

Moderator: Michelle Oswald
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Operator: Welcome and thank you for standing by. I would like to inform all participants that today's call is being recorded. If you have any objections you may disconnect at this time. Participants will be in a listen-only mode until the public comment portion of today's conference. At that time you may press star 1 on your phone to make a comment. I would now like to turn the conference over to your host, Michelle Oswald. Thank you. You may begin.

Michelle Oswald: Great. Thank you so much Sara and thanks everyone for joining us today. My name is Michelle Oswald and I am a partner lead in the Partner Relations Group in the CMS Office of Communications, and I will be serving as your moderator today.

I want to welcome you to this listening session on the Dr. Todd Graham Pain Management Study. This study will give CMS important information about treatment, outcome and help us to understand the roles of behavioral health, specialty care integration, care planning, health disparities in pain, opioid use and opioid use disorders treatment.

So, before we get started, I just wanted to make one announcement. This call is open to everyone. However, if you are a member of the press, we invite you to listen but ask that you please refrain from asking questions during the call. Those inquiries can be directed to press@cms.hhs.gov.

At this time, I'm going to turn it over to Dr. Shari Ling who is the Deputy Chief Medical Officer for the CMS Center for Clinical Standards and Quality. Shari?

Dr. Shari Ling: Hi Michelle and thank you for this convening today. And I'm Shari Ling, Deputy Chief Medical Officer here at the Centers for Medicare & Medicaid Services, and a geriatrician and rheumatologist and I just want to take a couple of minutes just to say thank you so much for joining this call today, with a special thank you to each of you who either provide care to our beneficiaries, care for or advocate on behalf of our beneficiaries who have painful symptoms, many of who live with pain symptoms.

Over the past few years in my capacity as the Deputy Chief Medical Officer here at CMS, I've had the honor of representing CMS as part of the Health and Human Services department on the department's effort to address the national opioid crisis and as part of that has the honor of interacting with and learning from our critical colleagues and the pain best practices task force and thank them immensely for the work that they have led.

And so this conversation today builds on what has been learned but also fulfills some of the expectations that are laid out and by the Support Act. And as representing CMS as one of larger payers for healthcare services and care delivery CMS really has had a vital role in addressing the opioid epidemic and crisis and has focused on three main and key areas, including prevention of OUD, treatment of OUD and making data available to permit targeted prevention and treatment effort.

But really critically important prevention as our Assistant Secretary for Health has so eloquently put it, better pain management actually is OUD prevention. So managing pain, enabling better pain management using safe and effective therapeutic option that may rely less on prescription opioids is one of the pillars of our efforts put forth in the opioid - CMS opioid road map in 2020.

So with that I will turn to my colleague Ellen Blackwell who will say a few words about this specific provision as the Support Act and what we're gathering here to - and how we will learn from you in support of our implementation of this provision. So Ellen, to you.

Ellen Blackwell: Okay, thanks Shari. I'm Ellen Blackwell, geriatric social worker and a senior advisor and member of the Center for Clinical Standards and Quality. And as Shari just said, today's session goes on other work that we're doing across our agency to remove the care of acute and chronic pain in both Medicare and also the Medicaid program.

So we are extremely glad that you're with us today. We're very interested to hear what you have to say and we totally appreciate your help and effort. So the Todd Graham pain management study is officially Section 6086 of the Support Act, which outlines national strategies to help address the opioid epidemic and advances policies to improve the treatment of pain and substance use disorders.

So what we hope to get out of this study both from an HHS and CMS standpoint is information about services delivered to Medicare beneficiaries with acute or chronic pain. We want to better understand the chronic landscape of pain relief options in Medicare for our beneficiaries and we want to help inform future decisions around payment and coverage for pain management intervention and that includes those that minimize the risk of substance use disorders.

So in this work, we have the marvelous help of our colleagues at the Agency for Healthcare Research and Quality who will be helping us compile evidence or look at the evidence in certain areas where there are gaps and also HHS is also the Assistant Secretary for Planning and Evaluation where our partners

there will be working with those to prepare a report to Congress that addresses a number of other issues related to pain.

So as we embark on this work we want to acknowledge the clinician who inspired it. I think it's always very important. Dr. Todd Graham, our clinician who practiced in Indiana and he was beloved by his family, his community, his coworkers and especially his patients. So we really appreciate and acknowledge the role of Dr. Graham and really starting us down this path.

So with that Michelle, I'm going to turn it back over to you and let you start the discussion so we can hear what our guests today have to tell us.

Michelle Oswald: Great. Thanks so much Ellen. So this session is a follow up to the Dr. Todd Graham Pain Management Study listening session that was held on Thursday, August 27th which was through our CMS Medicare Learning Network. And that session targeted clinicians and state national organizations that represent healthcare professionals.

There may be some of you who were able to join that call and participate in that session, but today we've gathered advocacy groups and other individuals and organizations that represent patients and beneficiaries and are hoping to hear more of those perspectives today. So, CMS is seeking input on four topic areas today, and for those topic areas there'll be an opportunity for you to get into the queue to provide your comments.

The operator will provide additional instructions on this. We ask that you please limit your input to the topic area that we announce. If there's time at the end of the call, we can open it up for general comments. Also, please be prepared after your comment to provide any follow up response just in case we need some clarification on your comment, and then lastly please be sure to

say your name and your organization or affiliation before you provide your comment so we know who you are.

And as a reminder this is being recorded and transcribed. So our first topic is barriers to care. At this time, I'm going to turn it over to the operator so we can take our first comment for discussion. Sara?

Operator: Thank you. If you would like to comment on this topic, please press star 1 and speak your name and affiliation clearly when prompted. You may withdraw your comment by pressing star 2. Again, to make a comment on this topic please press star 1. Please stand by for comments. Our first comment comes from Cindy Steinberg from the U.S. Pain Foundation. Please go ahead Cindy.

Cindy Steinberg: Yes. So as you said, I'm Cindy Steinberg from the U.S. Pain Foundation. And you asked about barriers to care, so of course cost is one of the big barriers to treatment, including deductibles, copay and coinsurance when things are partially covered.

I think another big barrier is really the lack of understanding on the part of physicians and patients. That multi-modal treatment for pain is really best practice as well as the lack of knowledge on the part of those physicians and patients of the full range of therapies that are effective for pain.

Physicians definitely need more training on pain best practices and Dr. Ling had mentioned the report that was done, and that needs to be disseminated. That is not known by the average PCP who handles most people with pain. The other big thing I would say is a barrier is the lack of time spent with patients to really create a pain management plan and modify it when needed.

Pain patients are complex. They really can't be handled in a 10 or 15 minute appointment. And so we would hope that Medicare and CMS would allow some codes for additional time spent on the part of doctors to work with these complex patients. Thank you.

Michelle Oswald: Thank you so much Cindy for your comments. We appreciate that. Sara, we can take the next comment.

Operator: Thank you. Next, we have Penney Cowan from American Chronic Pain Association. Please go ahead.

Penney Cowan: Hello my name is Penney Cowan from the American Chronic Pain Association, and I was going to say pretty much what Cindy just said about all those same things, the actions to care.

I think one of the most important things especially to prevent the acute pain going into the chronic pain is giving those providers the time they need and paying for their time. I don't know if they don't have the time, that they're not being reimbursed for the time that they need to spend with their patient to actually make a good assessment to determine what treatments are best for them rather than just a quick appointment and giving them specific prescriptions or something. But let's really understand what it is.

It might be physical therapy. It might be counseling or something else. So I think that's one of the key things, the education for providers, cost of all of those treatments for medication to you know, provider to - paying for their provider as well as the follow up to all the other treatments. We get a lot of calls from people who can't - who have been prescribed physical therapy but can't afford it. The company won't cover it. CMS won't cover it. So that's been a real problem for people so thank you very much.

Michelle Oswald: Yes Penney. Can you explore that a little bit further about the comment of lack of coverage, physical therapy? Any other potential therapies that you would want to see CMS cover?

Penney Cowan: Yes. Actually they get a lot of the acupuncture. Some of them are referred to massage therapists. Those, that's another one. Some of them are even referred to specific treatments whether it's getting that, you know, nerve stimulator or those kinds of treatments. It's not always covered.

It depends on I guess Medicare but then if they have extended care they have a supplemental with their Medicare whether or not that's covered and the process to go through it. I think part of the problem is too is not just the coverage but the time it takes to get that approval. For somebody living with pain they want to feel better yesterday.

And, so to tell them to wait three weeks, a month or so to get that approval to get the test, that's another issue but a lot of people that we struggle with. And sort of another comment, it's not just the people with pain but those living with them, caring toward them. They're probably suffering and experiencing many of the same frustrations and emotions that the person with pain is feeling.

Michelle Oswald: Great, thank you so much.

Penney Cowan: You're welcome.

Michelle Oswald: Sara, we can take the next comment please.

Operator: Thank you. Next we have Carla Rahn Phillips from the Restless Legs Syndrome Foundation. Please go ahead.

Carla Rahn Phillips: Thank you. It's a pleasure to be invited here. Restless Leg Syndrome is not chronic pain but we're often lumped with chronic pain, and that is a problem of education for - of providers and also of the general lack of understanding of - that restless leg syndrome is a neurologically based sleep disorder, and its management should not fall under the exclusive purview of pain management specialists, especially when opioid therapy is indicated.

It's only indicated in the extreme case in which standard therapy does not work and low dose opioids often the dosage does not change for decades. But when that therapy is indicated these days our community is often referred to pain management clinics and the people in the pain management clinics do not understand what it is, even as much as their standard clinicians understand. But the standard clinicians for various reasons no longer feel able to prescribe these low dose opioids and therefore these people are shunted into pain clinics.

So that's really why I am representing our foundation to urge that better education, better research and the ability to understand that restless leg syndrome is not chronic pain. It's chronic but it is a chronic neurologically based sleep disorder and really cannot therapeutically be lumped with chronic pain. I have all kinds of articles from the American Academy of Sleep Medicine, from the Mayo Clinic, from the New England Journal of Medicine and other well researched articles that I can provide to CMS or to Michelle in case anyone is interested in this.

But as others of you have noted, education and the understanding of what conditions are is absolutely crucial and the more that that can be fostered at

the federal level the better off we will all be. So barriers to care, lack of education but also along with that barriers to getting the medications that will make this life changing condition bearable. Thank you.

Michelle Oswald: Thank so you much Carla for your comment. There will be a slide later in the deck that we will share that you can see where you can share your information with us so thank you for that.

Carla Rahn Phillips: Wonderful, thank you.

Michelle Oswald: Sara we can take the next comment.

Operator: Our next question - I'm sorry. Our next comment comes from Shilpa V with the Global Healthy Living Foundation.

Shilpa V: Hello thank you. This is Shilpa, Associate Director of Patient-Centered Research at the Global Healthy Living Foundation, more popularly known as Creaky Joints and as the name suggests, we work with the community of patients, also with clinicians and rheumatologists and researchers around chronic pain from autoimmune - mainly autoimmune but also other conditions, and I'll say that I'm a patient myself.

I think through two things that we've learned from our project on chronic pain actually with the patient in terms of goal-setting – patients have very different goals compared to clinicians. We also talk about to target the paradigms of goal-setting. And I think those are great there in terms of gaps between what clinicians are setting as goals and what patients are setting as goals.

And so the breakdown and that shared decision, and that's the first thing. And then the second thing has to do with continuity of care also released to the

notion and the concept that those with little understanding about the multi-modal need for care when it comes to chronic pain. And, so the continuity of care is what is also - and perhaps things like telehealth might help.

We've seen recently given the COVID situation (unintelligible) regular in-person meetings with the clinician alongside telehealth might help establish that continuity of care as well. That's all for me, thank you.

Michelle Oswald: Thank you so much for those comments Shilpa. So, outside of telehealth, how can CMS support these recommendations that you've made for goal-setting, shared decision making and improved continuity of care?

Shilpa V: So, I think there's, you know, there are many ways to look at this. I think first of all, I think it all begins with education. I think patient-supported outcomes is something that's really important because again things like fatigue and pain often the patients find very important in terms of goals and also the scans and x-rays and blood work.

And so that marrying of communication between clinician set goals that are about bringing down biomarkers - sort of control of biomarkers, in a patient's bloodwork and marrying that with patient goals. And patient goals are often short goals, right? Can I open this door? Can I walk up the steps without pain?

So marrying those two I think will establish better communication between clinician and patients and that itself will help to achieve some sort of shared decision-making in terms of common goal settings as well.

Michelle Oswald: Thank you so much. I appreciate the additional comments.

Shilpa V: Thank you.

Michelle Oswald: We can take the next comment please.

Operator: Thank you. Next we have Joan Sanborn with ACPA. Please go ahead.

Joan Sanborn: Thank you for including me today with this. Now I have had chronic myofascial back pain since 1981 although it took me 16 years to get that diagnosis, and then I developed fibromyalgia so I'm very familiar with chronic pain.

Now I find that another barrier - I agree with what's been said so far but I agree another - I found that another barrier to care is actually finding a pain management doctor. It's getting harder and harder to do these days. I had one doc - I have one pain management doctor. He went out of the business. I had another one who stopped Medicare, and every time you have to find a new pain doctor it's very stressful because a lot of them aren't doing that.

There aren't very many of them around these days. The only other thing I would like to add is that I would like to see platelet rich plasma injections covered because they're very helpful and I had to pay for mine, which was for six months. Thank you.

Michelle Oswald: Thank you, Joan. We appreciate your comments. Going back to your comment about difficulty finding a doctor, do you have any thoughts on anything that CMS can do to help support that piece and improving that barrier or breaking down that barrier?

Joan Sanborn: No I don't. I haven't really thought about it, but if I think of anything I will definitely send it along. It's just as a new doctor and when you finally have -

get to talk to one, I talked to one who wanted me to cut what I - the dosage that I had been taking for years in half before he would even dare to take me on as a patient. Those are the kinds of things I have to deal with.

Michelle Oswald: Right. Thanks for sharing your story and your experience.

Joan Sanborn: Thank you.

Michelle Oswald: We are going to move on to the second topic area, which is Medicare coverage. So Sara, can we take our next comment on this topic area? Thank you.

Operator: Our next comment comes from Vanila Singh with Stanford University Medical Center. Please go ahead.

Vanila Singh: Hi, good afternoon everybody. I want to applaud Dr. Ling and Ellen Blackwell at CMS for doing these listening sessions. This has been amazing. I had the privilege of treating patients at Stanford and just prior to this, chairing the very important HHS Pain Task Force effort and report.

I want to echo everybody who just made their comment on the barriers to care aspect because it all ties in. In essence we know that time is of essence in terms of having ample time. So, the reimbursement and coverage for that as I reentered seeing patients from the policy making arena and realizing that the challenges have only grown. And, so I definitely want to highlight that there is still a great need of time for the complexity of medical conditions that many of these patients suffer from, and they certainly aren't the same as what we are maybe used to otherwise in terms of treating patients with other medical issues.

There's the bio affect, the social affect and many different aspects of healthcare, yesterday alone I saw a young girl who's 23, dropped out of college, lost her job all because of her chronic widespread pain and she's in essence homeless. The expense of social and bio-psycho aspects of her own care has really showcased that even young folks are susceptible to unbelievable issues, and we just need the time and also need coverage.

One of the big things of late in terms of medical - of Medicare coverage that has been brought up that I really wanted to emphasize today was that even treatment that we know have been shown to be effective for certain patients such as those chronic migraine sufferers is now being required to have pre-authorization at CMS.

This is something I've been hearing across the nation as I've been to different places and we are experiencing it in our own clinic. That is given to be another hurdle in the Medicare population, secondly big concern about the advances in neuromodulation or peripheral nerve stimulators and the anticipation that there's going to be a greater hurdle with potentially in Medicare that has been proposed.

I just want to say that I really hope that we consider greatly before we move in that direction as it is. Chronic pain is a multitude of different medical conditions and what we really need are all the tools in the toolbox - and at a time when I think we see the challenge so great, to hear of any hurdle, whether these are people who are on long term opioids with complex conditions that have helped their functionality or people who are getting interventions that are highly advanced in this time.

I think that it seems like a bit of a step back, progressive if you will when people find that it's going to be that much harder to obtain their care. And

this ties into barriers to care. Education, stigma are - remain a big issue in workforce and I think all of those really tie in again to if Medicare coverage remains seamless, I know that there are other issues that CMS has to consider in terms of utilization issues, et cetera. But I think the bigger issue also looking at functionality, timely treatment so that people don't lose their job, their sense of identity. It's a much greater cost to society as well as the individual.

And so I want to emphasize that we need to be timely and hopefully have less hurdles in terms of Medicare coverage from a variety of different things, treatment modalities that are there and often they're just one part of a larger treatment regimen but necessary for that person to have big (unintelligible) in a productive life. And then finally I want to emphasize and Dr. Ling knows this as well as the other crew members but we definitely need to continue to disseminate the task force, the primary care folks out there even when we are trying to get things and they are authorized and covered.

But just to get it in a timely manner people still need - my colleagues, clinicians, doctors are still needing help, and I think dissemination of the report which was specifically written really for all stakeholders whether they are specialists, whether they are psychologists, pharmacists, really was intended so that people could understand the very complex, large spectrum nature of acute and chronic pain and be on the same page. Thank you very much for the opportunity to talk today.

Michelle Oswald: Thank you so much for your comments. You touched on a lot of different points there, so we appreciate the points that you've made. I do want to say I'm seeing some folks raise their hand in the webinar portion of this call, and unfortunately we're not able to respond to those. So, I please ask you to just go through the queue and that way we can get your answer verbally and be

able to have that transcribed. Thank you. Sara we can take the next comment please.

Operator: Thank you. And as a reminder if you would like to make a comment please press star 1 and state your name and affiliation. Next we have Sanjay Gupta with American Pain Association. Please go ahead.

Sanjay Gupta: Hi - Thank you for having me here. I have two comments. The first is regarding the coverage for some of the therapies Dr. Singh said and Cindy said. One of the things which we have seen in the practice and I'm sure many of you have seen it too, that the use of medical marijuana and cannabis or cannabidiol, CBD, is helping a lot of these patients in pain management non-opioid alternatives.

The only problem, what we are seeing, is these are very expensive options. So - and many a times these patients are - they'd rather take opioid or oxycodone, or other opioid medication because insurance pays for it but insurance does not pay for cannabis or marijuana or CBD. So my suggestion is to seriously look at this option, at least for those patients who are willing to come off opioids but can't afford treatment like medical marijuana or cannabis.

So that was number one. And the number two I have is a suggestion for patients. Many of us who are paying doctors and treating patients, we have very limited access to their history, staff history, the drug use history, and my suggestion would be to have that information more available to doctors, because as somebody brought up it's already hard to find doctors.

So many of them are shutting practices off. So when a pain patient goes to a new doctor, they may not have all the history. So things like urine drug

screen, they should be part of patients' data which is being stored like - you know how every - all states have the data, PDMP data, they can include urine screen data in that, so any doctor who is seeing that patient, they can see the user - the patient's compliant in the last five to seven years and they can make better decisions in terms of whether to give up yours and what dose to give.

So - and also the history of any non-compliance with opioids for last five years should be part of the PDMP record with the state, because that'll make doctors' lives very easy. Right now, a patient goes to a doctor, doctor has very limited knowledge of their drug abuse, history or addiction history and many a time they just give them medication without knowing what to do. So these are my comments.

Michelle Oswald: Thank you so much Dr. Gupta for your comments. Sara we can take the next comment please.

Operator: Thank you. Next we have Jian Guo Cheng from the Cleveland Clinic.

Jian Guo Cheng: Hello everyone. Thank you for the opportunity. I'm going to keep my remark very brief. I'll make two points, one about the coverage. So, CMS actually - Medicare did a really good job on covering trigger point injections without preauthorization.

That makes the physician's life and more importantly the patient's life much better. So whether you can expand that, there are many different treatment modalities that need repeated visits when patients - in this patient population.

Many have mobility issues and many of the things that can be done in the same way and because of the burden for preauthorization the patient has to

come back and forth and spending money for talking and other things. So, this is one specific area that may be improved.

A second point is Cindy and others have mentioned about access to care, very difficult to find qualified providers. So the question is what CMS can do to improve that. So I have been Program Director at the treatment clinic for pain fellowship for more than 10 years. So more recently I'm invited to give Grand Rounds to the military fellowships, full fellowships along the country and they have - because of the tele or virtual lectures.

So I've been doing it for many years, and I think it's a really good way to help train the next generation of pain management providers. That's critically important because if CMS can have some initiatives to strengthen the training programs through various - sponsoring various educational activities, that'll be unbiased, not the industry supported and have a high standard.

We have a lot of talent around the country who are willing to help out. So I do this for the military for many years and it is free of charge and on my own vacation time. But that CMS can do to help and to larger scale nationwide for training the next generation of qualified highly ethical providers. Thank you.

Michelle Oswald: Thank you for your comments and thanks for expanding on the things that CMS could do. Sara we'll take the next comment please.

Operator: Thank you. Our next comment comes from Stefan Kertesz from the University of Alabama in Birmingham. Please go ahead.

Stefan Kertesz: Hi. Am I audible?

Man: Yes.

Stefan Kertesz: Can you hear me?

Michelle Oswald: Yes, you are. Yes we can.

Stefan Kertesz: Okay. Hello. Thank you for the chance to speak. I have been both taking care of patients and hearing from the patients across the country over the last four years who have been quite traumatized.

Many of these are patients who have long-term pain and have received opioids long term. So they're probably about 10 million people on long term opioids. At this point in time there are a number of forces that have created an effective mandate both to reduce the doses on patients who receive over 90 morphine milligram equivalence or to refuse to care for patients on doses over 90 morphine milligram equivalence.

While those forces are not just from CMS, several are coming from CMS and distorting care or causing patients to have none. But the first is the CMS high dose opioid metric which I know is proposed by the National Committee for Quality Assurance in which any patient at a dose of greater than 90 is regarded as receiving bad care.

This is operationalized in the incentive payments, and by design it mandates that doses are cut in patients who are currently stable, and obviously this contradicts HHS's own unified guidance on opioid taper. And the second is of course the CMS action where the number of patients as high dose is used as the basis of criminal referral by the OIG of HHS to DEA. It's something that the OIG has reported on this website.

This contributes to a perception for the physicians at least the continuation of care with any patient on long term opioids particularly high dose represents both a criminal and a professional liability. This distorts the care and leads to an all focus being on, “I can’t take care of you if you’re on these medicines” or “I can only discuss the opioids with you because that’s the entire matter that threatens me as a physician”.

I believe CMS could correct these matters both by reconsidering the quality metric, by broaching a discussion with the HHS OIG on the use of a CDC 90 milligram dose target as the base for criminal referral. And I also think that the ultimate purpose in care of patients with long term pain and serious illness should really focus on understanding the illness in the context of mental health and the management of multiple medications.

There actually are potential ways to bill CMS through Medicare for this service - I think with the coordination of care lines and a complex care line. But I don’t think many primary care physicians are even aware of them, and so I wonder if CMS should consider re-packaging some of its existing billing codes - so as to encourage physicians to engage in you know, multidisciplinary consultative care which often involves record review and counseling as key components of dealing with high dose seriously ill patients, rather than the current mechanism - to really lead to a decision not to receive them at all as patients, or to reduce doses and make the entire relationship about dose reduction. Thank you.

Michelle Oswald: Thank you so much. Thanks for your comments and for also providing some tangible suggestions on what CMS can do. So, at this time we’re going to go on to our next topic area. Our next topic area is Medicare beneficiaries with substance use disorder and here we go. So now that is on the screen so Sara we can take our next comment please.

Operator: Thank you. And as a reminder, to make a comment on this topic, please press star 1 and speak your name and association. We do have in the queue James Broatch. If you can please state your association your line is open.

James Broatch: Yes, CSA. I rather would not comment on this. I had a comment for the previous session if I may.

Michelle Oswald: Sure that's fine. Go ahead please.

James Broatch: Okay. I wanted to fortify the comment about the difficulty in finding a doctor for people with high impact pain. Most - a lot of members of our community will find specialists who do not accept Medicare. The other thing people with complex regional pain syndrome are facing is that there is no approved therapeutics. And, so some of the effective therapeutics such as compounded medicine, topical creams, medical cannabis are not approved, and I think that should be looked into.

The other two problem areas for people with complex regional pain syndrome are finding affordable dentistry and dentists who are familiar with chronic pain, and also there's a great deal of difficulty of individuals who are experiencing pain flares and interacting with the emergency department, and they'll perceived almost uniformly as drug seekers. And I think some education in those two areas should be on your radar screen, thank you.

Michelle Oswald: Thank you. Thanks so much. Sara we can take the next comment please.

Operator: Thank you. And next we have Robert Burns with the American Dental Association. Please go ahead, sir.

Robert Burns: Yes. again I'm with the American Dental Association and I really just very quickly wanted to bring up two points that you may - CMS might consider moving forward and it does pertain to the previous topic. Number 1, the Support Act put in place a requirement that those who are prescribing opioids for Medicare enrollees need to use a - do so electronically.

I just wanted to bring up that as you may know, the vast majority of dentists do not participate in Medicare other than maybe the Medicare Advantage plans and on top of which, believe it or not, a great number of dentists do not have the IT systems in place to do that sort of electronic prescribing, and I'm happy to discuss that in another venue without taking everyone's time on that. I wanted to let you know.

And the second point is that there's really no consistent unifying recommendation in dentistry about obtained management guidelines for acute pain for - in which case opioids are addressed. Also through the Support Act, the FDA has given us a grant recently to develop a pain management guideline for dentistry. We are in the early stages of developing that, and I wanted to put that up there in the event someone at CMS would like to talk about that at another venue. That's all I had to contribute.

Michelle Oswald: Thank you, Robert. Okay just a reminder we are now on the topic of Medicare beneficiaries with substance use disorder. I ask that you please stick to the topic for now and I hope that we have some time at the end to be able to go back and touch on the other topics. Sara, we can take the next comment please.

Operator: Thank you. Next...

Ellen Blackwell: Michelle this is Ellen. Can I just interject for our last commenter that we do have a provision on electronic prescribing of controlled substances currently in the physician fee schedule which is out for - in draft, a proposed one right now. And you are most welcome to send in comments until October.

Michelle Oswald: Thanks Ellen.

Operator: Our next comment comes from Ann Fuqua representing herself.

Ann Fuqua: Hi - I was trying to comment on the prior topic. Do you want me to wait till the end or make that comment now.

Michelle Oswald: You can go ahead.

Ann Fuqua: Okay. I would echo what Dr. Cortez had said about the high dose metric. This is basically labeling patients - labeling, you know, a treatment regimen as bad/negative without considering anything about how the patient was doing, how they came to deal with high dose, how social they are and factors they may or may not have.

And doctors, they see what's happening to other physicians and they have every right to be terrified to treat - to take on the added risk that they already have a great deal of risks prescribing to pain patients, but then prescribing to patients on Medicare creates an added risk because they got the issue of the federal government. They've got the ability to prosecute them for Medicare fraud.

That makes - that makes it even more reluctant to treat patients. And so then so many of us wound up having to not use the Medicare benefits that they're paying for because our physician, they're afraid to treat the patient on

Medicare because they feel like it's just putting them at higher risk, higher risk than they're already at regardless of whether they have a patient who's doing very well, improved, is compliant, has, you know, appropriate results on drug screens.

None of that goes into play with this high dose metric and then when patients - when they've got to get prior authorizations for medication frequently and doctors, they're afraid to sign prior authorizations because they know that that can put them - that can draw attention to them because they're requesting the prior authorization, it just kind of waves the flag - hey, this person is prescribing a high dose. And so they might note so many doctors, they're just like, I don't sign prior authorizations.

So then patients that are already having to pay out of pocket to go to their physician are often not even able to get insurance coverage for their medication. And this - these are patients that are even lucky enough to have medication, and this is just an incredible financial burden. There are people that, they are not able to afford their blood pressure medication and other basic things that they need, even food, to be able to just afford, you know, a good doctor because their medical care costs so much.

Myself personally for five years, I've had to fly from Alabama to California just to see a doctor and I have a wonderful doctor in Birmingham where I live, and he had taken care of me for nine years but he just - it was weird. He just left his pain management practice and basically moonlighting in urgent care, till he's retired. What I'm trying to say is this is not - the effort to try to protect patients from these high doses is really putting them at further risk because they're - I'm sorry.

They're not – this is interfering with their ability to get to the - I'm trying to read this. But basically what I'm saying, it's making an already difficult situation for continuing care for pain management which is already incredibly difficult for any patient. That makes it more difficult for Medicare patients and there are a substantial portion of the patients in pain management that are on Medicare.

So, this is a large portion of patients that are dealing with this. It's not protecting the patient that has those metrics. If they want to - does not look - if it looks at the patient or like the VA scores, that would at least be something more where there's a leg to stand on that if it's bad or good, you know, the (unintelligible) patient (unintelligible) you know, we just want to have a decent life and when something enables you to have a good quality of life but then the powers that be are just saying it's too dangerous.

If you're not able to get out and do the things that you want to do and you're not going to have a decent quality of life that's even worth living in your opinion, then that risk for many people is - well it's acceptable and yes there's risk but you mitigate it as best you can and just - people have to make difficult decisions and weigh risk in other situations in life. And it really feels almost like we're being treated as children in a sense, and we're not being given the - it's not that we want to make this decision or go out and just have opioids at Wal-Mart (unintelligible).

We want to make decisions about our health care with doctors that we know and trust - trusted for years and just like a patient gets cancer or anything else, they weigh their situation and they make that decision with their doctor. They don't have their doctor saying well, gosh, you know, yes you were doing well but I just - I can't do this.

Michelle Oswald: (Ann) I'm sorry. I don't mean to cut you off but...

(Ann Fuque): No, that's all.

Michelle Oswald: We appreciate your perspective today. I think all of us could probably say this is why we're here. We appreciate your patient experience and for sharing your stories with us today so thank you. Thank you so much for that.

So, I am going to go on to the next topic area. I suspect there's some folks in the queue that are going to go back to some previous topic areas. Essentially we can open it up, but I would like to open it to the pain care during the COVID-19 pandemic topic and hope to get some comments there. So Sara can we go ahead and open up the next caller for comment please? Thank you.

Operator: Thank you. Next we have Peter Pitts with CMPI. Please go ahead sir.

Peter Pitts: I'm going to speak and this has been a terrific meeting. I'm a former FDA Associate Commissioner as well as being in the Center for Medicine in the public interest, and one of the things that the FDA has done over the past couple of years is have discussions about how its regulations and review procedures can help or hinder the development of non-opioid therapeutics for pain.

And whether it's for patients at risk or whether it's for patients without access during the epidemic, my question is - I guess my comment is - CMS should engage with FDA possibly in a joint task force to discuss how both agencies can assist in broader access to non-opioid therapeutics -- I'm not specifically speaking about Rx products. They're certainly in Part D and Part B, and the thought being that a therapeutic that is on one hand available, not available because of access purposes isn't helpful, and a product that was never

developed because of the policies out of CMS sent a negative signal, certainly can be reversed and the first part of that is to understand and explain.

So, my suggestion is for CMS to work more closely with FDA to understand how they can help to incentivize the development of new non-opioid treatments to pain. Thank you very much.

Michelle Oswald: Thank you Peter for that comment. I'm not going to speak for other folks at CMS, but I do know they're having some committees working internally that have included CMS and FDA, but I appreciate your comment to further that. Sara we can open it up to our next comment, and I do encourage folks that if you have comments on the Medicare beneficiaries with substance use disorders topic area or the pain care during the COVID-19 pandemic, we would love to hear from you. Sara?

Operator: Thank you. Next we have Cindy Steinberg with the U.S. Pain Foundation. Please go ahead.

Cindy Steinberg: Yes. And answer the question about what we can do during the COVID pandemic, telehealth has been very beneficial for pain patients, and we would hope that the coverage would continue for this after the pandemic. Pain patients have tremendous mobility, transportation, and stamina issues in getting to doctor's offices, driving or finding transportation, waiting in line using public transit are all very difficult to manage with severe pain and mobility issues.

And so, I would really hope that the great effort that you have made to cover telehealth would continue after the pandemic. And I wanted to just go back to the question on what kind of coverage CMS could do, and I want to focus largely on complimentary care for coverage. One is chiropractic for

treatments appropriate to your condition. Right now, Medicare only covers one specific technique for chronic lower back pain. As an example, I have thoracic back pain, and I see a chiropractor helps me with a different technique on a different part of my back.

If I had Medicare, these treatments would not be covered, and I would have to pay out of pocket, and that's pretty much unaffordable - particularly where you might see somebody for several times a week. Secondly, a similar comment on acupuncture - it's great that Medicare is now covering acupuncture for chronic low back pain but there's some problems with it.

One, is it for treatments from licensed acupuncturists who are not a physician or not supervised by a physician. Many people see these people, and that isn't covered as I understand it, and also it's of course only covered for chronic lower back pain, so one particular condition where many patients that are members of U.S. Pain Foundation use acupuncture for other things.

Another is therapeutic massage. This treatment is not covered at all. It is helpful to many people with pain, and it's unaffordable. A recent survey of 1,500 patients with chronic pain the U.S. Pain did, we found that patients most want access to massage therapy but can't afford it because of cost barriers. Another important one is therapeutic exercise programs like tai chi, the pilates particularly for chronic pain, and there are ones that are for chronic pain and those are not covered.

Self-management patient education programs are very important. We talked about the lack of patient and physician education on multi-modal treatments. There are some validated programs but CMS could - should either provide grants or partner with a federal agency for the development of these types of self-management patient education programs.

Another is ongoing support groups that include patient education. The U.S. Pain Foundation has a program that trains leaders in our model and it includes ongoing support and training for the leaders. The support groups are also now done through Zoom and other online methods, and they help an enormous amount of people for a long period of time who have to live with a chronic illness that's going to go on for a long time.

And then, finally we were asked about models too I believe, and with value-based models that pay for patient improvement and function and the ability to manage their pain. People talked about that earlier with a treatment plan rather than for each treatment visit. I know you want to move to that sort of payment structure, and that would be really, really helpful like in cardiac care and other types of bundled care like that rather than paying for each visit - pay for improvement on a pain management plan and function for patients.

And then, just a final comment I want to make is echoing the comments that we have heard and on the HHS Task Force that I sat on and heard from many patients, and Dr. Cortez and other patients here and that is the punitive measures for opioids. Opioids do help a large number of patients living with pain. We constantly are hearing from every single week, we've heard from hundreds of patients who have been dropped from care. And the punitive measures with opioids particularly those with above 90 but any opioids, because they are used in combination with many other modalities but for very severe pain, medication of some kind is needed.

So, I know it's a difficult situation with that, but I just want to echo that.
Thank you.

Michelle Oswald: Thank you. Thank you for all of your points. Sara, we can move on to the next comment please.

Operator: Thank you. Next we have Anne Burns with the American Pharmacists Association. Please go ahead.

Anne Burns: Hi - Thank you for the opportunity to make a comment, and it's actually just echoing the previous speaker. I also serve as a caregiver for a patient with chronic pain, and just want to thank CMS for opening up telehealth as a modality of service delivery for patients with chronic pain for all the reasons that were discussed by the previous individual. It's just made a significant difference in how we receive care and also the after effects of care coming home from a visit, riding in the car and so forth can make the pain levels go up for a day or more. So thank you to CMS for that.

The only other comment that I would make is just encouraging CMS to continue to leverage pharmacists as providers who can be optimized in assisting patients with their medications and pain management. And, also to advocate for an integrative model to care that better coordinates the care for patients with pain.

Personally we are - we currently have nine physicians in the mix, and we are the individuals who are coordinating our care, because we are not lucky enough to be in a program where our providers are speaking to each other. So, thank you for the opportunity to comment.

Michelle Oswald: Thank you Anne. Could you expand a little bit more on what that integrated model of care would look like? Sorry to put you on the spot or if you're already on mute. All right, I think we may have lost Anne. All right Sara we can go on to the next caller. Maybe Anne will follow up by email, thank you.

Operator: Next we have Deepti Loharikar with the Association for Behavioral Health and Wellness. Please go ahead. Deepti Loharikar with the Association for Behavioral Health, if you could please check your mute function. Your line is open.

Deepti Loharikar: Yes I was on mute. I apologize. Thank you. Thank you for the opportunity to come and hear and thank you for doing these listening sessions. So, I'm with the Association for Behavioral Health and Wellness, and we represent payers who manage behavioral health benefits.

So just a couple of comments for your consideration, first thank you for reiterating in the physician fee schedule, what was in the SUPPORT Act which was allowing the home to be a telehealth site for people who have substance use disorders. This has been a big deal especially in light of COVID so thank you for that.

Another area that we are very focused on is modernizing the confidentiality of substance use disorder records or 42 CFR Part 2. We advocate to harmonize this with HIPAA as much as possible, so that there's no gaps in care. And I know there's going to be another rule because of the CARES Act is coming through SAMHSA, so anywhere where CMS can work with SAMHSA to express that, it is necessary to align Part 2 with HIPAA would be much appreciated.

Another area that we are very supportive of is the prescription drug monitoring programs, you know, physicians and pharmacists and other providers have access to it. We advocate for insurance companies to also have access to PDMPs, so that we can be a strong partner in making sure that we're helping in the fight against the opioid epidemic.

And my last comment is we did - we do have comments that we're submitting on the electronic prescribing of controlled substances RFI to all of you. In there we talk about removing the in-person evaluation requirement as well as increasing the number of providers who can treat SUDs. And this is - I know this falls under the DEA but we encourage you to take a look at our comments so that you can work with DEA on those issues and thank you very much again.

Michelle Oswald: Thank you so much. Thanks for your comments today and thank you for commenting on the RFI. We really appreciate it.

Deepti Loharikar: Thanks.

Michelle Oswald: Sara we'll take our next comment please. Thank you.

Operator: Next we have Penney Cowan with the American Chronic Pain Association. Please go ahead, your line is open.

Penney Cowan: Hi thank you very much. I can actually talk about the pain care during COVID. We just actually did a survey of 1,000 of our members on the impact that COVID was having on their pain care. A lot of people because of COVID had been using Zoom which is good, but there's a lot of people who don't have access to those kinds of electronics, so they can't do that.

So they've been shut off from their care. Another thing that we've heard from that survey or learned are people that can't get out to their physical therapist or their massage or even other forms of complementary or alternative medicine, something that's hands on, and they're really missing that. They feel shut off – the swimming – being able to go and do swimming.

The other interesting thing that I heard though, is a lot of people don't feel very much different at all because they've been so isolated because of the pain that the COVID really hasn't changed their way of life at all. They're still very isolated and very much alone so I think that was the impact on that. It's not been very different for a lot of people. There are about 50% of them.

There were several of them who are experiencing a lot more depression because of the isolation but also because of being shut off. There were a couple of them that actually talked about that suicide would be the way out from all of the issues that are going on right now. So that's what we have on the survey, and I'd be happy to share the results with you if you'd like.

The other thing I wanted to make a comment on though, we've heard so much about provider education, a little bit about the responsibility of that person with pain, and I think what we really need to focus on is that it's a team approach when you're living with pain. So the person with pain really has to be at the center of that care and they have to take a responsibility for their care as well.

So now I work with a lot with the VA, and I know they do the shared visits, and I think that would be something that CMS could look at about even for the substance use disorders, any of these because so often people learn from each other in their own learned experience with people, their peers who have walked in their shoes, and they really understand that. So first of all, those peer groups, I know that was mentioned before. We have been doing that for 40 years now educating more folks.

We also have trained leaders and we have been training them and supporting them. But I think that you know, empowering that person with pain and

letting them know that they are part of a treatment team and they do have a voice and they should be sharing and make informed decisions based on knowledge that they understand. But I think they need to have the education about exactly what is going on and what is being communicated by the provider.

We have developed a lot of graphical tools that are interactive that they can track things and hopefully have that meaningful conversation with their providers and a lot of healthcare providers have used these. They've been used globally - not just here in the U.S. but around the world. So, I just also wanted to say that, that we look at what providers can do but I think we also have to step back and say the role of that person living with pain, that they are part of the treatment team. Actually, they're at the center of the team and they need to be just as - they have to be - take an active role in their recovery rather than that path to patient. They really need to become an active participant so thank you.

Michelle Oswald: Thank you Penney for that and thank you for your comments. Sara we can take the next comment please.

Operator: Next we have Shilpa V with Global Healthy Living Foundation. Your line is now open.

Shilpa V: Thank you. This is Shilpa again. I'm going to just make two quick comments about pain care during COVID. So we developed a study with over 20,000 patients who are dealing with chronic pain from both autoimmune and other forms of other main conditions. And we also had conversations, we've done some qualitative interviews, et cetera. And, we've learned two things that keep popping up. One is patients are scared to go in person to their doctors, to their laboratory appointments to follow up appointments, et cetera.

And, so we developed telehealth (unintelligible) as well with patients and as many people have stressed I think that's a great - something that we'd like to test. We're advocating for it within telehealth. We're also advocating that states ensure that (unintelligible) concern because some states don't allow that and could increase access through to care in areas particularly with low (unintelligible) for example.

And then the second thing of course we've come across in general and as we've seen increased conversations around the disparity and affordability around healthcare. And so improving access to home care whether that's home infusion for patients who have autoimmune forms (unintelligible) infusion for their pain control or blood work, et cetera to be done at home, so that patient doesn't miss appointments and again, going back to that point about continuity of care which is so very important with managing chronic pain. That's all from me, thanks.

Michelle Oswald: Thanks again Shilpa for your comments. Sara we can take the next comment please.

Operator: Next we have Jan Towers. Your line is now open. If you could please state your affiliation.

Jan Towers: I'm with the American Association of Nurse Practitioners. I would just like to emphasize three points. One is that we find it - we think it would be very valuable to continue to emphasize the utilization and reimbursement of not only physicians and psychologists but other mental health frameworks and particularly nurse practitioners who can provide care in this particular realm, One that there needs to be - two, that there needs to be another emphasis -

increased emphasis on non-pharmacological treatments and reimbursement for them.

That's often the barrier because of the payment which has been pointed out by a couple of other speakers today. And the third is to think about how we can combine a bundle payment for some of the things that maybe one identified activity does not do the whole trick, but if you have two or three combined that could be reimbursed far and wide, that would make things a lot easier for everybody. And that's been brought up several times too and would like to emphasize that, thank you.

Michelle Oswald: Thank you Jan for your comments. Sara if we can get the next comment please.

Operator: Thank you. Next we have Meredith Raymond. Please state your affiliation.

Meredith Raymond: Hi, this is Meredith Raymond from ACL and just wanted to have a couple of quick comments. ACL does fund a couple of chronic pain management programs. And so just to add, we would love to have further conversations if CMS wants to talk with us offline about specific programs or policies we would definitely be open to that.

Michelle Oswald: Great – thanks Meredith. Sara we can take our next comment please.

Operator: Thank you and as a reminder to make a comment please press star 1 and record your name and affiliation. Next we have Deepti Loharikar from the Association for Behavioral Health and Wellness. Please go ahead.

Deepti Loharikar: Hi, I just forgot to mention earlier when I gave my previous comment, I wanted to touch on something one of the other participants had mentioned at

the beginning of the call related to stigma. So I just want to put it on CMS's radar that ABHW had launched a campaign a few years ago called Stamp Out Stigma to reduce the stigma surrounding mental illness and substance use disorder.

It challenges each of us to transform the dialogue and you know, talk out loud about these problems. The goal is to change the perception and reduce stigma of mental illness and substance use disorders by encouraging folks to talk about it. I bring it up only that if CMS is interested in partnering in any way or wants to use this platform, we are happy to help with - in any way that we can with that so thank you.

Michelle Oswald: Thank you. Thanks for calling back in and pointing out that comment, thanks. Sara we can open it up to another comment please.

Operator: Thank you. Stand by for the next comment. If you just press star 1 to join the queue please check the mute function on your phone. Your line is now open. State your name and affiliation. Please go ahead.

Joel Roverson: Hello there. This is Joel Roverson from the Public Act - Protecting Act Pain Relief Coalition. Thank you so much for holding this call today and hearing from stakeholders. I wanted to specifically speak to the access to pain relief during COVID-19. We have found as part of our coalition, which is a group of public health organizations that represent patients and providers that serve those with persistent pain, that older Americans have had real challenges visiting their healthcare providers due to shelter at home orders either because they've been a lack of access to transportation as it's been referenced before or that they're worried about their health if they do go to the doctor's office and whether they might have COVID-19 when they're trying to address their pain issues.

So, I want to support comments made by the U.S. Pain Foundation about supporting options. We found that that's an extremely helpful to older patients to get access to their caregivers without risk to them or without requiring them to go to the doctor's office. So we certainly support an extension of that. We also support the development of comprehensive pain management plans with providers and insuring that CMS is covering the development and maintenance of those comprehensive pain management plans.

And the last piece that I would mention is that we also have a coalition in view that's critically important to consider over the counter alternatives which also address some of the access issues during COVID-19 when someone might be able to make it to or have a caregiver pick up OTC alternatives when they can't get a prescription. They can't always solve the problem, but in many cases they can, and something that we worry about as a coalition is issues that we talked to CMS about before where FDA has proposed a limitation on access to acetaminophen over 325 mg in order to address other issues of abuse or lack of understanding about risk of acetaminophen.

And that would create real problems for older adults, especially during COVID-19 because those patients and consumers with persistent pain do need access to pain relief that can solve the problem and limiting access to about 50% of Americans can only take acetaminophen. They can't take NSAIDs so we appreciate your help on reaching those issues, bringing telehealth, bring comprehensive pain management plans and ensuring Americans have access to over the counter alternatives when that's determined by a professional as appropriate.

Michelle Oswald: Thank you, Joe. Thanks for those points. Sara we can open it up to the next comment please.

Operator: Thank you. We currently have no one in queue. If you would like to comment please press star 1 and record your name and affiliation. Please stand by for further comment. Next we have Joan Sanborn with ACPA. Please go ahead.

Joan Sanborn: Thank you. I just want to follow up on a few things that were said about looking for a - finding a pain doctor. The two times I've had to find a new pain doctor, I found that the doctor that I'm interviewing essentially has always called the previous provider to see what kind of a patient I am. And I just want to say with the things that Penney brought up, I agree with that survey and hi Penney by the way.

And when people say how you doing with COVID, it's like it's not much different than my normal life. I spend a lot of my life all by myself. Thank you.

Michelle Oswald: Thanks Jan. Thanks for following up with that additional comment.

Operator: We have no one else in queue.

Michelle Oswald: Well, I can take this time to move on to the next slide and you can see there's a few resources here. One is if you have additional comments once you hang up from this listening session, you can send those to the pain mailbox there. There's also a link to the HHS pain management best practices, their agency task force report as well as the additional CMS opioid misuse resources here.

We also have our partnership mailbox. Again I'm with the Partner Relations group so if you are interested in partnering with us on any projects, please reach out to us and we're happy to follow up with you and look forward to talking with you. Sara just want to check one last time and see if there any additional folks who want to comment.

Operator: We have no one in queue.

Michelle Oswald: Great. Thank you from all of us at CMS for taking the time to talk with us today. Again your feedback and your information is very important to us. If you think of anything after this call, please feel free to follow up with us during - with the email addresses that we provided and I hope you have a good afternoon and take care. Thank you. Goodbye.

Operator: Thank you for joining us in today's conference. You may disconnect at this time.

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