Alaska Opioid Policy Task Force
a partnership of the Advisory Board on Alcoholism and Drug Abuse, Alaska Mental Health Trust Authority, and Alaska Department of Health and Social Services

431 North Franklin Street, Suite 200
Juneau, Alaska 99801
907.465.8920

Alaska Opioid Policy Task Force Meeting Notes

July 22, 2016

Dr. Jay Butler convened the meeting at 9:10 a.m. He welcomed the group and explained that today's topic is harm reduction. Harm reduction is a tertiary prevention strategy designed to prevent the harms from drug use.

Kate Burkhart called the roll.

Catriona Reynolds and Dr. Sarah Spencer, MD – Homer Syringe Exchange Pilot

Dr. Spencer shared that they have hosted three evening syringe exchange events. The syringe exchange operates every other Tuesday. It has started slowly. Nine clients have come to the syringe exchange events and received services. Feedback from clients is positive; they are happy and thankful for the services. Community support has been "overwhelmingly positive." She expects a sense of trust will grow over the next few months, which will bring more clients and allow them to collect the information they need to determine the scope of an ongoing project.

Catriona Reynolds works at Katchemak Bay Family Planning Clinic. They are offering sexually transmitted infections (STI) counseling, testing (rapid HIV and Hepatitis C testing) at the syringe exchange events. This provides a venue for outreach, and helps people learn more about the clinic's health services. All of the syringe exchange participants are volunteers except the STI testing staff (paid by the clinic). That limits the hours and frequency of the syringe exchange events.

They have naloxone kits at the events, for clients with insurance. The kits have the medication, alcohol wipes, etc. needed to safely administer the overdose intervention medication. Dr. Spencer donated 10 kits, and community members donated the other four. The least expensive kits are $75 each, through a discount program from the maker of Narcan nasal spray.

All of the Homer Police Department officers have been trained in naloxone. Officers have used the kits once, administering to the overdosing person while waiting for the ambulance.

Dr. Spencer said the Homer City Council lifted the local ordinance banning drug paraphernalia, which might have prevented the needle exchange program from operating.

Jeff Jessee asked what the consumer experience is at the syringe exchange events. Dr. Spencer explained that the volunteers are trained (some have medical experience, some don't) to speak with the clients about the services available, as well as how to inject safely. It takes a while for people to trust enough to come in. People who have come said they feel safe there, and would recommend it to their friends. Jessee asked if anyone who comes is seeking treatment. Dr. Spencer said it's too early to judge, though a few clients have asked

for treatment information. Reynolds added that access to clean equipment makes a huge difference in their lives. People coming in recognize they can improve their health and well-being, even if they haven't decided to get treatment. Word is getting out about the service, and the atmosphere at the events. The family planning clinic just had a new client who shared that she came there because her friend had been treated so respectfully and without judgment at the syringe exchange event.

Heather Davis, Executive Director, Four A's

Four A's Syringe Access Program (FASAP) is open every day. FASAP provides needles, alcohol wipes, etc. and provides disposal services for used syringes and needles. They also provide other services (condoms, STI testing) as well as education. For example, clients sometimes need education for how to take care of wounds/abscesses (page 3 of powerpoint).

FASAP staff work to educate and support individuals in making better decisions; they do not tell people what to do. That is part of the harm reduction philosophy. Syringe exchanges do not promote drug use – they mitigate the harm related to drug use (like transmission of HIV or Hepatitis C). FASAP is seeing much more Hepatitis C than HIV (positive tests for HIV are rare).

Four A's participates in the local community council to ensure that the neighborhood understands the FASAP program.

Delia case study – FASAP provided strategies to help her stop sharing needles with her boyfriend.

FASAP provides needle disposal for clients. Some diabetics, etc. also drop off their needles for disposal. FASAP helps connect clients to health care services, understanding that not all practitioners are appropriate providers for people who are IV drug users.

FASAP provides rapid HIV tests to the community, but rapid Hepatitis C tests are reserved to FASAP clients.

FASAP provides education about how to prevent an overdose. Most clients do not have insurance, which puts naloxone out of reach.

Joshua case study – he was able to access clean gear while he waited nine months for treatment. He was able to get his STI testing prior to admission to treatment.

People coming into Anchorage (from rural communities) for other reasons come to FASAP. People come from the MatSu Valley, too. One person will collect thousands of needles for disposal, bring them in to FASAP, and then take thousands of needles back to MatSu.

Four A's has seen a dramatic increase in the demand for services, nearly doubling in FY2016 (page 14 of the powerpoint). This is because so many people start with prescription opioids. In FY16, FASAP clients were 57% male and 43% female, and most were under age 40 (pages 16-17 of the powerpoint). This is a "white" epidemic, nationally and in Alaska (page 18 of the powerpoint).

Four A's is seen as a statewide expert on syringe exchanges. Communities want to create their own programs. Money (or lack of money) is a barrier to program development. Funds for supplies is extremely limited, and often comes from HIV Prevention funds (which are limited). Skyrocketing demand is affecting all the organizations that fund HIV/AIDS prevention and service programs, which means there is less money to go around.

Linda case study – A regular client suddenly disappeared from the program. She'd not been in because she'd been clean for a month. She and her boyfriend quit together. They'd been doing well, until the day before she came in. They decided not to use because they had no clean gear. They waited until the next day, until they could get to FASAP, and by then were able to manage the craving. They are still clean.

Question & Answer:

Dr. Coleman asked if syringe exchanges have ever been combined with Assertive Community Treatment style services (street outreach models). Davis answered "not in Alaska." FASAP refers out for behavioral health treatment. Reynolds added that Homer considered a mobile exchange, but had space donated. Davis said they tried to get a van so they could get to MatSu. Her concern is that people worry about being seen at a needle exchange, so might be less likely to use a mobile/van exchange.

A member of the public asked about how they dispose of the needles and syringes. Neither program has their own incinerator, so they package it as medical waste and pay for a medical disposal service (Anchorage hospitals won't take it, but Bartlett Regional will in Juneau). A registered disposal unit comes and takes them from Four A's.

Elizabeth Ripley asked what their actual disposal costs are. Davis estimated it's about $10,000. Eric Scheunemann said there are only two private registered medical waste disposal companies in Alaska (in Anchorage and Wasilla).

Dr. Butler shared a disposal tube that was distributed in Juneau as an option (though expensive – one or two dollars each). Davis said they encourage people to bring them in to FASAP in a disposal container, but some bring in loose needles.

Davis said that last year they collected more needles than they gave out, which is a good outcome.

Ripley asked what training FASAP staff receive. The FASAP program manager is a nurse. They have volunteers, including nursing students, who staff the program. Everyone gets a half-day training and is paired with staff until such time as they are determined to be ready to work on their own. Some never develop the empathy needed for the program, and so they are moved on to something else.

Dr. Tina Woods asked if FASAP has relationships with communities where clients come from. Davis answered only when communities call them.

Katie Baldwin-Johnson asked if they teach people how to clean their needles. They do, but many people don't have the capacity to do that safely.

Davis commented that FASAP clients appreciate the attention and care the staff show them. They often feel isolated.

Dr. Coleman asked if FASAP uses motivational interviewing to guide people toward treatment. FASAP focused on serving the person where they are, rather than guiding them toward any particular outcome. Dr. Butler commented that these programs seem more effective when delivered holistically.

Kelly Henriksen, Department of Law

Henriksen is an assistant attorney general with the Alaska Department of Law. She provided an overview of SB 23.

SB 23 makes naloxone and other overdose prevention drugs more available to the people who really need them. It provides civil immunity for the prescription or administration of the overdose medication. It also adds pharmacists to the list of people who can provide or dispense naloxone.

The civil immunity extends to a medical provider or someone working in an opioid overdose program who prescribes or provides the medication to a person who has been trained in administering the medication. The civil immunity also extends to the person who administers the medication to someone in an emergency situation. Liability for acts of gross negligence, reckless disregard, or intentional harm is not precluded under SB 23.

There may be some discrepancy in the language of the bill as to who can prescribe naloxone, given that some professions in the list do not have authority to prescribe under their licensure. SB 23 permits a standing order or prescription for naloxone.

The Board of Pharmacy must establish standards and training, after which pharmacists can become eligible to dispense naloxone.

Anna Nelson asked if anyone has ever been sued for administering naloxone. No one knew of any. Nelson and Kate Burkhart spoke to the fact that the medication doesn't cause

adverse reactions. The conversation during the SB 23 deliberations was that there have been no documented cases of adverse reactions for a properly administered dose (whether the person was overdosing or not).

Dr. Butler commented that the perception there might be liability was a barrier to prescribers. SB 23 addresses that. Erin Narus added that prescribers might have worried about prescribing the medication being seen as enabling drug use. Commercial availability of the medication is new, which increases demand and access. There were also concerns about the medication being used to prey on vulnerable adults.

Andy Jones, Chief of Emergency Programs, Division of Public Health

Project HOPE is an initiative of the Division of Public Health (DPH), created to reduce overdose deaths. The focus is on educating first responders – "opioid overdose first responders" (not just EMTs).

Education is important, but you also need to provide equipment (or access to equipment). They want to join networks already engaged in opioid overdose prevention efforts, with a focus on five local communities (identified through data) and the Alaska State Troopers. Outreach, education, and prevention efforts are being coordinated with other organizations. DPH has created an internal task force with the Division of Behavioral Health (DBH).

Project HOPE can teach people about what an overdose is and how to respond (basic first aid, calling 911). People are afraid to call for help – community EMT and community policing models will help address that fear. Project HOPE is working with local departments on this. Project HOPE provides outreach and education to shelter workers, too.

Project HOPE is tailoring concise education materials (10 minutes) to reach the "people on the street." What is an overdose, what causes an overdose, how to prevent an overdose, how to recognize an overdose, how to respond, and what aftercare is needed are covered in the materials. The messages are simple and straightforward. The materials will be in multiple formats so they can be used in various communities.

Project HOPE includes a naloxone distribution program. They want to put naloxone in the hands of "opioid overdose first responders." Naloxone is the first step to saving a life, like a tourniquet. It has to be followed by care.

Community based naloxone distribution efforts are underway. Project HOPE has the goal of providing the kits to the communities. Project HOPE has been talking to community and law enforcement leaders to address attitudinal barriers to distribution, and hasn't encountered any negative feedback.

Naloxone distribution programs aren't easy to put together. Pre-made kits are more expensive; making a kit is work. DHSS is exploring a standing order from the Chief Medical Officer to allow the department and partners to distribute naloxone. Prescriptions from providers are good, but many people won't go to see a doctor to get the prescription (due to stigma, fear, etc.). Standing orders from DHSS or a medical director at an agency allow program staff to distribute the medication/kits.

Project HOPE is looking at buying and assembling the medication (nasal form) in kits, using with federal funds. They are also looking at providing training tools so communities don't have to each do it on its own. They expected to have to build community buy-in, but that seems to already exist.

SAMHSA has $1,000,000 grant awards available to eleven states for programs like Project HOPE. Alaska has applied for one of these grants, and will know in the next month if it is receiving a grant.

Jones shared samples of the nasal spray and explained how safe it is. He spoke about how they will need to tailor the kit to the user. For example, troopers need a "lean and mean" kit that they can carry even when it's cold (the medication freezes). Jones shared a sample kit that might work for a trooper.

Kits need to prioritize calling 911 as a first step. They need to be designed so the user goes to the most important information first. They need to be practical for the environment (for example, don't use paper education materials if they are going to be used in homeless camps where they can get wet). Jones also explained that costs need to be balanced with practicality.

Jones echoed Henriksen's comments about ensuring that people are acting within the scope of practice when prescribing, dispensing, and administering naloxone.

Project HOPE will have a website full of resources for partners and the public.

Additional information:

- The Division of Public Health has an extensive website on heroin and opioids. Go to http://dhss.alaska.gov/dph/director/pages/heroin-opioids/default.aspx to see the information and resources.

Question and Answer:

A member of the public asked what the shelf life of a naloxone kit is. Jones and Scheunemann answered 18 months to two years. DPH has the capacity to store and manage inventory effectively.

Dr. Butler asked what would happen if the federal grant isn't awarded. Jones answered that they would continue to look for funding, because it's a priority for the department.

Narus asked how, if the FDA made the Narcan nasal spray a restricted over the counter medication, that would change the distribution plan. Jones answered that under the current model the easiest way is a standing order/prescription.

Task Force Member Discussion:

Are there issues statewide or in other communities about drug paraphernalia prohibitions, like described by Homer? There isn't a statewide statute, but there might be local laws. No one was sure. Ripley said she would check what the laws in MatSu are. Nelson said she wasn't sure what the Fairbanks law is (though they've run their syringe exchange for 26 years). She said that if the paraphernalia is in a medical biohazard box, law enforcement officers don't act on it or use it as evidence (and often call Interior AIDS Association to come get a box if found at a crime scene).

Ripley asked Henriksen if there is anything missing from SB 23. Henriksen hasn't looked at other states. She does think SB23 could have given more power to dispense the medication to other health care professionals than pharmacists.

Burkhart commented on the need for clarity around what "education and training" is needed on administration of the medication. The legislative hearings focused on workshops and training events rather than the way health care professionals usually educate people about how to use medications (usually done quickly and simply by pharmacists, prescribers, etc.). Jones agreed, noting that other similar emergency FEMA trainings are online, quick, and have a certification after. Dr. Butler added there are online video resources for patient education.

Ripley asked if there were statutory best practices we could look at. Burkhart said that could be pulled together.

Narus asked if someone was attempting suicide by overdose, and was prevented from overdose by someone administering naloxone, could they sue? Henriksen said there was no cause of action for "wrongful life."

Dr. Butler asked if the price for the naloxone products has gone up, particularly the talking self-administering unit. Narus said it's gone up exponentially ($3600/unit?). The nasal spray has remained more steady. What people are paying for is the new delivery mechanisms and not the medications. Dr. Butler commented that it seemed unfair to have medications to address public health crises become prohibitively expensive. Narus agreed. Jessee said we should bring this up with the federal officials. Senator Grassley is very vocal about this issue.

Additional information:

- S.3056 CREATES Act (Leahy, Grassley, Klobuchar, Lee)

  Summary (from Sponsor):

  The Creating and Restoring Equal Access to Equivalent Samples ("CREATES") Act targets abusive delay tactics that are being used to block entry of affordable generic drugs.

  Sample-sharing. The first delay tactic addressed by the CREATES Act occurs when brand name drug companies prevent potential generic competitors from obtaining samples of the branded product, so the generic company cannot perform the testing necessary to show that its product is equivalent to the brand-name product, a prerequisite for FDA approval.

  Participation in a shared safety protocol. The second delay tactic addressed by the CREATES Act occurs when brand-name manufacturers whose products require a distribution safety protocol (known as a Risk Evaluation Mitigation Strategy with Elements to Assure Safe Use, or "REMS with ETASU") refuse to allow generic competitors to participate in that safety protocol, again undermining the generic's ability to gain FDA approval.

  The CREATES Act allows a generic drug manufacturer facing one of these delay tactics to bring an action in federal court for injunctive relief (i.e. to obtain the sample it needs, or to enter court supervised negotiations for a shared safety protocol). The bill also authorizes a judge to award damages to deter future delaying conduct.

  The CREATES Act is intended to provide an efficient, tailored path for generic drug manufacturers to obtain relief so they can continue working to bring their lower-cost product to market. The Congressional Budget Office has estimated that similar legislation would save the government over $2 billion in direct savings over 10 years. The savings to consumers and private insurance companies would likely be far greater.

  Leahy Sponsor Statement

  Listen to the June 21, 2016 Judiciary Hearing on the Bill

Burkhart asked how the efforts described today will include or should include people receiving opioid medications. Dr. Butler said the new CDC guidelines encourage physicians to prescribe/educate on naloxone. Narus said that Medicaid does not require prior authorization for naloxone nasal spray (and there is no requirement of having an active opioid prescription, but medical necessity is still required). They are adding a flag on the third naloxone dispensing in a year, alerting the pharmacist to the extreme risk of death and

promoting a conversation with the prescriber about how to support the patient. This is a "parachute mechanism" to identify the highest risk patients in the Medicaid system. Nelson asked if they had considered that they might not be the one using the naloxone. Narus said yes, and they felt that there was still a need to do something at that point to balance prevention and medical necessity.

Additional information:

- New guidance from Alaska Medicaid on Naloxone Opioid Overdose Treatment, effective September 7, 2016, provides that the pharmacy can fill two naloxone prescriptions per year. When a second refill (third dispensing) is requested, the Medicaid claim will be rejected with direction to the pharmacist to contact the doctor, document the conversation including any changes to the medication regimen, and then override the rejection.

Ripley asked if we need to have a memorandum of agreement with hospitals statewide to accept needles and syringes as medical waste for the next three years or so, while we hopefully bend the curve on the opioid prescribing and use. She also asked what state public health centers could do to support the effort. Ripley explained that the first time she was approached with the idea was years ago, when Four A's was noting an increase in Hepatitis C in the MatSu Valley. That didn't go anywhere.

Four A's works closely with the public health center in Juneau. Can a syringe exchange operate at a public center? Dr. Butler commented that naloxone distribution is more aligned with the mission and work of the public health centers. Syringe and needle exchanges would be a different client population from the current pregnant women and children that are most often seen. It would require staff training and buy in to adjust to serving active IV drug users. He's open to exploring it.

Davis commented that you have to a space and staff with which the clients are comfortable. Jessee commented that policy decisions can't be based on staff discomfort. Dr. Butler said that stigma is an issue, as seen in the progression of AIDS services. Many people go into maternal and child health because they want to serve mothers and children, not to serve people with substance abuse disorders. Jessee responded that integration is changing the world of health care, and that people have to be willing to do the work of the organization. He also spoke about his personal experience with stigma around substance use disorders in the public health field. Dr. Butler said that health care providers have expectations about their practices (a pediatrician might have an opinion on having a needle exchange in the practice). Dr. Coleman said that there are ways to help health care providers come around.

Nelson commented that many IV drug users are not connected to health care providers. And many do not "look like what you think they do" so assumptions need to be checked. Davis agreed and said that their clients don't look like what people would think they do. And they are getting 80-90 new clients a month. Jones said he encounters the stigma and opinions discussed here, which indicates the need for education. Dr. Butler said health care providers' knowledge and education about addiction is lacking, despite the emphasis on integration of care.

Dr. Woods reminded the group about the presentation from Dr. Sonkiss about the science of addiction and the way medication assisted treatment works, and how effective that education is for other health care providers.

PUBLIC COMMENT

No public comment was offered.

Discussion of Federal Actions to Recommend:

In preparing for the Opioid Summit being hosted by Senator Sullivan on August 4, and the possible opportunity to meet again with federal officials on August 5, there was discussion of what to recommend.

- FDA making naloxone and other overdose medications over-the-counter (OTC) instead of prescription.
    - Narus cautioned if it's only OTC, then Medicaid might not be able to pay for it without changes to state plans.
- Expand licensed professionals able to participate in MAT, not just the numbers of patients a physician can see.
- Support efforts to expand access and resources to MAT and encourage adding psychosocial treatment as part of the treatment model – peer support, too.
- Incentivize health care professionals to specialize or get training in addictions (loan repayment, scholarships with service requirements, etc.).
- Team up with Senator Grassley's efforts (Narus will help frame that).
- Are there federal background check issues to be addressed?
    - Workforce (peer support)
    - Ban the Box issues that prevent people from getting meaningful employment
        - Dr. Coleman cautioned that it could be a sticky issue – we should dig up evidence first.
- Prescription Drug Monitoring Programs
- Look for options that promote communications between state systems (standardized prescriber IDs, reporting structures)

- Integration of Care -- more resources and more education for providers in those settings.
- Require education on addictions in federally funded residency programs.
- Continue to expand support for collaborative care – with funding streams to support it.
- Amend the IMD Exclusion to allow residential substance use disorder treatment.
- Revive the Safe and Drug Free Schools program and funding.

These ideas will be further developed and sent to task force members for comment prior to Senator Sullivan's Wellness Summit on August 4, 2016.

Jeff Jessee closed the meeting at 12:11 p.m.