



Dr. Todd Graham Pain Management Study Listening Session

Moderated by: Leah Nguyen
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Table of Contents

Announcements & Introduction.....	2
Presentation.....	2
Feedback Session 1 — Barriers to Care.....	4
Feedback Session 2 — Medicare Coverage.....	5
Feedback Session 3 — Medicare Beneficiaries with Substance Use Disorders.....	6
Feedback Session 4 — Pain Care During the COVID-19 Pandemic.....	9
General Feedback Session	12
Additional Information.....	18

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Operator: At this time, I would like to welcome everyone to today's Medicare Learning Network® event. All lines will remain in a listen-only mode until the feedback session. This call is being recorded and transcribed. If anyone has any objections, you may disconnect.

I will now turn the call over to Leah Nguyen. Thank you. You may begin.

Announcements & Introduction

Leah Nguyen: I am Leah Nguyen from the Provider Communications Group here at CMS, and I am your moderator today. I would like to welcome you to this Medicare Learning Network Listening Session on the Dr. Todd Graham Pain Management Study.

This study will give CMS important information about treatment and outcomes and help us understand the roles of behavioral health, specialty care integration, care planning, health disparities in pain, opioid use, and opioid use disorders treatment.

CMS seeks comment on four topics listed on slides 9 through 12 of your presentation. Before we get started, you received a link to the presentation in your confirmation email. The presentation is available at the following URL – go.cms.gov/mln-events. Again, that URL is go.cms.gov/mln-events.

This call is open to everyone. If you are a member of the press, you are welcome to listen, but please refrain from asking questions during the Q&A portion of the call. Direct your inquiries press@cms.hhs.gov.

At this time, I would like to turn the call over to Dr. Lee Fleisher, CMS Chief Medical Officer and Director of Center for Clinical Standards and Quality.

Presentation

Dr. Lee Fleisher: Thank you so much. It's really an honor and privilege to be here today. I'm very excited having joined the Centers about six and a half weeks ago in this role and having learned about this ongoing study and the work that's being done by CMS in collaboration with both the providers and our patients and trying to give better pain management.

It harkens back to about eight weeks ago when I was the Chair of Anesthesiology at the University of Pennsylvania and I continue to be a practicing anesthesiologist. And within my department at Penn, I had a quite large pain management program.

And over the years, under the leadership of Michael Ashburn, who is my Chief, I learned a lot about the issues that we had to address with pain management and how we think about pain management and how we've evolved over the years in thinking about treatment and just treatment with opioids or treatment of pain to really getting to what I think is incredibly important which is back to physical function, and that shift in our mentality of treating sort of the symptom manifestation and getting to that functional manifestation. And we've seen that quite a bit in our patients in how they worry about things like opioids and others and really now are much more focused on quality of life.



I also think it's incredibly important as has been outlined in the request for this study under the SUPPORT ACT and under many of these cause about the collaboration with mental health, behavioral health, and some of the questions that are addressed here.

And I think it's very important that we don't just think about substance abuse disorder and, certainly, that's a very important part, and the issues truly of mental health disorders, sort of DSM criteria, but the underlying importance of simple mild depression or other symptoms that, in concert, both increase the manifestation of pain, as well as make it difficult to treat the disorder and that – really that gets to the idea of the multi-disciplinary approach that is so well-outlined in some of these background slides and, importantly, in some of the questions and why the team today is listening.

You know, as I think about it quite a bit, that it really isn't just a pain specialist that needs to help these patients, but really a team that includes both the physicians and non-physicians, physical therapists, novel treatments, i.e., industry, both opioid and non-opioid approaches to pain tailored to the individual patient and how do we make sure, again, getting to what that – most important issue is that our beneficiaries and patients throughout the United States get back to the best quality of life.

So, again, I'm very excited that there are these two listening sessions as we try to think about addressing this issue that it's probably the most common condition in the United States that probably affects some of the most important issues of both people's financial stability and how this affects their ability to work for those who are working, as well as, importantly, their quality of life.

So, I want to thank, again, the CMS team for putting this together and listening to our stakeholders, and for everyone on the call today who really is trying to do the best thing and provides us with that diversity of opinions that can only get us to the optimal treatment for this quite debilitating condition of pain disorder and substance use disorder. So, thank you.

Now, I'll turn it back to Ellen.

Ellen Blackwell: Thanks, Lee. I'm Ellen Blackwell, a Senior Advisor in CMS' Center for Clinical Standards and Quality. I'm going to tell you a little bit about the Todd Graham Pain Management Study which is Section 6086 of the SUPPORT ACT, which outlines national strategies to help address America's opioid epidemic and also advances policies to improve the treatment of pain and the treatment of substance use disorders.

The study is going to provide CMS and HHS with information about services delivered to Medicare beneficiaries who have acute or chronic pain and help us in understanding the current landscape of pain relief options for our beneficiaries, as well as inform our decisions around payment and coverage for pain management interventions, including those that minimize the risk of substance use disorders.

We are performing this work with the help of our colleagues at the Agency for Healthcare Research and Quality, and HHS' Office of the Assistant Secretary for Planning and Evaluation, which is partnering with us to prepare a report to Congress.



And as we embark on this work, we wanted to acknowledge the clinician who inspired it, Dr. Todd Graham. Dr. Graham was beloved by his family, his community, his coworkers, and especially his patients. And, with that, Leah, I'm going to – Leah, I'm going to turn it back over to you and you can kick us off on our questions.

Feedback Session 1 — Barriers to Care

Leah Nguyen: Thank you, Ellen. CMS is seeking input on 4 questions today. There will be an opportunity to get into the queue for each question. So, please limit your input to the topic that we announce. You will have a maximum of three minutes to provide your input. As a reminder, this event is being recorded and transcribed.

Our first topic is barriers to care on slide 9.

Operator: To provide your feedback, press “star” followed by the number 1 on your touch-tone phone. To remove yourself from the queue, please press the “pound” key. Please hold while we compile the roster. Please hold while we compile the roster.

Again, to provide your feedback, press “star” followed by the number 1 on your touch-tone phone. To remove yourself from the queue, please press the “pound” key. Please hold while we compile the roster.

The first comment comes from the line of Laurie Cummings.

Laurie Cummings: Yes. Thank you. One barrier that I think impedes Medicare clinicians in utilizing non-opioid treatment is the reimbursement that comes along with some of the CPT codes for some of the higher-end implants and other procedural technologies that can be done.

Leah Nguyen: Blair, can we get our next comment?

Operator: The next comment will come from the line of Nilesh Patel.

Nilesh Patel: Yes. Thank you. I would echo Laurie Cummings' sentiments regarding barriers for implantable therapies. I also feel that the need for psychology clearance and the need for trials before going to a full implant are also large barriers that have to be overcome. Thank you.

Operator: To provide your feedback, press “star” followed by the number 1 on your touch-tone phone. To remove yourself from the queue, please press the “pound” key. Please hold while we compile the roster. Please hold while we compile the roster.

The next comment will come from the line of Richard Lawhern.

Richard Lawhern: Yes. If I may, I would offer one insight on barriers to care. I think we need to go back and study carefully the results of the June 2019 systematic outcomes review from the AHRQ group that basically identify over 5,000 published trials in the area of non-invasive, non-pharmacological therapies.



If you read that report with care, what you'll discover is that the state of the trial literature for non-opioid solutions for pain is abysmal. There has never been a study published that was structured as a direct either/or comparison between the alternative therapies and opioid therapy per se. And lacking such a study, I think the over-emphasis that I am seeing on so-called alternatives is really quite irresponsible. Until we get a much better literature that uses protocols that are really defensible because, right now, most of the literature does not. Thank you.

Operator: The next comment will come from the line of Camara Wilkins.

Camara Wilkins: Yes. I would like to also echo the reimbursement benefits are somewhat lacking with Medicare patients, as well as just in general at least in our area and maybe nationally the psychiatric resources that are necessary to help with coping and behavior modifications like CBT.

Operator: The next comment will come from the line of Nicole Connelly. Nicole, your line is open.

There are no further comments at this time.

Feedback Session 2 — Medicare Coverage

Leah Nguyen. Thank you. So, we'll move on to our second topic. But if we have time left at the end of this – of this presentation we'll give people an opportunity to queue up again if you have any additional thoughts during the call. Our second topic, Medicare coverage, on slide 10.

Operator: To provide your feedback, press "star" followed by the number 1 on your touch-tone phone. To remove yourself from the queue, please press the "pound" key. Please hold while we compile the roster. Please hold while we compile the roster.

Again, to provide your feedback, press "star" followed by the number 1 on your touch-tone phone. To remove yourself from the queue, please press the "pound" key. Please hold while we compile the roster. Please hold while we compile the roster.

The first comment will come from the line of Marie Link.

Marie Link: Yes. Hi. Are you able to hear me okay?

Operator: Yes. Go ahead.

Marie Link: Okay. So, regarding what evidence-based treatments and technologies and models can Medicare cover for the treatment of acute and chronic pain that it currently does not, Medicare Part D does have a drug utilization over drug management program, opioid over utilization model, the program that it uses, which employs pharmacists to essentially do population management around these high-risk opioid patients.

One recommendation would be to expand reimbursement in that method to more on a preventative side instead of – instead of more retroactive or responsive, but more proactive. There's definitely interventions and counseling. I echo the same comments. I agree with all the comments that were previously stated about



coverage – psychiatric coverage, and then, proof in the benefit of non-pharmaceutical approaches being – lacking. But certainly, we do know many things through – that we’ve learned through the Medicare Part D OMS program that could be applied to a treatment of acute and chronic pain. Operator: The next comment will come from the line of Richard Lawhern.

Richard Lawhern: This is not, in any way, to dominate your proceedings. But I would offer one insight on the overutilization criteria of CMS. They have very limited predictive usefulness with regard to identifying patients, and that is in part because, so few patients actually meet the criteria. There is an excellent study that is reported as a letter to the Journal of the American Medical Association. I can dig it out for people if you want to look me up.

There is one thing though that is quite different in this as far as treatments that patients themselves take to as something they don’t get enough support for. Massage therapy is frequently useful for people who are dealing with moderate to severe pain. And under current prevailing Medicare practice, the number of sessions per year that are funded or that can be funded under Medicare is limited to numbers that, in many cases, leave patients with periods of weeks between treatment.

So, the reimbursement of more frequent massage therapy is certainly in order at least for consideration with regard to one of the changes I believe you’re trying to develop evidence for.

Operator: We show no further comments at this time.

Feedback Session 3 — Medicare Beneficiaries with Substance Use Disorders

Leah Nguyen: Okay. Let’s see. Our third topic is Medicare beneficiaries with substance use disorders, on slide 11. How can Medicare improve care for beneficiaries with pain who have a current or past history of mental or substance use disorders or who are at higher risk for these conditions including people at increased suicide risk.

Operator: To provide your feedback, press “star” followed by the number 1 on your touch-tone phone. To remove yourself from the queue, please press the “pound” key. Please hold while we compile the roster. Please hold while we compile the roster.

The first comment will come from the line of Richard Lawhern.

Richard Lawhern: Hey, I’m sorry to barge in again, but one of the things that needs to be addressed in this area is that AHRQ has published in one of its most recent reports that acknowledgement that there are no presently validated profiling tools that usefully can be used or applied to the prediction of opioid dependency, tolerance, addiction, or opioid overdose risk. There just aren’t any that have been proven under field conditions.

So, if you’re going to improve the management of risk, you’re going to have to take a whole new look at just how you identify a risk in individuals. I know of one patient who has a – had a history of physical abuse as a girl who was denied treatment with opioids only on the basis of that history and that is ethically unsound.



So, we need a little more understanding and a little more focus on nuance and a whole lot less emphasis on risk because actual risk of opioid treatments is considerably lower than the common perception would have us believe. And there's excellent published data from the CDC to prove it. So, let's back up and think about things from original principles rather than starting from assumptions. Thank you.

Operator: Again, to provide your feedback, press "star" followed by the number 1 on your touch-tone phone. To remove yourself from the queue, please press the "pound" key. The next comment will come from the line of Nick O'Connelly.

Nick O'Connelly: Hi. I would – I have a little bit different perspective than the previous speaker. I would say that there has been adequate evidence of the harm of opioid. My barrier to helping patients understand the different approaches is related to the concept of time.

And I find one of the barriers in redirecting patients to different approaches is that it takes a lot of time in the office based on reimbursement that's often done at really very low reimbursement rates so that financial incentive is against spending a lot of time to help people understand the problem from a broader perspective. Now, I won't get into the details of the perspective, but that's my assessment. Thank you.

Operator: The next comment will come from the line of Drew Blacksock.

Drew Blacksock: Yes. I was wanting to kind of put in the option for treatment in this patient population using buprenorphine, not – a partial agonist drug even in the sublingual formulation versus the traditional Bupo with Belbuca or Butrans and wondered if there were thoughts on using it in this so-called higher-risk populations or those with past history of suicide or substance use disorders. Thank you.

Operator: The next comment will come from the line of Marie Link. Marie, your line is open.

Marie Link: Yes. Thank you. I agree that all of the – I agree with all the previous comments. And again, I feel that that does reinforce the time situation is certainly in the psychiatric and the mental support for many of these patients is important. Generally, pharmacists do see the patients on more of a monthly basis or a more frequent basis and have more face-to-face or phone interaction with patients to support whatever broader plan is needed to kind of oversee.

However, even given the limitations of the risk criteria identification under CMS' DMP OMS program, certainly, we do see additive risks where there are numerous providers, a high pill burden if a patient is having to dose themselves every hour to two hours with an opioid, a benzodiazepine on a chronic basis which would be length of therapy limits looking at evaluation of length in therapy, total pills per day, how many prescribers are involved, what the coordination of care is.

One thing that we do see in the DMP OMS program is lack of coordination of care which is something that we do look at. But there's no real focus on decreasing overall pill burden. Another thing we see is this practice of around-the-clock opioids and then we have what's called breakthrough PRN medication, but that seems to lose its credibility and true definition when it's used chronically.



So, we do see that the sequence or the repetitive refills of around-the-clock and PRN opioids are mimicked. So, if a PRN opioid for breakthrough pain is being refilled at the exact same rate and frequency as around-the-clock opioid, it – what's the difference? Yet the patient is now taking 6 tablets to 10 tablets of an opioid every day, along with all other drugs of abuse combined.

So, I think looking at the big picture, you can – you can identify a risk when there is amphetamines, benzos, muscle relaxers, gabapentinoids, opioids all on board from different prescribers.

Operator: The next comment will come from the line of Mike Geiger. Mark, your line is open.

Our next comment will come from the line of Richard Lawhern.

Richard Lawhern: I would agree that coordination of the treatment plan across multiple providers is certainly very much needed. I would also introduce one concept, however, that I think bears significant exploration early on in your deciding on policy.

We now have a very credible literature with regard to polymorphism in the P450 series enzymes – liver enzymes which metabolize opioids and several other medications as well. And that literature informs us that we have both poor metabolizers and hyper metabolizers in the general population.

So, the finding of the HHS taskforce that there is no one-size-fits-all patient and there cannot be any one-size-fits-all criterion for treatment is very germane because we see what may very well be a range of minimum effective dose in patients that we can extend all the way from something around 20 MMED to something over 2,000 MMED.

And there is a literature on case reports that shows patients who function very well at those higher levels. There's also an AMA position now declared publicly that the CDC should take steps, I might add that CMS should take steps as well, to advocate against the imposition of hard limits on either opioid dose or duration. That is a revolution in thinking that we need to get our arms around as we're trying to arrive at better positions with regard to patient care and patient welfare. Thank you.

Operator: The next comment will come from the line of Mark Geiger.

Mark Geiger: Thank you. Specific to peripheral nerve stimulation for the treatment of chronic pain, Medicare and other payers could reduce the barriers for patients to get access to PNS. In one recent published article of 39 patients, 18 different centers in the U.S., it was reported by Chuck Avarti et al., a 71 percent reduction in pain, a 72 percent increase in activity, and 89 percent of those 39 patients had at least a 50 percent reduction in their opioid use.

One issue is that there are too many barriers for patients who get – gain access to the technology. One is that this 15-minute to 30-minute procedure for most peripheral nerve stimulation products can be done while the patient is awake with a small stab incision. It resembles an over-the-wire implant technique hand. But Medicare only reimburses it for implants in hospital outpatient or ambulatory surgery center.



If that procedure could get reimbursed for in-office placement, that would reduce one of the large barriers for more patients to get access to this technology. And I echo the comments of others about the reimbursement with respect to how that matches up with the average selling price for peripheral nerve stimulations on the market. It is – it is a too small amount of money compared to other more established technologies that slowed the adoption. Thank you.

Operator: We have no further comments at this time.

Feedback Session 4 — Pain Care During the COVID-19 Pandemic

Leah Nguyen: Thank you. Our fourth topic is pain care during the COVID-19 pandemic on slide 12. How has the COVID-19 public health emergency, including federal waivers and other flexibilities impacted your ability to treat pain in Medicare beneficiaries, and their access in pain treatment?

Operator: To provide your feedback, press “star” followed by the number 1 on your touch-tone phone. To remove yourself from the queue, please press the “pound” key. Please hold while we compile the roster. Please hold while we compile the roster.

The first comment comes from the line of Laurie Cummings.

Laurie Cummings: Yes. What has impacted our pain practice the most has been the extension and the expansion of the telehealth capabilities under the current emergency order. That’s just been invaluable for the safety of our patients, for the ability for us to provide ongoing care that’s consistent with our treatment planning. It’s allowed for us to abide by the CDC recommendations for everything we need to do to be cognizant of COVID-19.

You know, the recommendation and the hope is, is that this reimbursement will continue at the level that it’s been, and that not only will there be the ability to do audio/visual telehealth, but also, to continue audio only in situations where you have elderly individuals that don’t have access to the tools that are needed. But overall, the telehealth capability for our pain practice has been tremendous and invaluable. Thank you.

Operator: The next comment will come from the line of Richard Lawhern.

Richard Lawhern: I should in the spirit of fair disclosure make known that I am not a physician or clinician. I am a patient advocate. I’m widely published in this field.

What I hear from patients in hundreds of contacts through social media every day is that the COVID-19 pandemic is impacting them, but in a very, I would say, non-uniform way. Some patients have benefitted, indeed, from the increased use of telehealth. Some patients have found that their physicians, however, are completely unwilling to expose themselves to potential censure for the administration of pain plans that include access to opioids by means of telehealth.

We are definitely seeing a contraction in the number of pain management practices and in the number of general care community clinics that are seeing pain patients. That’s an overall trend that I think COVID-19 has probably aggravated and enhanced.



So, part of what is I believe necessary – very deeply necessary – both within the context of the pandemic and in other wider context is that we've got to get pain management physicians some protection from censure because if any of them has a patient who is hospitalized for practically any reason, they can line up on the receiving end of a DEA or a local Drug Enforcement Administration state-level investigation that can put them out of practice whether they've done anything wrong or not.

So, that – my input to that from the perspective of patients is that the pandemic, indeed, is continuing to affect the denial of care that we're seeing on a very widespread basis with what may amount to hundreds of thousands of patients who are in pain.

CMS can do a great deal to demythologize some of these by more emphatically emphasizing that the management of patients at a distance is legitimate and should be a well-reimbursed – appropriately reimbursed practice. Thank you.

Operator: The next comment will come from the line of Nilesh Patel.

Nilesh Patel: Yes. COVID definitely have increased stress, anxiety, fear, uncertainty. All of these have amplified the need for psychological support and care. Psychological issues also in turn increase the need for pain medications and there's been an increase in alcohol abuse as well in the pain population.

So, because of all of these factors, the need for psychological care and, specifically, tele psych or audio psych are – is something that has been very valuable and that should be continued as Laurie Cummings was saying. Thank you.

Operator: Again, to provide your feedback, press "star" followed by the number 1 on your touch-tone phone. To remove yourself from the queue, please press the "pound" key. Please hold while we compile the roster. Please hold while we compile the roster.

The next comment comes from the line of Mark Geiger.

Mark Geiger: With respect to implanted medical devices, the COVID-19 pandemic has put a moratorium on all elective procedures, of which many of these implanted medical devices are categorized as.

So, many patients who have already been to the mountaintop with their pain journey, and some of which are ready to commit suicide, we hear from them all the time unless they get relief for their chronic pain, are put on hold. And those patients don't get the treatment that they need.

If this – again, related to my last – my last comment – if these patients have access to implantable medical devices for in-office implants instead of being relegated to hospital outpatient or ambulatory surgery center, that would be a way of providing access to these patients who need the technology for their chronic pain. Thank you.

Operator: The next comment will come from the line of Nick O'Connelly.



Nick O’Connelly: I think the COVID crisis has, I agree, shown the benefit of telehealth. I agree that, especially in the elderly, the telephone is often much easier for them to maintain follow-up care through the telephone when it might be difficult for them to get to the office alone or find someone to come with. So, I strongly encourage CMS to continue that after the crisis.

I also have found that home health has really shown its benefits, especially in getting patients physical and occupational therapy at home and in terms of helping patients with their pain treatment. I think that that can often be quite helpful on reducing fall risk in particular.

Thank you. Operator: The next comment will come from the line of Hadaya Green.

Hadaya Green: Thank you. I would echo the first and last callers’ sentiments as far as in the – with the ability of physical therapists to – physical therapy assistance to access patients not only in remote for monitoring, but the actual treatment has been invaluable and something that we would hope to continue beyond the pandemic.

Allowing the evaluation and intervention piece beyond the remote monitoring via telehealth has allowed us to align with what research we do have on early access to physical therapy and the benefits of that. Thank you.

Operator: The next comment comes from the line of Marie Link.

Marie Link: So, I want to agree or support the comment about the invaluable aspect that telehealth has brought to just health care in general and patient care. And I would like to also see that continue post-COVID if we ever get to that.

But one thing about – from the patient advocate point of view and also just looking at the misinterpretation of varying levels of risks as it relates to the combination of opioid and medication of abuse – combined use risk, it’s – agree again it’s not a one-size-fits-all.

There is a lot that can be – the criteria, yes, currently, for OMS is minimal. I believe that it could be tightened up to improve the accuracy. And when I say “tightened up”, really there is – we keep – people keep saying that there is a great need for a psychosocial emotional support which then also can involve the social determinants of health perspective because we really need to look at the bigger picture of the status of the individual, where they’re coming from, what their needs are, do they have a home, do they have food to eat, do they have – have they had suicide risk in the past, have they been incarcerated before, have they – have they had hospitalization for an overdose risk, the – have they used Narcan.

These are all things that are not — those social determinants of health which really tell a lot about the individual and their predisposal to risk when they use these medications especially in combination and in higher volumes. That is where we can identify who we need to monitor more closely. That currently is not really being done on a broad federal scale at least that we – that I have seen, which would be nice to see.

Operator: The next comment will come from the line of Richard Lawhern.

Richard Lawhern: I earlier mentioned the paper concerning the performance of the Centers for Medicare and Medicaid opioid overutilization criteria. The article was in the February 12, 2019 issue of JAMA. It is authored



by Yu-Jung Jenny Wei, Chen – excuse me Cheng Chen, Amir Sarayani and Almut G. Witterstein. It's very much worth reading.

Overall, what we do see is that the opioid crisis that we're now facing – and it is truly that, it is a crisis of both addiction and many, many socioeconomic and psychosocial factors. What we look at when we look at detailed data in places like the Commonwealth of Pennsylvania – or, excuse me, Commonwealth of Massachusetts, excuse me – what we see is that this crisis is dominated not by medical opioids, but by self-administered polypharmacy – polypharmacy that, even when an opioid prescription is detected in the state PDMPs, the number of people who have a current prescription and who also overdose on opioid of some kind is a – literally a tiny fraction. It's like 2.5 percent of total opioid-related deaths.

We're not facing a crisis that is caused by over-prescription and we need to get completely away from that mythology. And I know I'm being emphatic, and I don't mean to be impolite, but it is a mythology.

America's opioid crisis is indeed very deeply involved in the complex of psychosocial factors and what has been called a crisis in hopelessness and we are seeing that very widely. But it is not caused – and we can prove using the data that CDC itself publishes – that it is not caused by doctors over prescribing to patients in pain. That's just not true and we need to get past it.

I recommend a look at some of my own work. If you would – if you desire to follow up, I'll be happy to talk with anyone who's engaged in the session. What we see, for instance, is there is no correlation between prescribing rates and overdose rates on a state-by-state basis; just none. There's a 10-to-1 range in the level of – excuse me – 10-to-1 range in opioid overdose-related deaths. There's a 3-to-1 range in prescribing rates on a state-by-state basis.

And the states with the highest prescribing levels have overdose-related death rates that are below the national average. You can't get to an answer on supposedly medically caused overdose by assuming the medical model in prescription. It's just not there.

So, this is really a situation that needs serious original thinking on an evidentiary basis, and I encourage anyone to engage with the issue on that level. Thank you.

Operator: We show no further comments at this time.

General Feedback Session

Leah Nguyen: Thank you. At this time, we'll take your feedback on any of the four topics that we discussed today. Topic one is Barriers to Care – what barriers impede Medicare clinicians and beneficiaries for utilizing non-opioid treatment and technologies to help treat acute and chronic pain?

Topic two, Medicare Coverage. What evidence-based treatment technologies and models should Medicare cover for the treatment of acute and chronic pain if it currently does not?



Topic three, Medicare Beneficiaries with Substance Use Disorders. How can Medicare improve care for beneficiaries with pain who have a current or past history of mental or substance use disorders or at higher risk for these conditions including people at increased suicide risk?

Topic four, Pain Care During The COVID-19 Pandemic. How has the COVID-19 public health emergency, including federal waivers and other flexibilities, impacted your ability to treat pain in Medicare beneficiaries and their access to pain treatment?

Operator: To provide your feedback, press “star” followed by the number 1 on your touch-tone phone. To remove yourself from the queue, please press the “pound” key. Please hold while we compile the roster. Please hold while we compile the roster.

The first comment will come from the line of Richard Lawhern.

Richard Lawhern: Yes. This is a more general comment to the proceedings. We do, indeed, need to address evidence-based treatment, but we also need to address treatment or protocol procedures that are not well evidence-based and that do seriously interrupt care.

One of the serious issues here I think is a fundamental issue is the use of what is basically called first – fail-first therapies or protocols. My daughter is a Parkinson’s patient who has significant dystonia and pain issues. And in order to get authorization for a spinal fusion that was made necessary by a significant scoliosis of her spine that was – that was well detected and diagnosed – she had to go through three sessions of rational cognitive therapy. And that was imposed by her insurance provider as a necessary pre-qualification in some way.

When she went to an RCT therapist, the lady she talked to said, “Why in the world did they send you to me?” So, we really have to think a little bit about possibly discouraging fail-first protocols unless there is strong evidence that there is benefit to the patient in reducing the invasiveness of treatments.

In some disorders, particularly where spinal scoliosis is involved or where quite a number of other spinal-related injuries are involved, that really may not be effective and, you know, appropriate – medically appropriate. And I believe CMS can do some real good by, in their research and in their policy process, reconsidering where step therapy or so-called fail-first therapy really does apply and potentially does not.

Thank you for the opportunity to comment at length and I do hope I haven’t abused your process. I appreciate the time you allocated.

Leah Nguyen: You’re welcome.

Operator: Again, to provide your feedback, press “star” followed by the number 1 on your touch-tone phone. To remove yourself from the queue, please press the “pound” key. Please hold while we compile the roster. The next comment comes from the line of Nilesh Patel.

Nilesh Patel: Thank you. Because of the large body of literature supporting the spinal stimulation – spinal spacers and radio frequency for the treatment of neck, back and lower leg symptoms, there really has to be a concerted effort by CMS to remove all the barriers including the barriers for preauthorization, for psychological



clearance, and for any additional requirements for preauthorization. As an example, CMS has Medicare beneficiaries and the Medicare Advantage plans often places barriers even though the procedure may be covered by Medicare. So, that's the first thing.

The second thing is the adoption of the best practices interventional pain procedure section 2.4 should be advocated by CMS to both CDC, as well as the bodies that advise the CDC. Thank you.

Operator: The next comment will come from the line of Cindy Steinberg.

Cindy Steinberg: Hi. Thank you for taking my response. I wanted to address barriers. One of the important barriers I think is physician understanding of the need for a multi-modal approach to managing pain and lack of understanding of what it really takes to manage pain successfully.

And so, the pain management taskforce report should be disseminated and to the nation's physicians, particularly primary care providers who are caring for the bulk of people living with pain.

The other issue surrounding that is the time and the complexity that pain patients require. Physicians need to be reimbursed for spending time to work with the patient to get them on a plan that is really working for them.

As other people have commented, an individualized approach to pain management is really important and it takes time to get that done well and for a physician to really partner with the patient in finding the things that work for them. So, they really need to be given more time to work with complex pain patients.

Under the question about what should Medicare cover that it's not now covering, another person had talked about massage. Pain patients when asked in a survey of what they would most want covered that's not have asked for massage coverage. And it's my understanding that it's not covered now for people living with pain and I believe it should be. That's it for my comments. Thank you.

Operator: The next comment will come from the line of Mena Gupta.

Mena Gupta: Hi. Thank you for taking my call. I want to – I agree with what Dr. Cindy just said earlier before my call – comment – that it is a lack of subsidization do not – it's a lack of understanding of the complexity of pain management what it entails.

And one thing that I – nobody has mentioned is that there is not – many non-physicians are actually practicing pain management which is contributing to this crisis – physician assistants, nurse practitioners which – who do not have the adequate training and adequate understanding of complexities of pain management and what other non-opioid treatments can be utilized to treat the pain and you don't just have to rely on opioids to treat pain.

You know, as the saying goes that, if the only tool you have is a hammer, everything looks like a nail. That is kind of what I see happening with these providers for them. The only tool they have is an opioid that – or the only tool they know is that and that is what everybody gets.



So, having qualified practitioners – physicians rather than nurse practitioners or PAs who really don't have the grounding of the education in these complex – management of these complex patients is also contributing to this pain crisis.

And again, it also does take time and – to manage these patients. And if that opioid, just one prescription, is quick to write and that takes care of the problem and you can get reimbursed, that is what people will tend to do. So, adequately reimbursing patient – physicians for the time spent in managing these patients is very important. Thank you.

Operator: And again, to provide your feedback, press “star” followed by the number 1 on your touch-tone phone. To remove yourself from the queue, please press the “pound” key. Please hold while we compile the roster. Please hold while we compile the roster. The next comment comes from the line of Marie Link.

Marie Link: Yes. Thank you for the ability to comment. I agree with everyone's previous statements. I really like the comment about the complexity of the multi-modal approach, and maybe less barriers in – many of these patients know their care plan is known in advance that they have to go through the step therapy approach in order to qualify for surgical or invasive intervention with full knowledge up front that those other modalities are going to fail yet they still have to spend time, energy and utilize potentially opioids and controlled-substance medications for a longer period of time in order to get to the place where they can have approval for the intervention.

One of the pieces to prior authorizations and step therapies is strictly this focus on was A, B, C, D, F and G done first? Was that tried? And what – you know, did it fail? Versus taking a patient in, evaluating and looking at a comprehensive care plan that is well-drafted, it includes pharmaceutical, non-pharmaceutical, psychosocial risk management, pharmacogenomic information and saying, “Okay, well, if the patient is a candidate for surgery within the next 12 months to 24 months and we have a really strong plan in place, are all those other pieces really necessary and is the number of months on reliance on opioid medications to get them through really necessary as long as there's a really comprehensive forward-going plan?”

I look at charts all day long and there is a very wide variety on what I would call the quality of patient care plan that's put in place in charts for varying use of chronic pain patients. I could tell you what a good chart looks like and I could tell you what a less than quality chart looks like.

There is a very wide variety of approach to practice. They are not all equal and patient risk, you know, can fall through the cracks fairly easily. So, I think if there could be a shift of focus on jumping to so many hoops that we already know are going to fail versus having a criteria of measure being a really strong comprehensive care plan for the patient for management of the pain from a multi-motor perspective, that would be a more successful proactive model.

Operator: The next comment will come from the line of Richard Lawhern.

Richard Lawhern: If I may, I would applaud the sentiments expressed by the last speaker. I would also, however, add one data point, again, derived from the study published last year by AHRQ.



AHRQ did a systematic outcomes review of non-invasive, non-pharmacological therapies. It looked at about 20 different therapies for five major categories of pain. They discovered about 5,000 published trials.

Now, here's where things get just a little gnarly. They put those trials through a relevant reading, as well as a quality of evidence reading. And out of the 5,000 trials, only 218 of them survived review. In those 218, over 100 of the reports from the trials – the summaries of the trials and the detailed tables of the AHRQ report, over 100 of them listed the strength of medical evidence as weak and the degree of improvement in either pain or quality of life as marginal.

Now, this basically points us in the – in a direction of understanding what the role of the ancillary therapies needs to be relative to the role of medical therapies in either opioids or any neuropathy treatments, the gabapentinoids and others.

The alternative treatments, if we all call them that, really do not have a strong record of research behind them and we have to improve on that. We have to get protocols in place that are rigorous and we need to reperform a whole lot of the work that's already been published that is said to be, but, in fact, is not strongly supportive of the alternative non-medical and non-surgical answers to many of these questions.

I believe we are naïve if we believe that the alternative therapies can replace opioids. And I have that on the evidence of thousands of patient reports from people who have been actively injured by being tapered off involuntarily of a program of therapy that has very frequently been effective for them for periods of years, sheerly out of a fear of opioids.

This is a fear so strong in some clinicians that it could qualify as a phobia and it's not based on good evidence. So, again, not to be a nuance about this or a scold, but I am advocating for patients and the patients are telling you, yes, we do want access to more ancillary therapies, but let's recognize them as ancillary to a program of analgesic or anti-inflammatory or, in some cases, anti-depressant therapy because the core of this is not going to be dealt with in severe pain by measures that are comparable to RCT or to psychological therapy or to so-called therapy for catastrophizing which just drives patients crazy. If you want to hear patients go over the top, use that term.

So, to round it up, yes, this is a complex problem. Yes, this is a multifactorial problem. But let's not go over the deep end either in proposals for funding methods that really have fairly marginal effects. The first priority needs to be in improving the quality of the unified patient care plan that was just mentioned. And I think that may require a retraining of doctors who are authorized reimbursement on their Medicare – a great number of them.

The average doctor in medical school gets fewer hours in pain management than a veterinarian does. It's 9 hours average for most medical schools where a veterinarian gets 40 hours. We've got to do better than that. We know we've got to do better than that and it – that's a major thrust of the HHS report that was referenced by Cindy Snyber.

I've said enough, probably too much, and thank you for your time. I will leave the conference at this stage.

Operator: The next comment will come from the line of Cecilia Hall.



Cecilia Hall: Yes. I would like to ...

Operator: Cecilia, your line is open.

Cecilia Hall: I would like to make a comment as a nurse and a coder and a person that has experienced back issues and cervical neck issues. And at times when you need something to help relieve your pain that's stronger than a Tylenol 3 or an arthritis Tylenol, nowadays, you can even hardly get those.

And so, I think that contributing to the problem – and I was fortunate enough to tell the doctor after he did my neck injection that if look that at least it reflects the real business of helping me at least fall asleep because if you get a sleep-deprived, a pain-riddled patient, you are setting them up to look for whatever they can find to help relieve their pain. Thank you for letting me speak.

Operator: The next comment will come from the line of Nilesh Patel.

Nilesh Patel: So, I agree with the patient advocates, Cindy and Richard, that pain is complex. But it is naïve for the CDC guidelines to assume the treatment that they're advocating are going to be sufficient for most of these patients because they rarely are.

If you look at the published literature on NNTs, which basically is a measure of how effective a therapy is beyond placebo, the NNTs for therapies advocated at the CDC is very, very poor. NNTs for gabapentinoids is over 7. NNTs for selective [inaudible] is over 6. So, you need to give the treatment to 6 people for one person to get a 60% relief of pain. And the NNTs for other treatment such as acupuncture and physical therapy are probably much worse, and for topical that the CDC advocates is on 10.9.

So, why are we continuing to advocate these therapies and force physicians to use these therapies when, in reality, they're not effective? It is for this reason that the best practices report that are published in May of 2019, which is much more of a comprehensive look at the patient should be advocated and should be – should be sent to all the primary care doctors, and we should en masse abandon the CDC guidelines because that's clearly not effective in terms of achieving relief of pain or improvement in function in our communities. With that, I'm going to stop. Thank you.

Operator: The next comment is from the line of Marie Link.

Marie Link: Agree fully with the last comment as well that a requirement and a focus on non-clinically effective approaches is definitely a large setback for patients who suffer chronic pain. And the reason I wanted actually to comment again is I didn't want my previous comments to come across that I am not as a – as an opioid review pharmacy specialist and med safety specialist, not advocating against the use of opioids.

I agree that there is an appropriate place for chronic application, but that it has – it – the – you know, the elephant in the room when it comes to risk is that we are not looking at the social economic – psychosocial and economic determinants and characteristics and background of the full picture of the – of the patient and incorporating that into their care plan and into their approach on how we're – what is – what is the pain, what's the root of the pain and what's the plan with the 12-month plan, the 24-month plan and the 5-year plan, what



does that look like, how is risk going to be monitored and managed, what actions you're going to take should things develop or go off track, what's the approach going to be.

So, just like if you're building a home and you have your architecture blueprints, you know, you have this plan laid out up front and it has very specific design elements that you look for and that should be included in any chronic pain plan.

Operator: We show no further comments at this time.

Additional Information

Leah Nguyen: Thank you. An audio recording and transcript will be available in about two weeks at go.cms.gov/mln-events.

Again, my name is Leah Nguyen. I would like to thank our presenters and also thank you for participating in today's Medicare Learning Network listening session on the Dr. Todd Graham Pain Management Study. Have a great day, everyone.

Operator: Thank you for participating in today's conference call. You may now disconnect. Presenters, please hold.