

Centers for Medicare & Medicaid Services
Special Open Door Forum:
Sharing Federal Strategies to Address the Opioid Epidemic
Wednesday, August 15, 2018
Moderator: Jill Darling
1:30 pm Eastern Time

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. Today's call is being recorded. If you have any objections please disconnect at this time. I'd now like to turn the call over to Ms. Jill Darling. You may begin.

Jill Darling: Thank you (Ted). Good morning and good afternoon everyone. And I'm Jill Darling in the CMS Office of Communication. And welcome to today's Special Open-Door Forum Sharing Federal Strategies to Address the Opioid Epidemic. Before I hand the call off to one of our speakers today I have one brief announcement. The special open-door forum is not intended for the press and the remarks are not considered on the record. If you are a member of the press you may listen in but please refrain from asking questions during the Q&A portion of the call. If you have any inquiries please contact CMS at press@cms.hhs.gov. And now I will have a call over to Jeane.

Jeane Nitsch: Thanks. Let me again welcome you to today's special open-door forum. My name is Jeane Nitsch. And I'm the Director of the Division of Compliance Projects and Demonstrations here in the Centers for Medicare and Medicaid Services. I'll be helping to facilitate today's discussion. We are so fortunate to bring together representatives from the Center for Medicare and Medicaid Services, the Office of the Inspector General, the Centers for Disease Control and Prevention, the Food & Drug Administration and the Substance Abuse and Mental Health Services Administration to discuss several strategies to address the opioid epidemic.

We have a full agenda but we're hoping to have time to take questions from the audience at the end. So at the end we will let you know how to do that. So when we get to the Q&A portion we'll announce how to call in. So without any further delay let me introduce a very special guest we have joining us, we are fortunate to have Kim Brandt with us. Ms. Brandt is the Principal Deputy Administrator in the Centers for Medicare and Medicaid Services. She works on a range of key crosscutting initiatives including CMS's approach to addressing the opioid crisis. Ms. Brandt will kick us off and provide a general framework for CMS's focus on this issue and how the agency coordinates with the department and other agencies we have with us today. So I'll turn it over to you.

Kim Brandt: Great. Thanks Jeane and good afternoon everyone. We really just want to thank you and we're heartened by the huge response we have. I think at last count we had nearly 1000 people on the phone and are very excited to have so many of you helping attend this special open-door forum today because this really is an important topic as we focus on the opioid epidemic which is currently facing our country. As Jeane mentioned I serve as the Principal Deputy Administrator here at CMS. And one of my roles is to work on crosscutting projects including the opioid epidemic. And that includes working with our counterparts from other agencies such as other agencies within the Department of Health and Human Services who you'll hear from today to help coordinate our efforts.

Some of those agencies including the Centers for Disease Control, Food and Drug Administration, Substance Abuse and Mental Health Services Administration and the Offices of Inspector General have been very good partners with us as we looked at ways to collaborate and work across the HHS

family to really think of new and creative ways to help be able to bring more resources and more solutions to bear on this important epidemic.

From a CMS perspective you're going to hear shortly about how we formulated a strategy that's been based on feedback from a wide variety of health system stakeholders in coordination with the broader administration focus on this issue. Secretary Azar has made the opioid epidemic one of his top areas of focus and we have taken the charge very seriously at CMS and have tried to focus our efforts accordingly. However the best part of our work thus far has been the public input that we had. And a lot of our strategy is going to continue to be refined based on that public input.

We also have looked at the Congressional focus in conversation like the types of stakeholder listening sessions that we've had to allow us opportunity to share our key initiatives and hear questions or concerns from you. In fact many of our stakeholder input to date has helped shape a lot of the initiatives that we've gone ahead and decided to focus on as CMS. As prescribers you all are important partners in these efforts and strategies to help prevent and treat opioid use disorder.

By the end of the session today our objective is that you will you hopefully first gain a high level understanding of the various activities occurring across CMS and other HHS agencies. And second take away some ideas or tactics that could be applied on a local level to amplify the strategies to address the opioid epidemic. Thank you again for your interest in this topic and we'll kick it off with the presentations since I know we have a lot to get through today.

Jeane Nitsch: Thanks so much. We really appreciate you taking the time to be with us today. Next up we have Devon Trolley (unintelligible) and managing the key opioid

initiative. Ms. Devon Trolley will discuss the key components of CMS's strategy for addressing the opioid epidemic, so Ms. Trolley.

Devon Trolley: Great thank you. So first of all just note that CMS did publish our roadmap to address the opioid epidemic that highlights some of the areas I'll talk about today. So for folks who are interested in reading through that in more detail you can go ahead and find that on our Web site but I'll hit on some key themes today to kind of set the stage. So the main three areas that CMS is focused on are prevention, treatment and data. So I'll walk through each of those to give you a little bit more detail about what those encompass.

First prevention which really is focused on preventing and reducing opioid use disorder by promoting safe opioid prescribing and encouraging non-opioid pain treatments, the second category of treatment is really focused on increasing access to evidence based treatments for opioid use disorder and the third category of data is focused on leveraging CMS data to target prevention and treatment efforts and to also support fraud, waste and abuse detection as well.

So first under prevention, the key theme around prevention is that in 2016 an estimated 11.5 million people misused prescription opioids which puts them at higher risk for dependence on prescription opioids and developing opioid use disorder. Further over 40% of all opioid overdose deaths involve a prescription opioid. Across Medicare and Medicaid two of our programs many patients rely on prescription opioids to manage pain which creates a responsibility for CMS as a payer to ensure that prescriptions are not misused.

So that's the goal of our prevention work is to promote pain management using a safe and effective range of treatment options to address the unique needs of each patient. We're doing this in a couple of ways. First we're

focused on reducing the volume of prescription opioids particularly at high levels that are above evidence based recommendations and that put patients at a higher risk of developing an opioid use disorder.

Already in a Medicare prescription drug program we've implemented policies that promote safe opioid prescribing practices many of which are consistent with the CDC recommendations and focusing on these has resulted in a 40% decline in the number of Medicare beneficiaries who received higher than recommended opioid doses from multiple doctors.

Moving forward we're building on this progress to implement additional policies starting in January 2019 some of which you may have already heard of through the regulations and call letter for this published earlier this year. One change adjusts the default fill of prescription opioids for acute pain to seven days. And this is specific to opioid naïve patients who have – who are not currently using prescription opioids but are at the time receiving a prescription opioid prescription. And another policy directs pharmacists to coordinate with the prescribers when a patient has received multiple prescriptions that result in a higher than recommended dose. It's our hope that these policies really address the issue of prescription opioid volume and prescribing that – prescribing patterns that are above the recommended level as based on evidence.

The second main way that we are focused on prevention is to promote non-opioid alternatives to pain management. We're highly cognizant at CMS that many patients rely prescription opioids for pain and we do not want reductions in opioid prescribing to negatively impact pain management. We have a few levers that we're using to explore this area. One is that we're looking at coverage of non-opioid pain management alternatives but also we're leveraging projects like those led by one of our quality improvement

organizations that work with ten Colorado hospitals on non-opioid pain management and saw a 36% reduction in opioid use and a simultaneous 31% increase in alternative medications over a six month period. We're continuing to work with providers and prescribers to find solutions that work on the ground and plan to disseminate best practices to forums like this one and other communication channels. Safe prescribing practices and non-opioid pain management are areas that prescribers in particular will be essential partners. So that sums up the main activities on our prevention bucket.

The second area is treatment. And what we're really focused on here is that nationally over about 2 million people suffer from opioid use disorder which is characterized by an opioid user's unsuccessful effort to cut down or control opioid use or opioid use resulting in social problems and a failure to fulfill obligations at work, school or home. And while treatments exist estimates show that only about 20% to 30% of people with opioid use disorder received evidence based care like medication assisted treatments and counseling.

The goal of our treatment effort is to expand access to these such treatments, we're doing this in a few ways. First we're looking at ways to expand coverage for medication assisted treatment which includes things like buprenorphine, methadone and Naltrexone and also the overdose reversal drug Naloxone to better programs including Medicare and Medicaid and the exchanges. We're also keeping an eye on rural areas as we know this could be a problematic area as well.

A couple of examples so we are working very closely with state Medicaid agencies to improve their beneficiary access to medication assisted treatment through substance use disorder demonstrations. You may have heard of these as 1115 waivers as well. About a year ago CMS announced additional state flexibility to cover a comprehensive range of opioid use disorder treatment.

And we now had 15 states take advantage of these flexibilities with approved waivers, and we continue to discussions with additional states.

One example of success is Virginia's Medicaid demonstration that significantly improved access to treatment by increasing reimbursements. It led to a 49% increase in people accessing opioid treatment services and a 39% decrease in opioid related emergency department visits in the first five months. We also continue to look at other flexibilities to expand access to treatment in Medicare especially through flexibilities in innovative (PMM) models that we could potentially implement. Many of the successful opioid use disorder treatment models we've seen have acquired commitment from across the entire system of care from hospitals, to primary care physicians to behavioral health service providers. This cross system coordination will be a key element that will continue to encourage the best practices and payment policies moving forward.

Finally under our last category which is data we believe the data is critical to monitor the success of interventions and to help us target our policies and outreach. The goal of our data effort is to use data to better identify patients at risk of opioid use disorder and to target areas most in need of prevention and treatment efforts. We work regularly to share Medicare data with prescription drug plans and prescribers to help people identify patterns of potential misuse as early as possible. For example we regularly share information with prescription drug plans are about Medicare prescribers who prescribe higher levels of opioids than their peers and have also shared this information with the prescribers directly as well.

We've published detailed geographic data of Medicare prescribing habits down to the county level to help others target prevention and treatment efforts within their communities. And finally we're looking forward to gleaning

additional insights from data submitted by Medicaid agencies as more becomes available through a recent standardized reporting system. So that summarizes our key efforts under again prevention, treatment and data which really underlies the first two.

As CMS undertakes all these efforts we know we are just one piece of the solution. This is a complex issue that will take attention and coordinated effort from across the entire medical system and beyond to have a meaningful impact on the opioid epidemic. We look forward to continue our work with partners such as yourselves across the healthcare system to develop solutions, share best practices and implement changes that will effectively address this national epidemic Thank you.

Jeane Nitsch: Thank you. Prevention and treatment and data really are such important issues to address in this opioid epidemic. I thank you for being here. Also you had mentioned the CMS opioid strategy. I just want to mention to those on the phone I was able to easily find that by just googling opioid, CMS opioid academic roadmap, And it came right up so if you're looking for more information that's an easy way to find it, so again just Google CMS opioid epidemic roadmap.

Okay our next presenter is Dr. Julie Taitsman. Dr. Taitsman is the Chief Medical Officer for the US Department of Health and Human Services Office of the Inspector General. As Chief Medical Officer Dr. Taitsman is OIG's primary resource on clinical and scientific issues and lends medical expertise to audits, evaluations, inspections and enforcement actions. Dr. Taitsman founded OIG's Quality of Care workgroup to foster collaborations across the agency's multiple components. And she also leads OIG's Physician Education Initiative to prevent fraud, waste and abuse. Dr. Taitsman's out in the field today on an investigation and don't worry we won't ask you where you are

but we'd like to thank you for stepping away and joining us for our forum. So Dr. Taitsman I will turn it over to you.

Dr. Julie Taitsman: Thank you very much for that introduction. And thank you also to CMS for hosting this open-door forum and thanks to all of you for taking the time to participate today. Combating opioid misuse is a top priority for the Office of Inspector General. At OIG we often talk in the negative. We'll say things like preventing opioid misuse instead of promoting opioid appropriate use. And that's because we're an oversight agency. We don't run the programs but we try to protect the programs from fraud, waste and abuse and promote economy and efficiency.

So you'll hear me talk all about combating misuse but please don't take that the wrong way OIG supports appropriate opioid use and we are not trying to cut off access for patients who need pain relief or make doctors afraid to treat their patients pain how they feel most appropriate. OIG recognizes that pain management is a critical need for many beneficiaries and we understand that appropriate opioid use can be a useful component of an effective pain management regimen. However misuse can be extremely dangerous not just for the individual beneficiary but also for the community especially when potentially dangerous drugs are overprescribed or diverted for illicit use.

OIG also supports promoting access to good quality treatment for drug abuse and addiction as a key component of any successful strategy to combat the opioid epidemic. And I was so gratified to hear the previous speaker talking about medication assisted therapy and other treatments. Law enforcement tools are a big part of our strategy to combat the opioid epidemic but law enforcement is not the only part. Another part of our strategies behavior change, changing how doctors and other healthcare professionals prescribe medications and changing how patients seek and take medications. I will talk

about law enforcement first that's our main tool to combat the true bad actors, the folks running pill mills and committing other crimes involving opioids and potentiator drugs. We pursue criminal, civil and administrative actions against doctors and pharmacies that run pill mills and against other individuals who divert opioids and take prescription drugs to sell on the street.

A big success was our 2018 National Healthcare Fraud Takedown. OIG worked with our law enforcement partners to bring charges against 601 defendants for fraud involving improper opioid prescribing or dispensing or other practices that could harm patients. As part of the takedown OIG sent exclusion notices to 587 individuals. Exclusion is a way to protect the Medicare and Medicaid programs and protect program beneficiaries from harm by keeping known bad actors from participating in those programs, so an excluded doctor or an excluded pharmacist can't bill federal health care programs and can't harm Medicare and Medicaid beneficiaries going forward.

Another role for law enforcement is stopping some frauds related to treatment. The people engaged in these frauds steal money from taxpayers but these frauds can be particularly cruel when they prey on individuals with substance use disorders who are trying to get help and the frauds work to trap those people in the cycle of addiction. We have found some schemes where bogus treatment facilities or ancillary service providers like urine drug testing labs pay kickbacks to fraudulent sober living facilities to get them to bring their residents for treatment or testing. But instead of working to help these patients recover the fraudsters work against that goal and try to keep the beneficiaries addicted so they can keep billing their insurer for drug testing and other services.

We talk a lot about partnerships. And partnerships are very important. We look at what different skills and resources each entity can bring to the table

and how OIG can be a valuable partner. OIG combines powerful data analysis capabilities with our boots on the ground auditors, investigators and evaluators. So we thought about what we could do to best help our partners in both the public and private sectors folks who operate health insurance plans, and process prescription drug claims, physicians who prescribe opioids, pharmacists who dispense opioids and other healthcare professionals.

This process led us to develop several innovative products the stray pretty far from what many people think of as a traditional law enforcement role but given our unique access to crosscutting data we were uniquely positioned to create these new resources. The results were several data briefs that shed light on the scope of the problem and a toolkit to identify patients at risk of misuse or overdose. We published two data briefs on opioid use in Medicare one this summer and one last summer. The 2017 data brief is entitled Opioids In Medicare Part D, Concerns About Extreme Use and Questionable Prescribing. And the 2018 data brief is entitled Opioid Use in Medicare Part D Remains Concerning.

As I mentioned OIG is oversight and we often talk in the negative so we don't create resources on how to prescribe opioids correctly and no one needs that from us any way you have CDC for that. Instead we produce resources on how to identify when opioids are prescribed incorrectly. And our data briefs do a great job of that. We found that one in three Medicare beneficiaries was prescribed an opioid. One in three is a national figure. We also provide a breakdown by state. The lowest states were Hawaii and New York where it's about one in five Medicare beneficiaries and the highest were Alabama and Mississippi where it was closer to half getting opioids.

CDC published guidelines recommending prescribers use caution for dosages of 90 milligrams or more of morphine a day. In the data brief from this

summer we found about 460,000 beneficiaries received high amounts of opioids. We considered high amounts to be 120 milligrams a day for more than three months. And we found 71,000 beneficiaries were at serious risk, 58,000 beneficiaries had extremely high amounts of opioids that's more than 240 milligrams a day for the full year and 15,000 were doctor shopping, they had high amounts of opioids from four or more doctors and four or more pharmacies.

We found a few real extreme outliers. One beneficiary obtained 101 opioid prescriptions from 26 different prescribers and filled those scripts at 28 different pharmacies obtaining over 10,000 pills over the course of the year. We also identified 300 prescribers with questionable prescribing patterns that merited follow-up. These numbers are down a little from the data brief in summer 2017 so that's a little bit promising. Medicare spending actually dropped significantly between the two data briefs. It dropped from \$4 billion in spending for 2016 to \$3.4 billion in spending for 2017. But most of that drop was accounted for by decrease in price of the drugs and less so from decreasing utilization. We are also developing data to shed light on opioid use in Medicaid. Our first report looking at use in Ohio is posted on our Web site.

Another resource we developed is the toolkit using data analysis to calculate opioid levels and identify patients at risk of misuse or overdose. The toolkit is a practical guide. The target audience is Part D plan sponsors, private insurers and Medicaid fraud control units. The toolkit is highly technical and includes programming code and instructs how to program systems to identify patients at particular risk for opioid misuse so that they can target the appropriate intervention. The data briefs and the toolkit are available on our Web site as is more information about the 2018 takedown and other law enforcement actions. I look forward to hearing from the next speakers.

Jeane Nitsch: Well thank you so much Dr. Taitsman. Since you won't be able to join us at the end for the Q&A portion I hope you don't mind if I pose a question to you. You mentioned about doctor shopping and the data brief found about 15,000 patients were doctor shopping and that was probably a lot more than we really even know. What does the OIG recommend to prevent doctor shopping?

Dr. Julie Taitsman: Right. And we put a real high threshold on that. So four prescribers and four pharmacies and high amounts from each and that doesn't capture the beneficiaries that are savvy enough to pay for their prescriptions in cash. So, you know, as I mentioned spending has gone down opioid prices have gone down if beneficiaries pay in cash they're not captured in the data. So one of the suggestions we've had and that CMS will be adopting is lock in, and that's been successful in Medicaid in the past.

And what lock in means is when you identify beneficiaries who are at high risk you don't cut off their access to care but you manage their care in a certain way like requiring that they only see certain providers, certain prescribers, certain physicians or fill their scripts at certain pharmacies as a way to control and better manage what they're getting. So it makes sure that they get the care that they need but cuts off one way of abusing the system to get multiple prescriptions from multiple providers who may not have information about each other and not have appropriate ability to coordinate care.

Jeane Nitsch: That's great. Thank you. Does that lock in occur through the Prescription Drug Monitoring Program or it's through a different program?

Dr. Julie Taitsman: We won't be operationalizing that so...

Jeane Nitsch: Oh okay.

Dr. Julie Taitsman: ... (unintelligible).

Dr. Julie Taitsman: So I can check in on that one.

Jeane Nitsch: Okay.

Devon Trolley: So that will be implemented through the Medicare Prescription Drug Program. So that will be the Part D the prescription drug plan that will be implementing that...

Jeane Nitsch: Okay.

Devon Trolley: ...starting in January 2019.

Jeane Nitsch: Great okay. Well thank you Dr. Taitsman. We know you have to get back to work. We still appreciate your time today. Now joining us is Dr. Jan Losby. Dr. Losby is the team lead for the Opioid Overdose Health Systems team at the Centers for Disease Control and Prevention, Division of Unintentional Injury Prevention. Dr. Losby is responsible for advancing and implementing CDC's Guideline for Prescribing Opioids for Chronic Pain, conducting applied health system research and building scientific evidence to support state, community and tribal efforts to address the opioid overdose epidemic. So Dr. Losby I'll turn it over to you.

Dr. Jan Losby: Great, thank you so very much. And thank you for the opportunity to be a part of this forum and to address this important public health issue. CDC's work is organized into five pillars and complements much of the work that the other federal agencies on today's; call CMS, FDA, OIG and SAMHSA are also highlighting. I'll touch on each of our pillars briefly just to give you a sense of

our work and then I will turn to some resources that may be of particular interest to this audience.

So the first pillar is using data to monitor emerging trends and to direct prevention activities. CDC collects and analyzes data on opioid involved nonfatal and fatal overdoses and officiated harms to better monitor the epidemic and evaluate prevention efforts. We also track data on prescribing including high risk and high dose prescriptions. The second pillar is strengthening state capacity to respond to the opioid overdose epidemic. We currently fund 45 states in addition to Washington DC to support surveillance and prevention efforts.

The third pillar is supporting providers, health systems and payers. CDC aims to save lives and prevent prescription opioid overdoses by equipping providers with the knowledge, tools and guidance they need. For example in 2016 we published the Guideline for Prescribing Opioids for Chronic Pain. The guideline can help providers make informed decisions about chronic pain treatment for patients 18 years and older in outpatient primary care settings outside of active cancer treatment, palliative or end of life care. In a few minutes I'll share some resources intended for providers that specifically translate content that's in the guideline and that might be helpful to this audience.

The fourth pillar is partnering with public safety. As the opioid epidemic has worsened with the rise in illicitly manufactured fentanyl, CDC is coordinating with public safety such as HIDTAs, high intensity drug trafficking areas and community based partners to rapidly identify overdose threats, reverse overdoses, link people to effective treatment and reduce harms associated with illicit opioids. The final CDC priority is increasing public awareness about the

risks of opioids. CDC launched the Rx Awareness Communication Campaign in 2017.

The goal of the campaign is to educate consumers about the risks of opioids and the importance of discussing safer and more effective pain management with their healthcare providers. The communication campaign incorporates testimonials from people whose lives and families have been directly affected by the epidemic.

Specifically for this call I'd like to highlight two particular areas: Prescription Drug Monitoring Programs or PDMPs and secondly electronic health record clinical decision support tools. Both of these are potentially helpful resources for healthcare providers.

PDMPs are state managed electronic data databases of controlled substances dispensed typically schedule two through four or five on patient specific prescriptions, 49 states in addition to the District of Columbia have operational statewide PDMPs.

There is considerable variation in PDMPs across states for example the purpose of the PDMP, where the PDMP is housed in a state -- it could be a public health department, it could be public safety or it could be a professional licensing board. There's also variability in who has access to PDMP data. It could be prescribers and pharmacists. And in some states they may also permit access to insurers, researchers, or law enforcement or medical licensing boards. And how the PDMP is incorporated into other data systems such as EHRs also varies.

PDMPs can be used as a tool to improve patient safety PDMPs allow clinicians to check a number of key data points. One is to identify patients who are obtaining opioids from multiple providers, another is calculating the

total amount of opioids prescribed per day or the morphine milligram equivalent per day and third is identifying patients who are being prescribed other substances that may increase risk of opioids such as benzodiazepine. In thinking about what an individual prescriber may look for or what are the data pieces or elements that they would be attending to in the PDMP I'll just give a couple of examples and one is high dosage.

As a clinician you could talk to your patients about the risks of respiratory depression or overdose, considering tapering, as well as prescribing Naloxone for patients who are at 90 morphine milligram of equivalence a day or more. Another area contained in the PDMP is multiple providers, it has already been briefly discussed by earlier presenters. You can counsel your patients and coordinate care with their other prescribers to improve safety and discuss the need to obtain opioids from a single provider. The third area is drug interaction and whenever possible avoiding prescribing opioids and benzodiazepine concurrently. There's an opportunity to communicate with other prescribers to prioritize patient goals and weigh the risks of concurrent opioid and benzodiazepine use.

As a tool to help inform clinical decisions PDMPs utility was highlighted in CDC's Guideline for Prescribing Opioids for Chronic Pain there's a specific recommendation statement #9 that indicates clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain -- ranging from every prescription to every 3 months. Many states have specific laws or statutes regarding requirements in terms of checking the PDMP. Clinicians should see what the specific requirements are in your own states.

It is important to also keep in mind and consider that patients should not be dismissed from care based on PDMP information. The information that's

included in the PDMP can be used as an opportunity to provide potentially life-saving information and interventions. Providers who identify uncertain medication behavior can respond clinically, make referrals to mental health or substance abuse treatment, offer a range evidence based treatment usually medication assisted treatment with buprenorphine or methadone in combination with behavioral therapy for patients who meet the criteria for opioid use disorder.

I'd like also to bring your attention to several PDMP resources that CDC has created and has available on its Web site. We have a PDMP fact sheet that walks through the basics of what I've just covered – what to look for in the PDMP and potential actions based on the information that's contained in the PDMP. And that's you can simply Google PDMP CDC fact sheet or it's available at our Web site www.cdc.gov/drugoverdose/prescribing/guideline and then you'll see a whole suite of translation materials that are available and one of which is specifically on PDMPs.

CDC also has free online training such as Webinars and Web based modules so clinicians can earn their CEs or CMEs. These trainings are related to the content of the guideline. These online trainings are available to provide interactive scenarios, and videos, and knowledge checks as well as tips and resources. There's one specifically on risk mitigation strategies which includes the topic of using PDMP data and walking through clinical scenarios on how to interpret that information. All of these are available on our Web site www.cdc.gov/drugoverdose/training

Lastly I'll turn to the topic of EHR embedded clinical decision support tools. In thinking about the opportunity of helping to support ways to encourage the uptake and use of CDC's guideline, one way to do that is to actually

incorporate the guideline into clinical workflow. One important way to do that is to incorporate the content into EHRs.

CDC is collaborating with the Office of the National Coordinator for Health IT or ONC and also physician informaticists who have been providing great support in identifying value sets and artifacts to translate the recommendation statements of the guideline into an EHR. And all of this information is publicly available at the GitHub Web site as well as the FHIR Web site, and that's FHIR. So I'll end here and I'm very pleased to be a part of this panel and look forward to the discussion. Thank you.

Jeane Nitsch: Thank you so much Dr. Losby. A lot of good information especially about the CDC opioid prescribed guidelines. I'm sure or at least I hope that all the prescribers on the line are very familiar with them and if not they will check them out. You talked a lot about the PD, the Prescription Drug Monitoring Program. Do you think it's had a big impact on opioid prescribing?

Dr. Jan Losby: Yes it has. There have been a number of research studies that have been published that specifically looked at prescribing rates in specific states. So for example Florida once they introduced their PDMP combined with other efforts to regulate prescribing and dispensing they reported a 25% reduction in oxycodone caused death and they had reduced opioid prescribing as well. In New York and in Tennessee they had a reduction in the number of opioid prescription from multiple providers which is one of the risk indicators as well. New York saw a 75% reduction and Tennessee saw a 50% reduction.

Jeane Nitsch: Wow impressive numbers. Thank you so much. I want to move us on to Dr. Scott Winiecki. Dr. Winiecki practiced pediatrics for 12 years prior to joining the Food and Drug Administration in 2011. He's currently Director of the Safe Use Initiative. This is a group whose goal is to reduce preventable harm

from medications by collaborating with both public and private groups within the healthcare community. We've heard a lot about how important it is to really do some collaborations. We're happy to have you join us Dr. Winiecki, the mic is yours.

Dr. Scott Winiecki: Thank you. So I want to talk about FDA's role in confronting the opioid epidemic and just to stress what my colleagues have already spoken much of what we do is in collaboration with other federal agencies especially those within HHS. So there's a great deal of collaboration and discussion of ideas and actions both to inform each other and to avoid duplication of efforts. I think I would start the story for FDA last year when we got a new Commissioner, Dr. Scott Gottlieb. And in his first address to FDA staff he cited that opioid crisis was really the number one priority for the agency. And I think that still holds true.

The first thing he did really was to create an Opioid Policy Steering Committee which is the sort of senior level leadership of FDA to look at this issue and address it. And because we are the people who regulate drugs right we're involved in the approval and assuring that drugs are safe and effective I think it's very important for us to solicit public input. So that's really what FDA began to do to have public meetings open dockets so people could submit comments even if they couldn't come to FDA for a particular public meeting. And we really received hundreds and hundreds of comments which I think points out really how important this issue is. Frequently FDA might have a public meeting and it might not stir, create or broad public interest but clearly the opioid epidemic does.

FDA has really four priorities and I'm going to talk about each one just a little bit. The first is decreasing exposure and preventing addiction, the second is supporting treatment of those with opioid use disorder, next fostering the

development of novel pain treatment therapies and lastly improving enforcement and assessing benefit risk. And I think from listening to the earlier presentations these kind of matchup with some of the other priorities from the agencies. Obviously each agency has a unique mission but there is clearly I think some overlap in the ultimate goal of each of those HHS agencies and really just to say FDA derived those priorities from HHS Strategic Priorities and other things out there like the National Pain Strategy recommendations and the Presidents Opioid Initiative.

And so touching upon each of these individually first decreasing exposure and preventing new addiction I think really FDA's emphasis there -- and we've heard this another presentations too -- is facilitating appropriate prescribing. So prescribing, you know, when indicated not prescribing when it's not necessary and in the appropriate amounts. And I think to that end we're looking very much into what research is out there and funding supporting additional research about indications specific dosages.

So really what do people need after a particular is a surgical procedure, what do most people use and that way perhaps we can facilitate some sort of consensus on what kind of prescription do people need after a given surgery for example a knee replacement, what is going to treat most people's pain adequately for those who aren't adequately treated they can always of course contact their provider. But to both prescribe an appropriate amount so people aren't using more than they need and also so there isn't a lot left over which may be prone to diversion or people misusing.

A second strategy in terms of decreasing exposure is talking about packaging perhaps even single use packaging something like what is often done for steroids where there might be a blister pack. And to end there was a workshop held last year to talk about that. We also in January met with people talking

about the packaging of the over-the-counter antidiarrheal medicine loperamide known as Imodium. People do use it sometimes to prevent opioid withdrawal. Unfortunately in those high doses it can also lead to life threatening heart arrhythmias. So the idea was before that medication to be available in appropriate amounts to use for several days for its antidiarrheal indication and make it more difficult for people to misuse it by using very high doses.

Another discussion is around mandatory education. Certainly some states are to have mandatory education and how would that be operationalized? And I don't know that, that question has been answered fully but training is made available through the Risk Evaluation and Mitigation or REMs program. You can take a, providers can take it at no or low cost training related to right now the extending acting, extended release long acting opioids. Pretty soon that's going to change so that the sponsors of the makers of all opioid products will participate in in that program and they'll have education available both to prescribers but also to nurses and pharmacists. And the focus of that is moving away from opioids to a more; broader pain control strategy, non-pharmacologic therapy, and non-opioid pharmacologic therapy as well as the use of opioids.

Thinking about support for those with opioid use disorder facilitating the increased access to Naloxone, Naloxone is available without a prescription or a standing prescription in many states but perhaps at one point will have that switched to over the counter Naloxone which is being explored. And also the development of new medication assisted treatment options. And to try to promote the use and more widespread use of MAT and also to break the stigma associated, maybe this is most important, to break the stigma associated with medications used to treat addiction because I think that certainly remains a significant barrier.

Moving on to that third priority, thinking of foster the development of novel pain therapies FDA has partnered with a lot of different both public organizations, and nonprofit organizations and other HHS agencies working toward this goal. And one aspect of this is the idea of abuse deterrent formulations. Abuse deterrent formulations aren't necessarily, they're not less addictive but they are perhaps harder to manipulate so that you could snort or inject them. And one idea would be to try to make opioids more difficult to abuse.

I guess if you're highly motivated you'll still figure out how to do that but hopefully to deter some people who might try that and just to make these medicines safer by making them more difficult to manipulate. And also I think FDA has used its various approval mechanisms like Fast Track or breakthrough therapy to try to evaluate different pain therapies as expeditiously and efficiently as possible.

Thinking about enforcement and assessing benefit risk FDA has spent a lot of time thinking about their different seizure authorities and import authorities specifically thinking about the international mail facilities, \$94 million was allocated last year for FDA to expand efforts into international mail facilities because a great deal of illicit drugs or even prescription drugs are simply mailed in a legal fashion into the United States. And you might imagine with millions of packages coming in intercepting those packages which might contain something illegal is quite a challenge. So FDA is expanding those efforts.

And we also back in June recently held a summit with Internet stakeholders trying to get Internet sites to limit illegal online sales so legitimate sites who perhaps might have content or people posting there trying to sell opioids online and trying to get various Internet providers to address that issue

themselves. We've also taken action including recommending market withdrawal. I think many people are familiar with the Opana ER situation that happened in June 2017 where an opioid could be manipulated. It was being injected and it led to a fairly loud large outbreak of HIV and HCV and as a result that was withdrawn from the market.

And I think we're trying to work toward that end to improve the robustness of benefit risk assessment. For most drugs is not really an issue right? Nobody takes amoxicillin out of a medicine cabinet and sells it on the street or injects it. But with potentially addictive medications certainly there's not only a concern for the person that is prescribed the medication but for the larger public health issue of it can affect people in that family and beyond in terms of diversion so continuing to assess the benefit risk of a drug not only in the context of this patient but in the larger public health concern.

And I think one area there that's sort of an example of that is looking at safety labeling changes to prescription cough and cold medications containing codeine particularly now not for children who are 18 years or younger. And the reason for that again is just to try to decrease exposure. There's not a lot of good data out there supporting the use of codeine for suppressing cough. And so therefore perhaps the benefit is minimal or none and there is significant risk when you have an opioid out there and people may be using it.

So I think those sort of four items summarize where FDA is. We're obviously continuing to evaluate and looking at new and different strategies and working with our federal partners really on a very frequent or even daily basis. But those are sort of a good summary of what we've done maybe in the last year to 18 months and I'm happy to take questions during the Q&A session. Thank you.

Jeane Nitsch: That is a lot of really great information. It seems like, you know, they talk a lot about these abuse deterrent formulations, can you just mention more, a little bit – more about that and what that really is?

Dr. Scott Winiecki: Sure. So the idea would be to try to take a pill and make it say harder to crush or more difficult to dissolve so that it wouldn't be as easy to snort or to inject right? One way to abuse opioids is simply to take them orally right and to take a higher dose orally. There's not much you can do to prevent that action. But in terms of people abusing opioids via a different route snorting or injecting you can do certain physical and chemical things to make that more challenging to do.

And again I don't think that's going to decrease a very highly motivated individual but hopefully what that does is discourage the casual user or, you know, somebody who is just sort of going through the medicine cabinet and experimenting from trying that kind of thing. So I think it's an attempt simply to make it more difficult for people to abuse. But there's I don't, I think we would all say there's no perfect way to do that and I don't - I can think of a way that you could make that work in oral routes so that there would be no way to do something but at least it's harder to manipulate to inject or snort.

Jeane Nitsch: So the pharmaceutical companies would actually do this?

Dr. Scott Winiecki: Right. So when they design a new medication not only do they put it through the usual clinical trials to demonstrate that it's safe and effective but they also follow a specific guidance if they want the particular labeling to say that this is an abuse deterrent formulation. They have to show that it's effective in that way, and there's a whole guidance around that. So the drug company would do all those test and then in the usual way submit that

information to FDA when they're seeking drug approval. So it's all part of the approval process.

Jeane Nitsch: Are a lot of pharmaceuticals doing it?

Dr. Scott Winiecki: I mean there are a number on the market absolutely. The issue is they are currently branded drugs.

Jeane Nitsch: Oh.

Dr. Scott Winiecki: And so therefore there are more expensive. So in that respect I think that's a major barrier to uptake in the market. So at present while there are multiple drugs out there that are abuse deterrent formulations they have generally a small market share and I think again the major reason there is cost.

Jeane Nitsch: Thank you so much. I appreciate your time Dr. Winiecki and we know you'll stay on the call for questions at the end.

Dr. Scott Winiecki: Sure.

Jeane Nitsch: Let me go on to our last federal agency. We have Dr. Christopher Jones. Dr. Jones currently serves as the first Director of the National Mental Health and Substance Use Policy Laboratory at the Substance Abuse and Mental Health Services Administration. The policy lab created in the 21st Century Cures Act -- many of you may be aware of the Cures Act -- is charged with identifying, and coordinating, and facilitating the implementation of policies to improve mental health and substance use prevention, treatment and recovery, and advance innovation and dissemination and adoption of evidence based practices and programs related to mental health and substance use. So go ahead Dr. Jones.

Dr. Christopher Jones: Thank you. And thanks to all of my HHS colleagues who have gone before me. I think it really reflects the scope of HHS's work in the space of addressing the opioid crisis. So I wanted to talk a little bit about what SAMHSA's is doing in the opioid space. Certainly we'll try to be brief in the interest of time because I think the questions from participants will certainly be very informative.

But SAMHSA's work really focuses in four areas. The first is around surveillance and data dissemination. And I'll highlight that we have been working to put out information around populations who are at risk, prescription opioid misuse or heroin or illicit opioid use largely through our national survey on drug use and health. And the 2017 data will come out in just a couple weeks in September. But, you know, we continue to see based on the 2016 data more than 11 million people who report misuse of prescription opioids, almost 1 million people reporting use of heroin, over 2 million people with an opioid use disorder in the past year. So we see like many other indicators that there is a large population of individuals in the US who are being impacted by the opioid issue.

The second area of SAMHSA's work is really looking at strengthening state and local capacity. In particular to we want to address prevention treatment and recovery of substance use disorders and opioid use disorders. And we are putting out about \$2 billion this year in discretionary funding to address the opioid issue in particular. And that covers community and school-based prevention efforts through the expansion of medication assisted treatment to the implementation of recovery support services in communities to address and help individuals who have opioid use disorders to achieve long-term recovery. Our largest funding announcement is for \$930 million that goes to states. And applications actually were due earlier this week.

I think what's informative in particular in the context of what Devon shared earlier around CMS's work in looking at reimbursement and sort of systems level change is that we are really trying to leverage the SAMHSA funding to build a system of care to address the comprehensive needs of individuals with opioid use disorder and other substance use disorders in particular looking at innovations like the hub and spoke model that has been implemented originally in Vermont that other states are now replicating in different formats leveraging things like project ECHO to help address a lack of capacity for addiction specialists in many areas but connecting primary care providers and others with those specialists in order to implement evidence-based treatment in their practices.

We're also supporting the expansion of naloxone access to both healthcare providers as well as to first responders through grant programs as well as specific funding for recovery support services. And I think this is a really critical investment to help make sure that our investments in treatment are being maximized and that individuals when their integrating back into their communities and their families have the support services to be successful in the long run.

And so we are looking at things like recovery coaches in the emergency department to connect with individuals who have come in with an overdose or dispatching people in recovery or other community workers to someone's house after an overdose to engage them in a conversation around overdose risk reduction as well as treatment. So a lot of exciting innovation that's happening with the dollars that are coming out from SAMHSA.

The third area of our work is really around training and technical assistance. And you heard from Jan earlier around a number of resources that CDC has

made available in particular around their prescribing guideline. SAMHSA has a number of resources that are available on our Evidence-based Practices Resource Center that covers the spectrum of activity around opioid prevention treatment and recovery. We also provide training and technical assistance to clinicians which may be of particular interest to individuals on this call through our providers' clinical support system for medication assisted treatment which provides at no cost to individuals training to get a waiver for buprenorphine, training around other topics related to opioid use disorder prevention and treatment.

It also offers a peer mentoring service where providers can be linked up to an addiction specialist, a thought leader in the field on a one-on-one basis to have mentorship about how do I do buprenorphine in my practice or how do I do Vivitrol in my practice, you know, how do I integrate this into a rural primary care practice that's already very busy? What are the things that I need to know to be successful? And I think it's an underutilized resource.

And when we look at recent research and research others have done for barriers as to why people don't prescribe buprenorphine or don't prescribe to many patients lack of self-efficacy among providers or concerns that they don't really know how to manage individuals with opioid use disorders or they have concerns about managing individuals with opioid use disorder it's commonly raised. And so avenues for additional training as well as mentorship through PCSSPCSS MAT I think are really an opportunity to help expand the number of providers who are able and willing to provide care for people with opioid use disorders. We also have regional training programs and technical assistant programs through our addiction technology transfer centers which exist in all the HHS regions and are a resource to provide information around the latest science and translational science into practice around addiction. We will soon be bringing online technology transfer centers for

substance use prevention to help advance the prevention field around substance use.

Then my last area of SAMHSA's work is really the research and evaluation side, in particular looking at innovations in service delivery to advance the adoption of evidence-based practices. And a couple of highlights there. We recently did a survey of what waived providers who got a waiver to prescribe buprenorphine in 2017 for the first time or got an increase in their limit for the first time and are using the data from that survey to help inform our training and education as well as our policy work.

We're also evaluating some innovative medication assisted treatment service delivery models such as emergency department initiated buprenorphine, safe stations which are essentially leveraging, you know, police or fire stations to connect people very quickly into treatment when they come forward seeking treatment, looking at the connections of safe stations to federally qualified health centers which are funded through HRSA within HHS and also looking at a variety of other models for expansion of medication assisted treatment. And we'll be disseminating that information as results become available.

And our hope is that other agencies that we work with, in particular CMS, can then take that information to help inform payment policy change to help sustain a comprehensive system for addiction care in the US. So with that I will turn it back over. Thank you.

Jeane Nitsch: Thank you so much Dr. Jones. It's a lot of initiatives coming out of SAMHSA. Can people just go to the Web site and find some of these if they want to get more information?

Dr. Christopher Jones: Yes. So the Evidence-based Practices Resource Center I think is a good place to start if you're looking for particular guidance documents or toolkits related to substance use or we have a specific section on opioids. It also has a link to all of our training and technical assistance centers on that page as well.

Jeane Nitsch: That's great. Thank you so much. I really appreciate you being with us today. Before I asked (Ted) to give the audience information on how they can call in with your questions, I just want to remind the audience that Dr. Taitsman from the OIG had to leave the call as did the CMS speaker. We do have – oh I'm sorry, (Kim) had to leave but Devon Trolley is still here from CMS. So we still have Dr. Losby and Dr. Winiecki and Dr. Jones from SAMHSA are still with us. So I'll turn it over to (Ted) if you want to give this audience information.

Coordinator: Yes. The phone lines are open for questions. If you'd like to ask a question on the phone please press Star 1 and record your name. If you would like to withdraw your question press Star 2. Thank you.

Woman: Yes.

Jeane Nitsch: Just while we're getting people, we do have some people we see in the queue that are coming onboard. Just before we get started just back to you real quick Dr. Jones, you talked about some of the innovations, one of the innovations you saw at the state. But how are states pursuing some of the opioid funds, using some of the SAMHSA opioid funding to do innovations or anything in particular that really jumps out at you that you've seen at the state level?

Dr. Christopher Jones: Well I mean I think the exploration of things like hub and spoke in different context is certainly innovative. So for many years Vermont has had hub and spoke in place. Rhode Island is doing a sort of variant on that of

which they're calling Centers of Excellence. But essentially it's trying to address many of the barriers that particularly primary care providers cite as a concern around prescribing medications or adopting medication assisted treatment in practice in that there's often a lack of access to specialists or sort of a backstop if you have a patient who gets in trouble, you know, how do you best address that, who do you go to? Maybe they need a higher level of care than you can provide in primary care practice and these models are doing that.

California is taking an approach where they're doing sort of a regional hub and spoke as a very large state. And they're attaching some of their spokes to Indian country, a high burden population. So it's very exciting to see those types of things that are happening with our dollars. And as we're now reviewing the applications that are coming in for the \$930 million I think we'll identify even more innovations.

Jeane Nitsch: And I'm sure the people on the call are going to think well how do I get in on that? So thank you soon so much. (Ted) do have anyone keyed up?

Coordinator: Yes the first question in the queue from (Gerald Rogan). Your line is now open.

(Gerald Rogan): Hi. Thanks very much. I'm a family doctor, ER doctor. And want to mention that you haven't mentioned the use of ice cooling machines such as a DonJoy Iceman for post-operative management of hip and knee surgery. So I just had a total hip arthroplasty and I used this DonJoy ice machine on my surgical site for four days and the total narcotic prescription I used was zero. And I used the same thing when I had a total shoulder repair for a torn supraspinatus tendon. And I used another one of these ice machines and I used one narcotic pill once. So I've looked on the Web sites, I looked on the CDC guidelines

and I haven't seen anything about the use of ice treatment for post-operative pain management. And I did find one article on PubMed which I'm sending you an email.

But my Kaiser Permanente's providers use these on a routine basis for hip and shoulder and knee surgery. And they also use continuous infusion of topical narcotics through the infused underneath the skin both for knees and for shoulders. There's a device for that. So I would recommend you guys think about non-medication methods to handle postoperative pain.

Jeane Nitsch: Thank you (Gerald). Does any of our speakers want to comment on that?

Dr. Scott Winiecki: This is Scott from FDA and I'm happy to comment on that. One of the things that you could find on the Web site when you read about under that third priority of fostering development of novel pain therapies is encouraging use of medical devices. I think that's certainly one area. I want to be careful not to endorse anything in particular but I do think devices are an important thing. Another important thing as you point out is non-pharmacologic treatments and disconnects then not only from postsurgical but to people that have a certain degree of chronic musculoskeletal pain.

You know, sometimes there are other modalities that can help right -- ice, heat, physical therapy, yoga. Certain people find, you know, exercise, you know, makes them feel better, certain people make it feel worse. I think one of the areas of research that's going to be explored in coming years is, you know, what of those modalities works best for which kinds of pain, you know, what might work best for low back pain, what might work best for shoulder pain?

And I think that yes that's an important thing to consider is that you can reduce opioid use or perhaps even avoid the use of opioids through these other modalities. I think unfortunately sometimes we hear stories of their being insurance barriers or frankly sometimes with something like PT. It does require time and effort, it's certainly inconvenient. It certainly can be costly so there are other barriers in the way some time. But I agree that non-opioid therapies both non-pharmacologic and pharmacologic can be quite important.

Jeane Nitsch: Thank you very much. (Ted) do we have another question in the queue?

Coordinator: Yes, (Holly Agurate), your line is now open.

(Holly Agurate): Hi everyone. I just had a quick question. I was listening to everybody's comments and so forth like that. But the one thing that I did notice is nobody mentioned that there's no care or treatment for chronic pain patients who are on opioids. I mean, if you think the addicts are getting better treatment than people who are actually in pain and have tried physical therapy, have spent thousands on devices physical therapy, massages, injection and nothing seems to work except for the opiate. So, I mean, what's going to happen to people like me that can't do anything but take medication?

Jeane Nitsch: I'll open that up to those on the call.

Devon Trolley: So this is Devon. I'll start and would welcome others to join in. I think especially from CMS's perspective I think we're very much trying to, you know, reduce prescription opioids where they, you know, are maybe at high doses or are not necessary. But I think we are very aware in wanting to protect the role of prescription opioids where they are appropriately used for chronic pain where other remedies are not available or not effective. So, you know, I think while we do talk a lot about wanting to reduce prescription opioids

where, you know, we are seeing sort of outliers high prescribing at the same time we're also very focused on ensuring that patients do receive care that is addressing their pain and...

(Holly Agurate): Right, but all of you guys are talking about is medical equipment. No one's talking about people who are actual pain that like I said who have tried everything. I mean the doctors have an excuse for every - well try this, try that. But like I said, when it gets to that point where nothing works and, you know, I can't get off the couch without it and, you know, feed my family and work what am I supposed to do just say don't take - and I've taken non-opioids that have given me brain fog where I can drive, I can't work, I can't walk.

But I'm fine on a dose of opiates but now I'm being labeled as you've got to take lower doses because this is what the guidelines are now. Who makes the guidelines? No one met with me. No one took my pain into consideration to see what I should be taking. They just gave my doctor a paper and said, "She should be taking this."

Jeane Nitsch: (Holly) it's - we can tell you're really dealing with a lot and we appreciate your comments. It's so difficult for people like you say who are in a different boat dealing with the opioid epidemic from those who are dealing with the chronic pain. You know, it's so much information and I know we're addressing kind of from a different slant on today's call. I think it would be like a whole other call to talk about really addressing how to deal with pain but thank you for calling in.

(Holly Agurate): Thank you guys for listening. I really appreciate it. Thanks a lot.

Jeane Nitsch: Thank you.

Dr. Scott Winiecki: This is Scott from FDA. I would say that when we in January we had what's called a Part 15 hearing. Basically the Opioid Policy Steering Committee was sitting there. And anybody from the public that wanted to come in and speak and say their piece I think people had like six minute blocks all day long. And clearly one of the messages we heard from that was from the chronic pain community. And I think that certainly there are a group of people who chronically need opioids, probably are not going to be able to entirely get off opioids. I think, you know, clearly that exists and we shouldn't say that, you know, that's - nobody's saying that's an appropriate care. And I think if you read the guidelines there they're just that and if Jan wants to comment on that.

But the guidance doesn't say you can't do this. The guidelines largely are trying to shape but we would call appropriate prescribing. And I think appropriate prescribing boils down to evaluating each basin carefully patient carefully and deciding what's appropriate and what that patient needs. And I think too often in the past we've gone to opioids perhaps too quickly or in too great a dose or too great amount. But nobody's saying that patients should live in pain and not be treated. I don't think any agency is advocating for that whatsoever.

So just to be clear we understand there are people who are in pain and who need these medicines. Nobody's saying FDA should take opioids off the market. They serve a very important role for people in pain. But I think in the chronic pain area you have to be very careful to evaluate each patient and decide what therapy is appropriate in what case. And I think that's a much more complicated and difficult area than perhaps addressing postsurgical pain where you're dealing with perhaps a very brief period. And often we kind of know what the recovery period would be for a certain surgery and that kind of

thing. So chronic pain is a very complex and difficult area and I don't think anybody's interested in denying people care.

Jeane Nitsch: Thank you Dr. Winiiecki for the follow-up comments. (Ted) do we have another question in the queue?

Coordinator: Yes (Cindy Steinberger) your line is now open.

(Cindy Steinberger): Sure, thank you. I know that in the roadmap CMS has talked a lot about covering complementary treatments, things like acupuncture, massage, tai chi, yoga for pain. But I don't - I haven't heard about any conference decisions that supports that. So I want to know specifically what is CMS doing in alternative care?

And then I am second part of that which is I'd also like to know if there are any alternative models like SAMHSA's doing for substance use for pain because they're similar things. There's not enough pain specialists. As you said it's complicated to treat. Typically providers need more time with patients and right now they don't what to do and they're discharging patients that can't get care.

So two parts. One is CMS what are you doing to cover treatments? And secondly what's being done to support PCP so they maintain care for people with pain?

Jeane Nitsch: Thank you (Cindy) for the question. I'll turn it over to Devon.

Devon Trolley: Sure. So for what CMS is doing we are actively looking at a whole range of alternatives for pain management and exploring the evidence base. So, you know, for folks who aren't familiar to cover something in Medicare, you

know, we typically look at what evidence is out there that would, you know, support effectiveness. And some of these areas were looked at many years ago but there has been additional evidence since then. So, you know, we sort of cracked open a few of these areas to more closely examine, see if there is additional evidence that warrants coverage of these, some of these alternative treatments.

And so we're actively doing that where we are finding evidence gaps. We're working with our partners at NIH to see if they have research or if they can, you know, add to the evidence base to sort of supply the research needed to kind of complete those coverage determinations. So we are, you know, sort of actively in the process. And, you know, since that, you know, does require a lot of analysis you haven't heard us, we haven't talked as much publicly about that yet but I would sort of expect that we would put something out in the next, you know, few months to over the next year that would start really moving into that area little bit more. So keep an eye have for those items but I just, you know, underscore that we are actively working on it although we don't, you know, admittedly have as much out there publicly.

And then, you know, as mentioned earlier we're also sort of actively working with providers and through our quality improvement networks to also see what people are already doing to, for areas that are covered or alternatives that, you know, either hospitals or providers can provide that are non-opioid based, you know, working at those as well to try to see if we can disseminate some of those as best practices.

Jeane Nitsch: That's sounds like a lot of constant and ongoing work in that area. Does any of our other speakers want to chime in on alternative models?

Dr. Christopher Jones: This is Chris Jones. So I know that there are through HRSA some of the community health centers have received funding to do some project ECHO type work around pain, not just on addiction. And certainly, you know, project ECHO model has been shown in hepatitis C treatment I mean, and a variety of other chronic conditions that typically need multidisciplinary care or advanced specialist care so that's certainly work that's happening there.

And then I do think, you know, there other I mean certainly in the VA and other systems that are using team-based care with psychologists, pharmacist, physicians, nurses, et cetera. I think, you know, there are sort of pockets of areas in the country that are doing that type of stuff. I'm not aware of specific funding necessarily like the SAMHSA discretionary funding for opioid use disorder that exists for pain but I do think there are pockets of models, practice models that are emerging.

(Cindy Steinberger): Right. So we do need that kind of funding. Of course the VA is a closed system. It's wonderful what they're doing in the VA, but translating that into care for, you know, the millions of people with pain that, you know, are not part of the VA system is what's really important. I think we need some funding and coverage of the innovative models of treatment for pain as well.

Jeane Nitsch: Thank you (Cindy) for calling in with that perspective. (Ted) do we have another question in the queue?

Coordinator: Yes (Carrie) your line is now open. (Carrie) if you're there you may have your phone muted but your line is now open.

(Carrie): Hello?

Coordinator: We can hear you.

(Carrie): I was concerned that there doesn't seem to be anyone there representing chronic pain patients and what's happening - how we're being denied pain medications. I know the guidelines, you know, were for primary care doctors and that they're not, you know, meant to take away medications but states of said laws and the DEA is actively, you know, going after pain specialists while just looking - you know, nobody wants to be an outlier prescribing over 90 MMEs. And that dose doesn't, you know, take into account that we have, you know, genetic factors that attack - that affect our metabolism medications like opioids and other things, you know, specifically the CYP 450.

So I was just wanting to know how we can protect, you know, the doctors that are funding it that the patients, you know, need the opioids along with all the other treatments they're receiving. And especially like someone like my mother, she can't take NSAIDs because of chronic kidney disease and her heart she is too weak for - to be able to have surgery, you know, to repair several things. And, you know, without her being able to manage her pain she's unable to keep moving and I'm afraid she'll be bedridden and, you know, how patients decline rapidly after that so...

Jeane Nitsch: Thank you (Carrie) for calling in and you seem to dovetail a lot of what the earlier caller (Holly) mentioned about people, patients who are dealing with the chronic pain. When you said we don't have a representative for the chronic care and that's true. We're really focused on the federal strategies and that's why we have the federal agencies on the call. But you bring up a good point about making sure we're protecting those physicians and prescribers who are helping those with chronic pain. And I think all the agencies have kind of mentioned during their presentation that we're really not saying that opioids is a bad thing for all people. We're really just looking at where it is an

abuse of that is going on. So does any of our speakers want to chime in on that?

Dr. Jan Losby: Hi. This is Jan from the CDC and definitely echo the concern about individual patients who either are dropped from care or no longer have access to opioids in terms of managing chronic pain. The guideline itself was not intended to be used in a way that individuals would not receive access to effective ways to manage chronic pain. Looking at those 5050 MME or the 90 MMEs, it was really intended for individuals who are first starting or initiating use of opioids for clinicians to proceed fairly slowly, carefully and cautiously as they consider benefits and risks when they are considering increasing dosages going up to 50 MME and 90 MME. Recognizing that there are many individuals that are on higher levels of morphine milligram equivalents. CDC encourages providers and patients to carefully consider both the benefits and serious risks of these medications in making decisions about chronic pain management. The guideline itself was, not intended that there would be dramatic or fast tapers for individuals who are perhaps doing very well on higher levels of opioids and managing their chronic pain effectively. The Guideline encourages providers and patients to consider all treatment options that can be used alone or in combination with opioids.

Jeane Nitsch: Thank you Jan for that. (Ted) do we have another...

Coordinator: Yes.

Jeane Nitsch: ...question in the queue?

Coordinator: Yes, (Penny Smith) your line is now open.

(Penny Smith): Hi. Can you now hear me? Hello?

Jeane Nitsch: Yes, we can hear you.

(Penny Smith): Okay. So I'm a family member of two recovering opioid addicts and I'm also a hospice nurse of the subject is something I'm really passionate about. And my greatest concern is with laws that allow family members to take possession of opioid medications after our patients die. Hospice nurses can encourage and teach about the destruction of those meds but they're not allowed to waste or assist in wasting them. You know, prescribers are careful to ensure that opioids are prescribed in the right quantities to the right patient, but then those drugs are allowed to go unmonitored into the hands of their heirs to do with what they wish. So this is a great concern for me and my colleagues in hospice and I'm wondering if this is being addressed?

Jeane Nitsch: Penny is that a state law you're referring to?

(Penny Smith): No, it's a federal law.

Jeane Nitsch: Okay.

Dr. Christopher Jones: Yes. This is Chris Jones. I mean I think that is largely the purview of the Drug Enforcement Administration as the oversight entity for the Controlled Substances Act. It's not really an HHS, it's not in our purview within Health and Human Services as far as the handling of controlled substances and what are the requirements for disposal.

Jeane Nitsch: Thank you for that information Chris and thank you for your call (Penny). You bring up a really good point and may be something to address with the other - a different federal agency. (Ted) do we have any other questions in the queue?

Coordinator: Yes (Chantelle Whitaker), your line is now open.

(Chantelle Whitaker): Yes, good afternoon. Just a question about prescribing guidelines. So I know that the CD has chronic pain guidelines. I was just curious if there are any acute pain guidelines in works and if so what's the timeline?

Dr. Jan Losby: That work is underway in terms of we're working with AHRQ to conduct a systematic review to determine what evidence is available for chronic pain and then specifically as you mentioned for acute pain. We are at the early stages and are waiting to see what that systematic review shows us. We are collaborating with our HHS colleagues on this topic.

Jeane Nitsch: Thank you (Chantelle) for that question. Thank you Jan for the response. I think we have time for just one more question. (Ted) do you have one more in the queue?

Coordinator: Yes, (Dennis Daley), your line is now open.

(Dennis Daley): Yes thanks everyone for a good discussion. Opiate use disorders create a specific burden and considerable emotional pain for families and children. And so my question is what is being done to focus on family related strategies aimed at one intervention? How can families get their loved one into treatment because we have low rates of treatment entry, treatment providing support and treatment to families and members affected by these disorders -- lots of depression, lots of upsetness -- and then prevention helping children of parents with opiate use disorders who are probably at risk for a substance use, mental health and academic problems. So my question is how were you thinking about the family perspective?

Jeane Nitsch: That's a quite great question (Dennis), let any of our speakers jump in.

Dr. Christopher Jones: Great. Now this is Chris Jones from SAMHSA so thanks very much for the question. I do think that it is really an area of great interest in particular as we see a rise in foster care caseloads over the last several years after many years of declines and really thinking about how the health system interacts with the social system which interacts with the justice system and how are all these parts fitting together.

Certainly at SAMHSA our funding and particularly our large opioid funding can be used to support primary prevention efforts or sort of, you know, upstream prevention activities to look at risk and protective factors broadly among youth, in particular youth who might be at particularly high risk for engaging in substance use. And states are implementing a number of evidenced-based programs to strengthen protective factors and reduce risk factors to subsequently then reduce substance use whether that be opioids or other substances.

We've also made some additional investments in family inclusive treatment, so in particular among pregnant and postpartum or parenting women which we know, you know, the data suggests that individuals who are able to have family members either engaged with or not have that additional stress of how do I manage my kids if I need to go to treatment tend to do better.

And so we've expanded some of our programs for pregnant and parenting women both from the residential side as well as the newer program in the last year or so that allows outpatient-based care for women who are in those circumstances. We think that's a really important step forward and certainly are, you know, looking for states to be innovative in thinking about how do we holistically address the needs of families and communities with the money

that's going out? So I think it's a really important question and one that we're certainly trying to move forward here at SAMHSA.

Jeane Nitsch: Thank you Chris and there's some good information on the family supports being offered through SAMHSA and in also talking about some of the states. Unfortunately that's all the time we have for today and I know we have several people in the queue, unfortunately we won't be able to get to your question.

But before we close out today let me thank all our guests, Principal Deputy Administrator Kim Brandt, Senior Advisor Devon Trolley, Dr. Julie Taitsman, Dr. Jan Losby, Dr. Scott Winiecki and Dr. Christopher Jones. We couldn't have done this without you. I'd like to give a big shout out to the team that made this possible – (Kristin Gerwin), (Shelly Ray), (Charlie Coles) and (Kathy Zizwarek). They worked very hard to coordinate today's call, kudos to the team. And I also want to thank Jill Darling and (Ted) for their assistance with today's call. It's much appreciated.

Finally let me thank you for joining today's presentation. We're glad – we're so glad you could find time in your busy schedule to call in and be part of this forum today. So on behalf of CMS I'm Jeane Nitsch saying thank you for joining us.

Coordinator: This concludes today's call. Thank you for your participation. You may disconnect at this time. Speakers please stand by.

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