and menthol flavors. Since the President's announcement, the FDA expanded the restriction to include disposable flavored e-cigarettes like Puff Bar and Mojo. The FDA clearly states they will prioritize enforcement efforts against businesses that violate the guidance outlined within the policy.[55] The FDA expects this policy to reduce the use of e-cigarettes/e-liquids by youth, limit accidental poisoning, and/or prevent its use entirely. The policy does not include flavored e-liquid used in open vape systems or menthol-flavored pod products, allowing more than 15,000 flavors to still be on the market. Additionally, the restrictions exempt sleek, open pod systems like Suorin and Smok, popular brands kids use to re-fill with flavored e-liquid. With the development and deployment of a comprehensive e-cigarette/e-liquid prevention strategy, Florida can better protect its youth and limit the negative health effects associated with vaping. This strategy may include:

- Comprehensive flavor ban without product, flavor or retailer exemptions reduces youth initiation and can promote cessation among adults
- Strong youth access laws accompanied with enforcement programs, including retailer education, that focus on retailer compliance instead of youth possession penalties
- State and local licensure requirements for businesses that manufacture and/or sale any tobacco product, including e-cigarettes, that is consistently implemented across all product types. [56]

6. Screening, Brief Intervention, and Referral to Treatment (SBIRT) is a comprehensive, integrated, public health approach to the delivery of early intervention and treatment services for persons with substance use disorders, as well as those at-risk of developing those disorders[57]. To evaluate what evidence-based practices are presently in use in Florida to identify problematic alcohol or drug behavior in the primary care setting and to promote the implementation of SBIRT in our state, the following is recommended:

- **The Department of Health lead an initiative to review the extent SBIRT and/or other evidence-based practices are utilized in primary care settings across Florida to identify and intervene with patients showing symptoms of problematic alcohol and/or drug use**
- **AHCA should report to the legislature on the availability of Medicaid coverage for SBIRT, and if not available, what changes to the state's Medicaid plan, billing and coding practices would need to be modified or changed to implement SBIRT**

Early identification and intervention is the key to addressing unhealthy alcohol and drug use and the likelihood of an individual developing a substance use disorder. SBIRT is an evidence-based practice used to identify, reduce, and prevent risky use that can have short and long-term health impacts and social, legal, and financial consequences[58].

The U.S. Preventive Services Task Force (USPSTF) recommends screening for unhealthy alcohol use in primary care settings in adults 18 years or older, including pregnant women, and providing persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce unhealthy alcohol use.[59] Additionally, an analysis of USPSTF recommendations included screening and brief intervention for alcohol misuse in adults as one of the highest priority prevention services in terms of cost-effectiveness and clinically preventable burden of disease.[60]

The USPSTF also recommends screening for unhealthy drug use in adults 18 years or older. Screening should be implemented when services for accurate diagnosis, effective treatment, and appropriate care can be offered or referred[61].

Typically, this practice is conducted in medical settings, including community health centers, and has proved successful in hospitals, specialty medical practices such as HIV/STD clinics, emergency department, and workforce wellness programs. SBIRT can be effectively streamlined in primary care workflows and enables healthcare teams to systematically screen and assist people who may not be seeking help for their substance use, but whose drinking or drug use may cause or complicate their ability to handle health, work, and family issues. SBIRT aims to prevent unhealthy consequences of alcohol and drug use among those whose use may not have reached the diagnostic level of a substance use disorder.[62]

Research validates that the SBIRT model reduces healthcare costs,[63] decreases severity of drug and alcohol use, and reduces the risk of physical trauma and the percentage of patients who go without specialized substance abuse treatment.[64]

SBIRT's use across healthcare settings is dependent on the state's coding and billing policies. States are working to "activate" Medicaid codes for SBIRT in their respective Medicaid plans.

7. When filling prescriptions for controlled substances, strongly encourage pharmacies to educate consumers on safe medication storage and disposal procedures. Establish a media campaign to educate consumers on reason for safe use, safe storage and safe disposal and the location of safe disposal boxes in each community.

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Several resources are available to help people in Florida understand the proper steps to dispose of unused medication:

- The Florida Department of Environment Protection (DEP) offers information online regarding pharmaceutical waste management for homeowners. In addition to addressing frequently asked questions, DEP's web page includes information about drug drop off locations and steps to take at home to properly dispose of old unused medication. DEP's web page is located here: https://floridadep.gov/waste/permitting-compliance-assistance/content/pharmaceutical-waste-management.
- The CVS Health locations with drop boxes may be found here: https://www.cvs.com/content/safer-communities-locate.

- The Walgreens locations with drop boxes may be found here: https://www.walgreens.com/topic/pharmacy/safe-medication-disposal.jsp.
- The Drug Enforcement Administration (DEA) Diversion Control Unit hosts National Take Back Days (https://takebackday.dea.gov/). There were 35,775 pounds collected in Florida during the April 27, 2019 Take Back Day. There were 138 law enforcement agencies participating and there were 204 collection sites across the state. The Florida National Guard also collaborated with partner agencies in North Florida to support Take Back events where more than 3,182 pounds of drugs were collected.
- Publix Pharmacy continues to partner with Informed Families/The Florida Family Partnership to feature the Lock Your Meds campaign. In-store signage was distributed to and displayed in 694 Publix stores at the pharmacy counter. Additionally, Publix "Carepoints" documents, featuring the Lock Your Meds message and an appeal to take the pledge to prevent prescription drug abuse, were printed and distributed with all prescription purchases. The month-long campaign reaches more than 1 million Floridians, or about 50 customers per store, per day. Those who took the pledge also received a home medicine inventory card download. They also had the opportunity to opt in to receive additional prevention education information throughout the year. Through their partnership with Publix, Informed Families also developed a web page focusing on safe disposal locations in Florida, which is consistently updated: https://www.informedfamilies.org/lym/safedisposal.
- Through the SOR grant, DCF is funding a safe use, safe storage, and safe disposal campaign based on the Use Only as Directed initiative from Utah. Over 1 million people have seen or heard a campaign message to date.

Treatment and Recovery

8. Expanding naloxone availability among people who use drugs and their peers through hospital emergency departments and floor units (with little to no paperwork, and no separate trip to the pharmacy), EMS/Fire Rescue naloxone leave-behind programs, county health departments, and Federally Qualified Health Centers.

Research shows that overdose mortality can be reduced by distributing naloxone to individuals at risk of experiencing an overdose and to their peers and family who may witness an overdose, through syringe access programs, drug treatment programs, community meetings, support groups for family members of people who use opioids, re-entry programs, mobile outreach programs, homeless service providers, and other community-based distribution programs that provide continuous, low-barrier access to naloxone.[65] It is conservatively estimated that one heroin overdose death is prevented for every 164 naloxone kits distributed.[66]

According to a recent statement from the FDA supporting the expansion of naloxone access, "Naloxone is a critical tool for individuals, families, first responders, and communities to help reduce opioid overdose deaths, but access to naloxone continues to be limited in some communities." The FDA reiterated that "all three forms of naloxone are FDA-approved and may be considered as options *for community distribution* and use by individuals *with or without medical training* to stop or reverse the effects of an opioid overdose." The FDA is also continuing the agency's efforts to make naloxone available over-the-counter.[67]

Bystanders are present in approximately 40% of opioid overdose deaths and approximately 65% of nonfatal overdoses.[68] Tragically though, when someone overdoses in America, a 911 call is made less than 50% of the time.[69] Fear of police involvement is the most commonly cited reason for delaying or deterring a call for help for an overdose victim.[70]

Fortunately, people who use opioids and their friends and family members can reverse opioid overdoses and revive individuals using naloxone. Naloxone is remarkably safe and has no potential for abuse. When given to individuals who are not under the influence of opioids, it produces no harmful effects. It is relatively quick and easy to train people who use opioids and their loved ones on the use of naloxone. Research confirms that bystander/layperson naloxone administration is a safe and effective community-based method for preventing overdose deaths and that the associated education effectively improves overdose recognition and response.[71] It is critical that we get naloxone into the hands of people who use drugs and their peers, as they are commonly the first responders at the scene of an overdose and are able to immediately administer naloxone to someone who is not breathing and save their life.

DCF initiated an Overdose Prevention Program in August of 2016. The program has been funded through a variety of sources, including General Revenue, the SAPT Block Grant, the STR grant, and the SOR grant. Organizations enrolled in the program distribute free, take-home naloxone kits directly to people who use drugs, people with a history of drug use, and to their peers and loved ones who may witness an overdose. There are currently 110 organizations participating in the program, including substance use and mental health treatment facilities, hospital EDs, harm reduction programs, peer recovery organizations, homeless service providers, FQHCs, and other community-based organizations. Since the start of the program, over 79,000 naloxone kits have been distributed among participating providers and 3,184 overdose reversals have been reported. In Palm Beach County, Rebel Recovery distributed 5,481 naloxone kits and documented 478 reported reversals.[72] Unsurprisingly, and much like the experience in other states, the most effective naloxone distribution programs enrolled in

DCF's program are operated by organizations that serve people who use drugs with a peer-oriented, harm-reduction framework.

Between 2006 and 2009, Massachusetts provided overdose education and naloxone kits to thousands of people who use opioids and their families, friends and social service providers. An interrupted time series analysis compared communities that did not implement the program to low implementation communities (enrolling ≤ 100 participants per 100,000 population) and high implementation communities (enrolling > 100 participants per 100,000 population). Low implementation communities experienced a 27% decrease in opioid overdose death rates, and high implementation communities experienced a 46% decrease in opioid overdose death rates.[73]

In 2013, North Carolina began prioritizing naloxone distribution to populations at high risk for overdose, namely people who inject drugs, individuals receiving medication-assisted treatment, people with a history of opioid use who were formerly incarcerated, and individuals engaged in sex work. A recently published evaluation of this program found that high distribution counties experienced a 14% decrease in opioid overdose death rates, and low distribution counties experienced an 11% decrease in opioid overdose death rates, relative to counties with no naloxone distribution.[74] Several other studies conducted in the U.S. have also documented reductions in opioid overdose mortality associated with naloxone distribution programs, all of which were evaluations of naloxone distribution programs that *prioritized people who use drugs and those around them*, most commonly through Syringe Exchange Programs and drug treatment programs, but also through mobile vans, HIV education drop-in centers, pain management clinics, and single room occupancy hotels, for example.[75]

Researchers recently simulated the impact of 13 different naloxone distribution models on overdose deaths and found that expanding naloxone distribution through a single Syringe Exchange Program can reduce a community's overdose deaths by 65%. Results showed that, "Optimal [naloxone] distribution methods may include secondary distribution so that the person who picks up naloxone kits can enable others in the community to administer naloxone, as well as targeting naloxone distribution to sites where individuals at high-risk for opioid overdose death are likely to visit, such as syringe exchange programs." [76]

Additional research demonstrates that distributing naloxone to laypeople, particularly those likely to experience or witness an overdose, is the most cost-effective way to prevent overdose deaths. Researchers analyzed the cost-effectiveness of 8 different naloxone distribution strategies among three target groups (laypeople, police and fire personnel, and EMS personnel). The top 4 most cost-effective strategies all involve high naloxone distribution to laypersons. Strategies that did not distribute a significant amount of naloxone kits to laypeople always ranked last. Thus, when facing resource constraints, naloxone distribution to laypeople should be prioritized.[77] Other research shows that people who use drugs deploy take-home naloxone to save a life at a rate nearly 10 times that of laypeople who do not use drugs, emphasizing the need to prioritize naloxone distribution efforts and resources among people who are actively using drugs.[78]

There is no evidence indicating that access to naloxone encourages or increases the use of heroin or other opioids. Rather, studies suggest that increasing health awareness through naloxone training and distribution actually reduces the use of opioids.[79] DCF's Overdose Prevention Coordinator and Harm Reduction Coordinator is available to help with training and technical assistance to organizations interested in establishing targeted naloxone distribution programs.

People who have experienced an overdose are treated in Florida emergency departments every day, making these important settings for expanding naloxone distribution. Nonfatal opioid

overdose remains the most significant risk factor for subsequent fatal overdose and provides an identifiable opportunity for overdose education and naloxone distribution. Research confirms that emergency departments are an effective way to provide take-home naloxone kits to high-risk individuals who have not previously received overdose education and naloxone.[80]

Hospital EDs and floor units should be offering take-home naloxone kits prior to/upon discharge to patients at risk of experiencing an opioid overdose. Hospitals should operate under non-patient specific naloxone standing orders in order to allow for broader distribution of naloxone, reduce the burden on prescribers and dispensers by removing the need to write individual prescriptions, reduce bureaucratic and system-wide barriers to receiving naloxone, and allow for ED and floor unit staff to hand naloxone directly to the patient (as opposed to sending the patient to a pharmacy where the medication may never be obtained due to cost, stigma, and other barriers). It is also important to allow for patients to receive more than one naloxone kit, as they may know people at risk of overdose, they can provide additional kits to directly and can provide kits to their friends and family that may witness an overdose.

Hospital EDs and floor units should offer naloxone kits upon discharge to:

- People who received treatment for an overdose.
- Patients being treated for other drug-related issues, such as endocarditis, cellulitis, abscesses, and vein/wound care related to injection-drug use.
- Patients identified as having an OUD.

The Florida Hospital Association issued the following guidelines to help increase access to naloxone in EDs:

"Emergency department providers and hospital-based pharmacies should operate under non-patient specific naloxone standing orders to ensure that take-home naloxone kits are offered and provided to anyone in the emergency department at risk of opioid overdose, and to the friends and family of those patients at risk of opioid overdose. Any patient in the emergency department due to opioid overdose should be provided with a take-home naloxone kit upon discharge. Friends and family members of the patient should also be provided with take-home naloxone kits upon the patient's discharge. Hospitals are encouraged to coordinate a follow-up process for individuals who need additional naloxone kits."[81]

Florida hospitals can have a role in helping to save lives by making sure opioid overdose survivors and those around them are easily and readily equipped with the antidote before they are discharged from emergency departments.

~~The Centers for Disease Control and Prevention has cited Emergency Departments (ED) as important centers for treatment and referral, including medication assisted treatment (MAT), which has been shown to be superior to motivational interviewing and referral alone.[82] [83] Direct linkage from the ED to community OUD providers, known as a warm handoff, is proving to be a better option to serve this population; however, these interventions are sparse. The Florida Hospital Association documents 209 EDs in Florida. Of these, only approximately 18 to date have been identified as having, or in the process of implementing, a warm handoff initiative.~~

~~As the opioid epidemic continues, EDs will play an integral part in mitigating the human toll on many levels through screening and identification of patients at risk for opioid use disorder, managing acute opioid withdrawal, initiating medication assisted therapy, and coordinating linkage to outpatient treatment. However, much work remains to be done to create, validate, disseminate, and implement effective evidence-based strategies to accomplish these challenging tasks within the unique care environment of the ED.~~[84]

Commented [MF3]: This section is already included in recommendation 10.

~~DCF's Substance Abuse and Mental Health Program Office, when allocating federal State Opioid Response grant funds, has prioritized the development of ED warm handoff programs for individuals experiencing an opioid overdose. Utilizing the resources of the Aetna All in for Florida: An ER Intervention Project grant program managed by the Florida Alcohol and Drug Abuse Association (FADAA), multiple issues related to the establishment of ED warm handoff programs have been surfaced including providing health care with non-recurring funding, available funding for community providers to accept ED referrals, issues related to peers working in the ED, a waiver to prescribe buprenorphine under the Drug Addiction Treatment Act of 2000 (DATA 2000) training for physicians, training for peers and providers, hospital pharmacy rules, legal considerations and hospital administration support.~~

In 2018, the Florida Legislature appropriated $5 million in recurring General Revenue Funds to the Department of Health "for the purchase of emergency opioid antagonists to be made available to emergency responders."[85] The naloxone distribution program established with these funds is called the Helping Emergency Responders Obtain Support (HEROS) Program. DOH can help expand these life-saving efforts by encouraging EMS/Fire Rescue to establish naloxone leave-behind programs. Some EMS/Fire Rescue programs leave naloxone kits behind at the scene of an overdose, with overdose survivors, friends, family members and bystanders who may be at high risk for witnessing or experiencing an overdose. The HEROS Program has the resources available to do evidence-based, targeted distribution through leave-behind programs.

It should also be noted that entities receiving naloxone through DOH's HEROS Program are required to enter data into EMSTARS or ODMAPS. Both of these surveillance and overdose hotspot mapping initiatives should be used to help guide the targeted deployment of evidence-based resources that prevent overdose deaths, like distributing naloxone directly to individuals who use drugs or who are likely to witness an overdose.

Consider the following directive, which comes directly from the *Overdose Spike Response Framework* guide for ODMAP stakeholders: "Developing a plan for messaging and engaging families and friends of individuals at risk is one key component to reducing injury and death from overdose. Family and friends of individuals at risk for an overdose will approach and manage their loved one's risk, based on their own stage of readiness for change, as well as the stage of readiness of their loved one. Therefore, family and friends require information on a variety of topics including: where to get naloxone, how to administer naloxone, and/or how to encourage their loved one(s) to seek treatment."[86] Rather than having emergency responders advise individuals at the scene of an overdose on where to obtain naloxone, they should just distribute naloxone at the scene. Currently, there are only six EMS/Fire Rescue naloxone leave behind programs in operation in Florida. DOH may need to review and revise (as needed) any track-and-trace rules, and any other rules, that may constitute barriers to establishing naloxone leave-behind programs.

CHDs and FQHCs can also help distribute naloxone kits to targeted at-risk populations. These entities can use EMSTARS to identify opioid overdose hotspots and develop outreach and distribution strategies to saturate at-risk individuals in those communities with naloxone. In response to public health emergencies, DOH is capable of mobilizing outreach teams through CHDs to engage individuals who use drugs in order to provide them with Hepatitis A vaccines, for example.

9. Encourage county commissions to establish Syringe Exchange Programs (SEP) to distribute naloxone to people who use drugs and prevent new cases of HIV and Hepatitis C.

In order to make a larger impact in reducing overdose deaths, Florida needs to do a better job of targeting naloxone distribution to people most likely to experience an opioid overdose. While SEPs are the most effective organizations at saving lives by distributing naloxone directly to people who use drugs, there is currently only one SEP operating in Florida: the IDEA Exchange in Miami-Dade County. The IDEA Exchange has distributed 3,443 boxes of Narcan and documented 1,807 overdose reversals.[87] During the 2019 session, the Florida Legislature voted to expand SEPs statewide through the passage of SB 366, which allows county commissions to pass ordinances to authorize local SEPs. County commissions are encouraged to pass ordinances establishing new SEPs throughout the state. The following county commissions have approved an SEP ordinance: Broward, Hillsborough, Leon, Manatee, Miami-Dade, and Palm Beach. Two counties have executed the Letter of Agreement with the Department of Health: Manatee and Palm Beach. DOH is finalizing the data screens that will be used to capture the required SEP data elements. The department is collaborating with the National Alliance of State and Territorial AIDS Directors (NASTAD) to deliver virtual capacity building trainings for community-based organizations around the state who are interested in becoming an SEP.

10. Encourage the continued establishment of warm handoff programs from hospital Emergency Departments (Ed's) to community Opioid Use Disorder (OUD) treatment providers to address opioid overdoses; issue naloxone to overdose patients before they leave the ED; and have AHCA report on the extent warm hand-off protocols have been implemented in ED's across the state.

The Centers for Disease Control and Prevention has cited Emergency Departments (ED) as important centers for OUD interventions and care transitions, including the induction of buprenorphine as part of the overdose protocol. This practice has been shown to be superior to motivational interviewing and referral alone. A 2015 study by researchers at the Yale School of Medicine tested three interventions for opioid-dependent patients were treated in a hospital emergency department. The first group was given a handout with contact information for addiction services. The second group received an interview on information about treatment options; assistance in connecting with treatment. The third group received an interview, plus the first dose of buprenorphine, with take home doses and a scheduled appointment with a primary care provider within 72 hours. The study found that 78 percent of patients in the third group (buprenorphine) were still in treatment 30 days later, compared with 45 percent in the group that only got the interview and 37 percent who only got the handout. [https://www.npr.org/sections/health-shots/2017/08/22/545115225/hospitals-could-do-more-for-survivors-of-opioid-overdoses-study-suggests]

Direct linkage from the ED to a community OUD provider, known as a "warm hand offs", is proving to be a better option to serve this population, however, these interventions are infrequently utilized. According to the Florida Hospital Association, there are 209 EDs in Florida. To date only a limited number have been identified as having, or in the process of implementing, a warm handoff protocol.

As the opioid epidemic continues, EDs will play an integral part in mitigating the human toll on many levels through screening and identification of patients at risk for opioid use disorder,

managing acute opioid withdrawal, initiating medication assisted therapy, and coordinating linkage to outpatient treatment. However, much work remains to be done to create, validate, disseminate, and implement effective evidence-based strategies to accomplish these challenging tasks within the unique care environment of the ED.

DCF's Substance Abuse and Mental Health Program Office, when allocating federal State Opioid Response (SOR) grant funds, has prioritized the development of ED warm handoff programs for individuals experiencing an opioid overdose. Utilizing the resources of the *Aetna All in for Florida: An ER intervention Project* grant program managed by the Florida Alcohol and Drug Abuse Association (FADAA), multiple issues related to the establishment of ED warm handoff programs have surfaced including providing health care with non-recurring funding, available funding for community providers to accept ED referrals, issues related to peers working in the ED, a waiver to prescribe buprenorphine under the Drug Addiction Treatment Act of 2000 (DATA 2000) training for physicians, training for peers and providers, hospital pharmacy rules, legal considerations and hospital administration support.

11. Expand additional fellowship and residency programs for physicians to obtain a specialty in addiction medicine with a goal of increasing physicians with an addiction medicine specialty.

There is an opportunity to expand the subspecialty of addiction medicine to help ensure patients with a substance use disorder are being properly treated by medical professionals. The Accreditation Council for Graduate Medical Education (ACGME) has accredited Florida institutions to sponsor Addiction Medicine and Addiction Psychiatry Fellowships, which are one-year training programs. For Addiction Medicine Fellowships, the University of Florida is approved for six positions and six are filled, the University of South Florida is approved for 2 new positions and both are filled, and Larkin Community Hospital is approved for two new positions and both are filled. For Addiction Psychiatry Fellowships, the University of South Florida is approved for two positions and both are filled, and Jackson Memorial is approved for three positions and none are filled, due to funding issues.[88]

The opioid epidemic in Florida is changing the dynamic on the delivery of substance use disorder treatment and care. The standard for care for an opioid use disorder is MAT combined with behavioral counseling. SUD treatment programs across the state have had to add and/or increase medical professionals on the treatment team in order to evaluate, prescribe, and medically monitor MAT medications. In addition, to prescribe buprenorphine medical personnel must complete a training course and pursue a waiver to prescribe buprenorphine under the Drug Addiction Treatment Act of 2000 (DATA 2000). In addition, there is a growing need for physicians certified in addiction medicine.[89]

Figure F. Addiction Medicine Specialties among Florida Physicians[90]

Specialty	Count
Addiction Medicine – Anesthesiology	51
Addiction Medicine – Family Medicine	40
Addiction Medicine – Internal Medicine	10
Addiction Medicine – Neurology	2
Addiction Medicine – Psychiatry	32

Total	**135 (N = 52,684)**

12. Pass model legislation that will align Florida law with the federal Mental Health Parity and Addiction Equity Act (MHPAEA) and require all state health agencies, health plans and commercial insurance to report annually on the implementation of the parity act in Florida. The reports should be transparent and available to inform the public.

In 2008 the United States Congress unanimously approved the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act, known as the federal parity law. Many state legislatures have passed similar laws to ensure parity enforcement. The federal law seeks to eliminate discriminatory access to mental health (MH) and SUD benefits in certain health insurance coverage. The federal parity law prohibits plans from applying financial requirements or treatment limitations to MH and SUD benefits that are more restrictive than those applied to medical/surgical benefits. Treatment limitations and financial requirements to be evaluated include co-pays, deductions, co-insurance, day or visit limits, pre-authorization policies, frequency of treatment limits, fail first policies, and non-qualitative treatment limitations.

Many states have passed model legislation to facilitate implementation and enforcement of the MHPAEA and to strengthen parity provisions within state law. Examples include: explicit oversight requirements for state regulators (RI); requirements for annual report on claim denials, complaints, appeals (VA); requirement for plans to submit parity compliance information to the state insurance regulator and/or Medicaid agency (CA, MA, CT); requirement for state agency to develop performance quality indicators to evaluate plan compliance (VT); state laws requiring coverage for prescription drugs for SUD (IL); length of stay protections (MD); and requirements for peer-reviewed clinical review criteria related to medical necessity determinations (NY).[91] During the 2020 Florida legislative session, three bills (SB 700, HB 102, SB 360) were introduced that would have better aligned Florida law with the federal parity legislation. None of these bills passed.

The Parity Tracking Project study highlights significant barriers to front-line state enforcement of the MHPAEA. The report concluded that regulators cannot conduct a complete assessment of parity compliance through form review with even a comprehensive data-gathering template because the required information is often not available in these documents. To address the barriers in parity compliance and consumer information, the report offered recommendations for consideration:

- Regulatory agencies should require carriers to submit their internal analyses for ensuring that plans are parity compliant.
- Regulatory agencies should use a parity compliance template.
- Regulatory agencies should develop model contracts that fully describe MH and SUD benefits.
- Regulatory agencies should inform consumers of their rights under the law, including how to take action.
- Regulatory agencies should enhance the provider community's capacity to identify potential parity act violations.[92]

In Florida, the majority of Medicaid recipients receive their services through a managed care plan contracted with the Agency for Health Care Administration (Agency) under the Statewide

Medicaid Managed Care (SMMC) program. The current SMMC contract contains a requirement that the health plan must comply with the Mental Health Parity and Addiction Equity Act:

- The Managed Care Plan shall comply with all applicable federal and State laws, rules and regulations including 42 CFR part 438, Subpart K, and the Act.
- The Managed Care Plan shall conduct an annual review of its administrative, clinical, and utilization management practices to assess its compliance with the Act under this Contract.
- The Managed Care Plan shall submit to the Agency an attestation of the Managed Care Plan's compliance with the MHPAEA no later than November 1 of each year, in a manner and format to be specified by the Agency.[93]

The health plan must develop distinct policies and procedures for monitoring and demonstrating compliance with the Act, including procedures to monitor for and assure parity in the application of quantitative treatment limits and non-quantitative treatment limits for medical and behavioral health services.[94] Each plan is required to submit an annual attestation to the agency detailing compliance with the Act.

The Agency has several other avenues for monitoring health plan compliance with parity. These include but are not limited to: review of health plan policies and procedures (including utilization management); monitoring of provider and recipient complaints; and monthly submission of complaint, grievance, and appeals reporting. Reports required by the Agency include quantitative treatment limits and non-quantitative treatment limits, in addition to the following:

Denial, Reduction, Termination, or Suspension of Service Report

- Medical necessity
- Service authorization
- Service amounts and frequency

Enrollee Complaints, Grievances, and Appeals Report

- Access to care
- Medical necessity
- Service authorization
- Enrollment/disenrollment
- Pharmacy benefits
- Excluded benefits

Additionally, the Agency conducted its own internal analysis of how the state plan benefits for mental health meet the Parity rule requirements. The state plan benefit categories of services reviewed for both Mental Health/ Substance Abuse Benefits and Medical/Surgical benefits included:

- Inpatient
- Outpatient
- Emergency care
- Prescription drugs

The Agency determined from the analysis that Florida Medicaid makes available a periodicity of services under the behavioral health benefits, which is not more restrictive than what it offers

under medical/surgical benefits. Additionally, the Agency determined that the behavioral health service limits were more expansive for adults than what is provided through the medical/surgical benefit.

13. State health agencies, health plans and commercial insurers should remove prior authorization requirements for evidence-based Medication Assisted Treatment to allow for use of medications such as buprenorphine and naltrexone especially where such an action would assist pregnant, post-partum and neo-natal populations.

Currently, Florida Medicaid covers behavioral health medication management services as part of a continuum of care for individuals diagnosed with a substance use disorder. Medication assisted treatment (MAT) is covered in conjunction with psychiatric evaluations, counseling, and behavioral therapies to ensure comprehensive treatment. For example, covered treatment may include monitoring current medication dosage and side-effects, as well as ensuring concerns or changes in health status are addressed properly. Behavioral health-related medical services such as screenings, verbal interactions and specimen collection are also covered to assist in drug management and treatment of substance use disorders. MAT services can also include methadone-based treatment. Florida Medicaid covers medication management services in addition to a bundled weekly reimbursement for MAT.

Additionally, several health plans provide expanded benefits for substance abuse such as additional behavioral health medical services, substance abuse treatment, and outpatient detoxification services. Expanded benefits are extra benefits above and beyond the minimum required benefits detailed in the State Plan. Health plans offer these benefits to their enrollees without a capitation payment from the Agency. A comprehensive listing of expanded benefits by health plan can be located on the Agency's website: http://ahca.myflorida.com/medicaid/statewide_mc/outreach_presentations.shtml.

Florida Medicaid enforces prior authorization standards for medication management services with all health plans. Additionally, Florida Medicaid requires continuity of care when a recipient is receiving MAT and changes plans. The new plan is required to cover the existing course of authorized treatment.

Specific to MAT, the Agency covers buprenorphine, naltrexone, and methadone patients with substance use disorder. The Agency allows Medicaid patients to receive up to a 7-day supply of buprenorphine, Suboxone film, or Zubsolv tablets for initiation of therapy for opioid use disorder without the prior authorization through the pharmacy benefit. This allows the prescriber to immediately start the patient on medication assisted treatment. If needed the patient can receive an additional 7-day supply of the buprenorphine for initiation of therapy within a 60-day period. The prescriber can then submit a prior authorization to Medicaid to continue treatment. Prior authorization requests are reviewed within 24 hours of receipt.

Medicaid patients can also receive the following medications to treat. These medications are available with no co-pay.

- Naltrexone tablets which are covered without prior authorization through the pharmacy benefit.
- Vivitrol (naltrexone) injectable can be received at the pharmacy through an automated prior authorization. The pharmacy computer system verifies that the recipient is 18 years of age or older and has a diagnosis of alcohol and/or opioid use disorder on file. If both are confirmed, the claim will pay. This automation eliminates the need for prior authorization paperwork submission through the pharmacy benefit. Vivitrol is also available through the medical benefit under J2315 if administered in a medical office setting.

- Sublocade (buprenorphine) injectable can be received at the pharmacy through an automated prior authorization. When the claim information is entered, the pharmacy computer system verifies that the recipient has received a minimum of 7 days of treatment with a buprenorphine-containing oral product. If confirmed, the claim will pay for Sublocade through the pharmacy. Sublocade is also available through the medical benefit under Q9992 if administered in the medical office setting.
- Methadone tablets are available through methadone clinics.
- Narcan (naloxone) nasal spray and naloxone vials are covered to treat overdose through the pharmacy benefit and under the medical setting under J2310.

The Medicaid preferred drug list is located at http://www.ahca.myflorida.com/medicaid/Prescribed_Drug/preferred_drug.shtml. MAT not listed on the preferred drug list require prior authorizations, which are reviewed within 24 hours of receipt. Medications on the preferred drug list are reviewed at least annually by the Pharmaceutical and Therapeutics Committee which is composed of physicians and pharmacists.

Medicaid has a single preferred drug list that the Medicaid health plans follow. The Medicaid health plans cannot be more restrictive than fee-for-service Medicaid. Under the medical benefit, plans can use step therapy or prior authorized medications.

When prior authorizations are required for treatment services, this may take up to several days to process with insurance providers. This processing time creates an immediate barrier to a patient's initiation onto medication assisted therapy (MAT) for substance abuse disorders. This delay forces patients to leave their provider's office without receiving potentially life-saving medication and requires them to return to receive it days later. During that time, treatment can be derailed. A patient may lose interest, lose access to their doctor, lose transportation, suffer an injury, or even die from an overdose. Self-treatment with diverted (i.e. misused) opioid medications is common among individuals with opioid use disorder who have recently experienced barriers to or delays in starting buprenorphine-based MAT.[95, 96, 97]

Prior authorization limitations to Medication Assisted Therapy for substance abuse disorder disproportionately affects pregnant and post-partum women and their children due to their vulnerability especially for low-income populations who have severely limited alternative resources. In 2014, prior authorization for prescription buprenorphine was still required for 35% of Health Maintenance Organizations (HMOs), 36% of Preferred Provider Organizations (PPOs), and more than half of Consumer Driven Products (CDPs).[98]

During pregnancy, universal screening efforts and enhanced substance abuse services—including accessible Medication Assisted Therapy (MAT) for all women who need it—are important goals. At birth, the systematic approach to screening infants, monitoring for withdrawal signs using a scoring tool, and managing care for the mother and infant offer numerous opportunities for improving outcomes including the measured use of MAT.[99]

MAT is considered the standard of care for opioid-dependent pregnant women. Service delivery and treatment capacity should be streamlined to ensure women have access to needed services in a timely manner, staying in their community or medical home whenever possible. Compared to medication-assisted withdrawal, MAT is associated with better relapse prevention, decreased exposure to illicit drugs and other high-risk behaviors, improved adherence to prenatal care, and improved neonatal outcomes. The goal of MAT is to prevent withdrawal during pregnancy and minimize fetal exposure to illicit substances.[100, 101]

MAT is not the only solution, it is also important to consider the implications of identifying prenatal substance abuse in efforts to increase access to care and improve clinical outcomes, but it is a centerpiece of managing opioid dependency in pregnancy, best applied as part of a comprehensive treatment program that includes obstetric care, counseling, and wrap-around services.[102] However, there is a treatment gap in pregnant women's receipt of substance abuse services overall. Barriers to care included lack of transportation, lack of child care services, intensive time requirements, additional costs and co-pays, stigma and regulatory roadblocks such as prior authorization.[103, 104]

The removal of prior authorization requirements allows a patient to be initiated onto treatment the same day they see their doctor. This immediate initiation reduces the patient's risk of overdose in the subsequent days and increases the likelihood that they will successfully engage in and remain connected to treatment. Due to regulations governing the provision of methadone, buprenorphine and naltrexone are the only FDA-approved medications for opioid use disorder potentially subject to prior authorization requirements. There is a lower risk of overdose with buprenorphine because there is a ceiling effect on respiratory suppression.[105]

If prior authorization requirements were removed, health insurance providers would then cover the full cost of MAT as a standard benefit and all requirements that a physician contact the insurance provider for approval prior to writing the prescription (a process called "prior authorization") are removed. Without these prior authorization requirements, prescriptions for MAT medications to treat opioid use disorder can be written and filled as soon as a physician deems this treatment necessary, free from artificial delays. Policy makers and healthcare providers should work collaboratively with health insurance companies and state Medicaid programs to design and implement this policy.

Reducing and eliminating barriers to prescribing buprenorphine to tread opioid use disorder is critical to ensure greater access and reduce opioid overdose deaths. As noted earlier, prior authorization requirements for buprenorphine represent a common barrier cited by prescribers that can delay or interrupt patient care. In a September 2019 report titled "National Spotlight on State-Level Efforts to End the Opioid Epidemic", the American Medical Association (AMA) Opioid Task Force recommended removing prior authorization and other barriers to medication-assisted treatment for opioid use disorder – and ensure MAT is affordable.[106] A 2019 survey of physicians conducted by the AMA found that 64% of physicians reported waiting at least 1 business day for a prior authorization decision from health plans, and 29% reported waiting at least 3 business days. For those patients whose treatment requires a prior authorization, the physicians reported that the process results in delays in access to care 91% of the time. Additionally, 24% of physicians reported that prior authorizations have led to a serious adverse event for a patient in their care, and 16% reported that a prior authorization has led to a patient's hospitalization. When asked how often issues related to the prior authorization process lead to patients abandoning their recommended course of treatment, 74% of physicians reported that a prior authorization can lead to treatment abandonment. While only 2% of physicians reported that the prior authorization process has a somewhat or significant positive impact on patient clinical outcomes, 90% reported the process to result in a somewhat or significant negative impact on patient care and health outcomes.[107] A study conducted in 2016 among a sample of New York City public sector buprenorphine prescribers found that medication prior authorization requirements were the highest rated barriers to practice.[108]

Florida Medicaid removed the prior authorization requirement for the first 7 days of treatment for the following medications to treat opioid use disorder: Buprenorphine single agent tablets, Buprenorphine/Naloxone combination tablets, Suboxone film, and Zubsolv tablets. However, a manual prior authorization is still required to continue treatment with these medications after the first 7 days, and a prior authorization is required to be submitted every 3 months in order to continue coverage of these medications. Additionally, the prior authorization requirement for naloxone was removed for up to one naloxone prescription per year under Florida Medicaid.

However, additional naloxone prescriptions within the same year still require prior authorization approval.

14. Promote legislation that adds the Secretary of AHCA and the Commissioner of the Office of Insurance Regulation as members to the Statewide Drug Policy Advisory Council.

AHCA is a health policy and planning entity for the state of Florida. AHCA serves as the single state agency responsible for the administration of the Florida Medicaid program, authorized under Title XIX of the Social Security Act. The Florida Medicaid program serves approximately 3.9 million Medicaid recipients at a cost of over $28 billion annually and has over 100,000 actively enrolled service providers. During state fiscal year 2017-2018, AHCA spent over $3 billion dollars on prescribed drugs through the Florida Medicaid program. AHCA shares similar goals with the Council and would be a valuable addition its membership.

The Office of Insurance Regulation (Office) is responsible for all activities concerning insurers and other risk bearing entities, including licensing, rates, policy forms, market conduct, claims, issuance of certificates of authority, solvency, viatical settlements, premium financing, and administrative supervision, as provided under the insurance code or Chapter 636, Florida Statutes, per https://www.floir.com/Office/AgencyOrganizationOperation.aspx. The Commissioner of Insurance Regulation who heads the Office would be a valuable member of the Council since the health insurance companies decide upon coverage and formularies affecting all of the residents of Florida. The OIR also places a significant role to ensure that Florida meets the requirements of the federal Mental Health Parity and Addiction Equity Act (MHPAEA).

15. Continue the statewide Recovery Oriented System of Care (ROSC) initiative designed to promote and enhance recovery efforts in Florida and support the continued development of recovery community organizations (RCOs) and a statewide RCO that helps link community initiatives.

Over the past several years, the Florida Department of Children and Families has led an initiative to transform Florida's substance use and mental health system into a Recovery Oriented System of Care (ROSC) which serves as a framework for coordinating multiple systems, services, and supports that are person-centered, self-directed and designed to readily adjust to meet the needs of persons served and their chosen pathway to recovery.

A ROSC is a network of clinical and nonclinical services and supports that sustain long-term, community-based recovery. As local organic entities, ROSCs reflect variations in each community's vision, institutions, resources, and priorities. Behavioral health systems and communities form ROSCs to:

- Promote good quality of life, community health, and wellness for all.
- Prevent the development of behavioral health conditions.
- Intervene earlier in the progression of illnesses.
- Reduce the harm caused by SUDs and MH conditions on individuals, families and communities.

- Provide the resources to assist people with behavioral health conditions to achieve and sustain their wellness and build meaningful lives for themselves in their communities.

Across the country, independent, non-profit organizations that are peer-led and governed by persons in recovery, family members, and recovery allies mobilize resources within the community to make it possible for the over 23 million Americans still struggling with SUD to find long-term recovery. Each organization has a mission that reflects the issues and concerns from within their community. These community groups, known as Recovery Community Organizations (RCOs), share three core principles – recovery vision; authenticity of voice; and accountability to the recovery community.

RCOs use three primary strategies to achieve their mission:

- Public education and awareness - putting a face and a voice on recovery to reduce stigma and educate the public, policy makers, service providers and the media that recovery is possible from SUD.
- Policy advocacy – to build recovery-oriented supportive communities, RCOs address public policy that eliminates discrimination against people in or seeking recovery and reduce barriers that keep persons seeking recovery from sustaining long-term recovery
- Peer-based and other recovery support services and activities – RCOs are innovating and delivering a variety of peer recovery support services and places to deliver those services, building a lasting physical presence in communities[109]

There has been a focus on the development of Recovery Community Organizations in Florida over the past several years. As a result of an Aetna Foundation grant to FADAA, RCO development activities have taken place in ten communities across Florida. Six of these organizations have completed the RCO development process and four are continuing to move through the development steps. Two additional communities have expressed a desire to begin the RCO development process. In addition, Floridians for Recovery, the statewide RCO, is working with key stakeholders in Putnam County to develop an RCO. These new and developing RCO's across Florida join the seven already existing RCO's bring the total number of RCO's in Florida fully developed or under development to twenty (20). In addition, Floridians for Recovery continues to build its capacity as the statewide RCO for Florida. Over the past year FFR received a Building Communities of Recovery (BCOR) grant from SAMHSA and FFR has established a Recovery Leadership Council engaging the leaders from all the RCO's in the state. A map displaying all the RCO's across Florida and a RCO locator with information on each RCO can be found on the Floridians for Recovery website at https://floridiansforrecovery.org/tst-locator/.[110]

16. Develop and implement a stigma reduction campaign designed to reduce the shame associated with substance use disorder and other mental illness/injuries. Messaging should increase the awareness of medically assisted treatment options, reduce the stigma associated with addiction, and inform the public of the many benefits that come with obtaining psychological and/or counseling services from a licensed professional.

~~(1)~~ Once a physician or mental health counselor has assessed and diagnosed an individual with a substance use disorder, they assist the client/patient in finding the best treatment. The mental healthcare provider develops an individual treatment plan that includes short and long-term goals for obtaining and maintaining their sobriety. Primary treatment goals often include evidence-based therapeutic modalities, medically assisted treatment, or a combination of the two.

Commented [MF4]: This paragraphs seems irrelevant to the recommendation.

Through ~~the~~ a stigma reduction campaign, Florida can (1) educate citizens on the benefits of recovery and (2) guide them in obtaining treatment. Parallel to this effort, Florida should continue to bring awareness to DCF's Overdose Prevention Awareness Campaign. DCF's initiative has educated Florida's citizens on the benefits of naloxone, the medication used to reverse opioid overdose. DCF also provides information on where individuals can access this medication within Florida. The targeted audience for this campaign should include high-risk populations, their friends, and family. Campaign materials include radio ads, interviews with key stakeholders, printed materials, and a website that allows individuals to search for the nearest naloxone distribution site in their area: https://isavefl.com/.

~~(2)~~ Individuals with a substance use or mental health disorder often experience three forms of stigma. These types include structural, public, and self-stigma. Societal norms and attitudes drive the first two types, while the third occurs when individuals internalize these negative opinions.[4, 5] Self-stigma causes lowered self-esteem, decreased self-efficacy, and amplified feelings of embarrassment and shame. As a result, stigma can impede an individual's willingness to pursue treatment, thus placing them at a higher risk for crisis and/or fatal overdose.

Through this process, Florida can (1) reduce the negative perceptions of addiction within the community and (2) increase the likelihood of an individual to seek out and engage in legitimate treatment.

With the development and deployment of a stigma reduction campaign, individuals suffering from a substance use disorder and the communities around them will gain a better understanding of addiction and the benefits of treatment.

17. Evaluate the impact of SB 1120 on agency background screening requirements related to the eligibility of individuals with lived experience/peers attempting to enter the workforce; continue efforts to reduce the administrative burden of the background screening and exemption process; promote consistency among state agencies related to the background screening exemption process; ensure an individual with lived experience is part of the exemption review panel; and have AHCA, DCF, and Department of Corrections to provide an annual report on the number of individuals that applied for an exemption, actual timeframes for the process and number approved/disapproved with reasons why.

The use of peers, individuals with lived experience, has grown significantly in Florida over the past five years. Research has shown that recovery from a substance use disorder or mental illness is facilitated by the use of social support provided by peers.[111] These individuals serve multiple roles which include recovery support navigator by assisting in transition from institutional setting (jail/prison) to the community; crisis support; peer wellness coach; employment support coach; housing support specialist; and recovery coach.[112] Peers are essential team members of Community Action Teams, Family Intensive Treatment Teams, and FACT teams. In addressing the opioid epidemic, peers serve a key role in emergency warm handoff programs encouraging, and at times transporting, individuals who have overdosed to pursue a treatment intervention. The 2019 Florida Legislature recognized the role of peers by codifying the definition of peer specialist in section 397.311, Florida Statutes.

Currently there is a shortage of peers working in behavioral health services. One barrier to the use of peer services is the fact that peer specialist~~s~~ candidates often cannot pass background screening requirements in sections 435.04 and 408.809, Florida Statutes. Persons who have recovered from a substance use disorder or mental illness often have a criminal history.

Common offenses would include using and selling illegal substances, prostitution and financial fraud. Section 435.04, Florida Statutes, allows persons with certain disqualifying offenses identified through background screening to apply to the respective state agency head (DCF, DC, and AHCA Secretary) for an exemption if it has been three or more years since their conviction. The applicant must provide all court records regarding their convictions (irrespective of how long in the past the offense occurred), letters of recommendation, evidence of their rehabilitation, education documents, evidence of employment, and fill out a questionnaire. The requirements of this exemption often deter persons from becoming peer specialists.[113]

Recent legislation, SB 1120, addresses individuals who have been disqualified from employment with a SUD treatment provider or recovery residence due to a disqualifying offense. The legislation requires DCF to exempt individuals disqualified during background screening for having committed certain offenses. As a result, more individuals with convictions in their past may be able to obtain certification as peer specialists and find employment in prevention and treatment and recovery programs. Also, private insurers and Medicaid managed care plans may see additional use of peer specialists.

Data Collection and Surveillance

18. Create a statewide dashboard of substance abuse data measures that are readily available to policy makers and the public and can be used to monitor trends and identify emerging threats.

A statewide dashboard of substance abuse data should be created in Florida Health CHARTS similar to the Opioid Use Dashboard: http://www.flhealthcharts.com/ChartsReports/rdPage.aspx?rdReport=ChartsProfiles.OpioidUseDashboard. Agencies should continue efforts to develop a more systematic and sustainable approach to linking data and developing indicators from existing datasets. This process will shift to the Behavioral Health Priority Area Workgroup which is established under the State Health Improvement Plan. This cross-agency workgroup covers mental illness and substance abuse issues and includes members from DOH, DCF and community organizations.

19. Encourage all counties and municipalities to implement the ODMAP system in locations and agencies that do not participate in real-time overdose tracking. Through wider utilization, law enforcement and non-EMSTARS fire departments can track suspected overdose activity throughout all 67 counties. Agencies can utilize information obtained through ODMAP to identify high risk areas, equip personnel for increased overdose activity, and to warn neighboring agencies of sudden overdose activity within their counties and/or suspected transit routes.

The Overdose Mapping System (ODMAP) has expanded to approximately 293 agencies located within 95% of Florida's counties. This is a significant increase as compared to early 2019, before the Seminole County Sheriff's Office (SCSO) received the ODMAP Statewide Expansion and Response Grant on behalf of Florida. The grant provides $750K to five sub-awardees executed over a 24-month period for further expansion of ODMAP. The five sub-awardees are Bay County Sheriff's Office, Pasco County Sheriff's Office, Charlotte County Sheriff's Office, City of Jupiter Police Department, and the Orange County government. SCSO will ensure the remaining funds are used to enroll new agencies into the ODMAP system. The SCSO has hired a grant coordinator ~~($60K annually)~~ to assist in facilitating ODMAP training and implementation within new agencies. There remains a large percent of Florida's many counties/municipalities that do not participate, nor benefit from the information obtained through ODMAP; therefore, many overdoses go unnoticed and the true expanse of Florida's opioid crisis remains undetected.

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