Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode until the comment session of today’s conference. At that time, you may press star one on your touchtone phone to make a comment.

I would like to inform all parties that today’s conference is being recorded for archiving purposes only. If you have any objections, you may disconnect at this time. I would now like to turn the conference over to (Nadine Doyle). Thank you. You may begin.

(Nadine Doyle): Thank you, Operator. Good afternoon everyone and welcome to CDC’s Opioid Prescribing Guideline Webinar. My name is (Nadine Doyle) and I’ll be your moderator today.

In a moment, I will introduce Dr. (Debbie Dow) who will provide an overview of CDC’s draft opioid prescribing guideline for chronic pain. First, I would like to go through a few logistical items so that everyone is on the same page with how today’s session will operate.
First, and as the Operator has already stated, all attendees will be in listen-
only mode throughout the duration of today’s webinar. During the comment
period, which I’ll describe in more detail in just a moment, you’ll have the
opportunity to provide a verbal comment -- time permitting -- at which time
your microphone will be unmuted.

If for some reason you’re having difficulty connecting to the webinar or
viewing the slides and are unable to communicate that to us via the comment
box, please email Opioidcomments@cdc.gov. That’s O-P-I-O-I-D comments
at cdc.gov.

You can also find a summary of the webinar information and instructions for
how to provide comments on what is being presented today online at www.
cdc.gov\drugoverdose\prescribing\guidelines.html. We’ll provide that URL on
screen for you later today.

Now I’ll walk quickly through today’s agenda. Following these welcoming
remarks, I’ll provide a brief introduction to the process then turn it over to Dr.
Dow for an overview of the draft guideline. We will not pause for comments
during the overview, however, following the overview we will move into the
open comment period during which each recommendation will be brought up
again.

The purpose of today’s webinar is to provide an opportunity for public
engagement and the review of CDC’s draft opioid prescribing guideline. The
target audience for the guideline are primary care providers such as family
practitioners and internists who are treating patients aged eighteen and older
for chronic pain in outpatient settings.
This webinar will be recorded to provide a complete and accurate record of the comments made. It will not be archived for public viewing and the slides will not be available after the webinar concludes. CDC staff will prepare a written summary of the comments made during the webinar. The summary will not include any names or affiliations of persons making comments and will be posted on a CDC public Web site in October 2015.

I will now move into an overview of the webinar comment process. First, and as I’ve mentioned, CDC will review the guideline development process and present clinical recommendation statements; after which we’ll move into the comment period.

During the comment period, participants may offer comments in response to each recommendation statement in one of three ways. First, you can comment verbally over the phone during the webinar, time permitting. Second, you can comment electronically, real-time via the webinar comment box on your screen.

Please note that only the webinar host will see your written comments and they will not be published to all participants. And third, you can comment via email sent to Opioidcomments@cdc.gov before five PM Eastern Daylight Time on September 18.

If necessary, CDC presenters may provide minor clarifications at the end of the comment period today, but will not otherwise respond to comments. However, we will record an archive of comments to inform CDC’s ongoing revisions and to provide them to peer reviewers for consideration. This allows for the maximum feedback possible from all of you on the webinar today within the time period allotted for each recommendation statement.
Given the high volume of individuals joining us today, we ask that you please treat this convening as you would any other business meeting and be concise, courteous, and professional when providing your remarks.

This next slide provides CDC’s disclaimer language. This information is distributed solely for the purpose of pre-dissemination review. It has not been formally disseminated by the Centers for Disease Control and Prevention. It does not represent and should not be construed to represent any agency determination or policy. And CDC provided funding for evidence synthesis and meeting supports.

I will now turn the microphone over to Dr. Dow.

Dr. (Debbie Dow): Thank you (Nadine). Here is an overview of our guidelines development process. An agency for healthcare research and quality sponsored systematic review published in 2014 on the effectiveness and risks of long-term opioid treatment of chronic pain, served as a foundation for the evidence based for the guidelines.

CDC conducted additional literature searches to update this evidence review as well as the contextual evidence reviews to help translate the evidence into recommendations. CDC convened a core expert group to assist in defining the scope of the recommendations, interpreting the evidence, and translating the evidence into recommendations.

These experts reviewed summaries of the scientific evidence and CDC’s draft recommendation statements, provided individual ratings for each draft recommendation statement, and discussed the draft recommendations with CDC during an in-person meeting in June 2015 in Atlanta.
CDC then provides the draft recommendations based on discussions and expert opinions expressed at the June meeting. CDC is now in the process of obtaining and reviewing comments on the revised draft recommendations. Comments have been or will be received from the core expert group, from federal partners, from a stakeholder review group including representatives from professional and community organizations with interests in pain management and opioid prescribing, from peer reviewers, and from the public.

To obtain perspectives from the public, including healthcare providers and prospective patients, CDC has convened this public engagement webinar. CDC will review comments from all of these groups, consider modifications, and revise the guideline.

In addition, CDC will share a summary of comments received from the public with our independent peer reviewers in order to inform their review of the CDC guidelines. CDC anticipates sending the revised guideline to the Department of Health and Human Services for review in early November and publishing the guidelines in January of 2016.

The Grading of Recommendations Assessment, Development, and Evaluation -- or GRADE method was used to rate the strength of hate recommendations. In GRADE, the recommendations are rated as strong, meaning most patients should receive the recommended course of action, and that recommendation could be adopted as policy in most situations; or as weak, implying that different choices will be appropriate for different patients, the clinicians must help patients decide based on the clinical situation and on patient values and preferences, and the policymaking requires much debate and stakeholder involvement.
In GRADE, four factors influence the strength of the recommendation’s ratings. First, is the recommended course of action effective in improving patient outcomes? Second, does the recommended course of action do more good than harm? Third, how much do values and preferences vary about the recommended course of action? And fourth, are the benefits worth the cost?

A recommendation is likely to be strong when the anticipated benefits are expected to be great relative to the likely harms.

The GRADE method was also used to rate the quality of evidence from the clinical evidence review. Quality of evidence could be rated high, moderate, low, or very low. Many factors influence this rating, such as study design, number of patients included in studies, and variation and findings across studies.

In GRADE, low quality evidence signals uncertainty, not an absence of evidence. Recommendations can be confidently made and are frequently made with low quality evidence. For example, for patients with septic shock it is standard of care to promptly administer fluids and medications in order to increase the patient’s likelihood of survival.

When the Surviving Sepsis campaign used GRADE to develop the international guidelines for managing septic shock, the panel strongly recommended this practice while rating the quality of evidence for it as low.

The twelve draft recommendations are categorized into three conceptual areas -- determining when to initiate or continue opioids for chronic pain outside of end of life care; opioid deletion, dosage, duration, follow-up, and discontinuation, and assessing risk and addressing harms of opioid use.
When published, CDC’s opioid prescribing guideline will include both recommendation statements and supporting rationales for each recommendation. The supporting rationales will explain the reasons behind each recommendation, citing supporting evidence, and will offer considerations for implementation.

I will now review all twelve draft recommendation statements without pausing for comments. After that, each draft recommendation statement will be brought up again, allowing the opportunity to comment.

Please note that each of the twelve draft recommendation statements is intended to be easily understood, digestible, and implementable by providers as our primary target audience. Your feedback to help us determine whether those aims have been met is much appreciated.

Recommendation one -- non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks.

Recommendation two -- before starting long term opioid therapy, providers should establish treatment goals with all patients, including realistic goals for pain and function. Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risk to patient safety.

Recommendation three -- before starting and periodically during opioid therapy, providers should discuss with patients risks and realistic benefits of opioid therapy, and patient and provider responsibilities for managing therapy.
Recommendation four -- when starting opioid therapy, providers should prescribe short-acting opioids instead of extended-release, long-acting opioids.

Recommendation five -- when opioids are started, providers should prescribe the lowest possible effective dosage. Providers should implement additional precautions when increasing dosage to fifty or greater milligrams per day in morphine equivalents and should avoid increasing dosages to ninety or greater milligrams per day in morphine equivalents.

Recommendation six -- long term opioid use often begins with treatment of acute pain.

Back to recommendation six so the slide matches up. Recommendation six -- long term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, providers should prescribe the lowest effective dose of short-acting opioids and should prescribe no greater quantity than needed for the affected duration of pain severe enough to require opioids. Three or fewer days will usually be sufficient for non-traumatic pain not related to major surgery.

Recommendation seven -- providers should evaluate patients within one to four weeks of starting long term opioid therapy or dose escalation to assess benefits and harms of continued opioid therapy. Providers should evaluate patients receiving long term opioid therapy every three months or more frequently for benefits and harms of continued opioid therapy.

If benefits do not outweigh harms of continued opioid therapy, providers should work with patients to reduce opioid dosage and to discontinue opioids when possible.
Recommendation eight -- before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid related harms. Providers should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid related harms are present.

Recommendation nine -- providers should review the patient's history of controlled substance prescriptions using C prescription drug monitoring program data to determine whether the patient is receiving excessive opioid dosages or dangerous combinations that put him or her at high risk for overdose. Providers should review prescription drug monitoring data when starting opioid therapy and periodically during long term opioid therapy, ranging from every prescription to every three months.

Recommendation ten -- providers should use urine drug testing before starting opioids for chronic pain and consider urine drug testing at least annually in all patients on long term opioid therapy to assess for prescribed medications as well as other controlled substances and illicit drugs.

Recommendation eleven -- providers should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

Recommendation twelve -- providers should offer or arrange evidence-based treatment, usually opioid agonist treatment in combination with behavioral therapies for patients with opioid use disorder.

I'll now turn the microphone back over to (Nadine), who will bring up each recommendation again while allowing the opportunity to comment.
(Nadine Doyle): Thank you Dr. Dow. One comment came into the box that we’d like to make a quick clarifying statement on. A question was asked about how to get a copy of the draft guideline to read before the comment period is up. I just wanted to clarify there that since the guideline currently is in draft format they will not be distributed. Rather, we are seeking comments on each of the recommendation statements that we will read again aloud during the comment period.

With that, I will now move into the comment period. During this period I will present each recommendation one at a time and open up a five minute comment period for each. As I shared earlier, there are three comment options.

The first is to follow the phone operator’s instructions to make a verbal comment. The second is to type a comment into the webinar comment box on the screen. And the third is to submit comments via email by five PM Eastern Daylight Time on September 18.

When making a verbal comment today, please keep your comment brief to allow time for others to participate. Also, when making a comment verbally via the comment box or by email, please note which specific recommendation you’re referring to.

As noted earlier, during the webinar CDC may provide minor clarifications as needed, but to allow maximum comment time will not otherwise respond to comments. Also, please note again that these slides are for purposes of today’s discussion only and will not be available for public viewing upon conclusion of the webinar.
I’ll now move to draft recommendation one. Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks.

And now, Operator, please provide instructions to queue up for verbal comments.

Coordinator: Thank you. We will now begin the comment session. If you would like to make a comment, please press star one. Unmute your phone and record your first name clearly. If you need to withdraw your comment, please press star two. It will take a few moments for those comments to come through. Please stand by. I am currently showing no comments coming in on the phone line.

(Nadine Doyle): Thank you, Operator. We’ll give everyone a few more minutes.

Coordinator: Please stand by. We have our first comment. The first comment comes from (Sid). Go ahead. Your line is open, please.

(Sid): Yes. Will there be something in the document to recommend reimbursement for non-pharmacologic therapies which presently are not well reimbursed by insurers?

(Nadine Doyle): Thank you for your comment. As a reminder to everyone on the line, we are not able to address specific questions during today’s webinar. If you could please state your feedback in the form of a comment for the archived webinar summary that would be much appreciated for future commenters.

Coordinator: The next - I’m sorry.
(Nadine Doyle): Go ahead.

Coordinator: The next comment comes from (Ray). Your line is open.

(Ray): Hi. It might be nice to have mention of what opioids have not proven beneficial for; for instance, chronic headaches.

Coordinator: Please stand by. The next comment comes from (Daniel). Your line is open.

(Daniel): I’m just confirming that the typed comment reached you appropriately. In this case it had to do with a question, which I understand we need not answer now or cannot answer now.

(Nadine Doyle): Thank you for your comment and your request for clarification. We are receiving written comments via this comment box. Participants on the webinar are only able to see the comments that they have made. The entire webinar audience will not see, but we are receiving them. Keep them coming. Thank you.

Coordinator: One moment, please. I believe the first name was (Burl). Your line is open.

(Burl Beasley): That’s correct. It’s (Burl Beasley). I’m a pharmacist with the healthcare authority. Just a comment on the non-pharmacologic therapy. It might be beneficial within the document to list those non-pharmacological therapies that may be suggested, such as acupuncture or massage or physical therapy.

(Nadine Doyle): Thanks to everyone for your comments thus far. Operator, we would have time for one or two additional verbal comments if any are in the queue.

Coordinator: We have - one just came in. One moment, please.
I apologize. There was not a name recorded. If you pressed star one to make a comment, your line is open. Caller, please check your mute function. Your line is open if you would like to make a comment. One moment, please. (Connie), your line is open.

(Connie): Hello. Thank you for reviewing all this. On the chronic pain management practitioner - and do you know if there’s any plans for future guidelines/recommendations for the long term treatment of chronic pain with a specialist?

(Nadine Doyle): Thank you for your comment today. Just as a quick reminder, we unfortunately are not able to address questions at this time due to our limited time.

Coordinator: I do have two more comments. Would you like to take them?

(Nadine Doyle): I believe we have time for one additional comment.

Coordinator: Thank you. (Robert), your line is open.

(Robert): No comment, please.

Coordinator: (Keith), your line is open.

(Keith): Thank you. I just want to make a point that there are some guidelines that have been issued by FDA under their risk evaluation mitigation strategy for long-acting opioids. And so these new guidelines are going to have to be reconciled with those guidelines to promote clarity among the prescribing community.
(Nadine Doyle): Thanks everyone for your comments. Our time for verbal comments on recommendation one is up. For those who did not get the opportunity to provide verbal comment who wish to, please consider typing your comment into the comment box on your screen or send via email. When doing so, please remember to indicate that your comment is in regard to recommendation one.

Before we move to recommendation two, I just want to say a quick few words for the benefit of those of you who are on the line only or who were able to view the slides and are now no longer able to view the slides. We’re having a few technical difficulties with our Web platform and we are working to resolve the issue as soon as possible.

In the meantime, I will be reading each draft recommendation verbatim and I will slow down my speech just a bit for those of you who do not have the benefit of the slides so that you can provide verbal comment or email the email address provided.

So with that I’m going to move to draft recommendation two. Before starting long-term opioid therapy, providers should establish treatment goals with all patients including realistic goals for pain and function.

Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

Operator, we’re now ready for verbal comment.

Coordinator: Thank you. If you would like to make a comment, again, please press star one. Please stand by. One moment, please.
Man: I wondered if we’re initiating opioid therapy and that it should be documented that the opioids improve the functioning in order to continue them.

(Nadine Doyle): Sir, the beginning portion of your comment was cut off. Would you mind repeating that?

Man: Yes. The beginning was -- it’s important to clarify that the goal of therapy should be limited to significant improvement in functioning, not pain.

(Nadine Doyle): Thank you. Are there other comments on recommendation two?

Coordinator: Yes. The next comment comes from (Scott). Your line is open.

(Scott): Will the CDC take a draft recommendation for having this put into a written form? Across the country people use what are called pain contracts or a written informed consent. Will there be some recommendation to include this in writing? Thank you.

Coordinator: Currently there are no further comments in the queue.

(Nadine Doyle): Thank you. We will then move on to draft recommendation two. Thanks to those of you that have commented thus far. Excuse me; we’re moving on to draft recommendation three.

Before starting and periodically during opioid therapy, providers should discuss with patients risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy. Operator, we’re ready for the comment period for recommendation three.
Coordinator: If you wish to make a comment, please press star one and record your first name only. Please stand by. One moment, please. The first comment comes from (Barbara). Your line is open.

(Barbara): I would just like to reinforce what the other person said with regard to this recommendation that the discussion about the benefits should be focused on function and should be realistic that opioids - any treatment is not going to eliminate pain. Thank you.

Coordinator: Next comment comes from (Earl). Your line is open.

(Burl): It’s (Burl), and going along with the previous caller I think this recommendation alludes to a pain contract. So maybe along the lines in this recommendation - should allude to somewhere about a - some type of contractual agreement or a pain contract. Thank you.

Coordinator: The next comment comes from (Dana). Your line is open.

(Dana): This recommendation and most of the ones before are very generalized. I think there needs to be more specifics like the inclusion of a pain contract or course of action plan that is signed by both patient and provider.

Coordinator: The next comment comes from (Linda). Your line is open.

(Linda): Thank you. I think included in the discussion between the patient and the provider it’s important to consider the patient expectations and goals rather than focusing so much on the responsibilities and the physician’s outlook on risks and beliefs. The patient-centered piece isn’t really stressed here. Thank you.
Coordinator: The next comment comes from (Bonnie). Your line is open.

(Bonnie): Hello. I agree with the comments thus far, except please do not use the word “contract.” Use informed consent or agreement or controlled substance agreement. But the word “contract” is a legal term and can get us into difficulties.

Coordinator: We currently have no further comments in the queue.

(Nadine Doyle): Thank you Operator. I’d like to pause very briefly here for a logistical update. I believe that for any participants who were unable to log into the webinar, we have sent out an email to direct everyone to the call-in line.

I wonder if we could pause for a moment - either if the operator is aware if there are any new phone participants joining us on the call or if we might unmute lines for just a moment to receive some indication if there are some joining us who have been previously unable to view the slides.

We’d be happy to take a few minutes to provide a brief recap and potentially begin again with recommendation one if it would be helpful to those of you who are unfortunately unable to review - to read the slides. And again, we appreciate your patience as we continue to work through some technical difficulties.

Operator...

Coordinator: Yes, we do have people joining the call currently; not a large number, but we do have enough in the conference that opening all the lines might provide a great deal of background noise. I might suggest that people enter the queue by pressing star one if they wish to have the items reviewed.
(Nadine Doyle): Thank you. Maybe we could pause for just a moment and anyone who would like to ask us to provide a brief recap or start with recommendation one, please do so quickly.

Coordinator: One moment, we have several people joining the queue.

(Nadine Doyle): Thank you.

Coordinator: (Mark), your line is open.

(Mark Stephens): Hello. It's (Mark Stephens). Sorry I joined a couple minutes late. Will this be recorded and be available for viewing later?

(Nadine Doyle): Thank you for your comment. This webinar is being recorded for archiving purposes only. It will not be made available to the general public at the close of the webinar.

Coordinator: (Amy), your line is open.

(Amy): I'm one of the people that was locked out for twenty-five minutes. So I would very much appreciate either a brief recap or access to the slides.

(Nadine Doyle): Thank you. Operator, I think we have a good sense that there are several on the line who may need a brief recap. Again, we'd like to apologize. We are doing really well on time and we also have the ability to stay on past the four o'clock hour if needed.

So with that, I turn it back over to Dr. (Dow) to provide a very brief recap of the guideline, and then we can begin again with recommendation one.
Dr. (Debbie Dow):  Thank you (Nadine) and we apologize for the technical difficulties we’re experiencing. Thank you for your patience as we try to work through these.

Let me just briefly summarize for people that weren’t able to join the call before. The purpose of today’s webinar is to provide an opportunity for public engagement in the review of CDC’s draft opioid prescribing guideline. The target audience for the guideline are primary care providers such as family practitioners and internists who are treating patients aged eighteen and older for chronic pain in outpatient settings.

When published, CDC’s opioid prescribing guideline will include both recommendation statements and supporting rationales for each recommendation.

Today we are reviewing the twelve draft recommendation statements. I will turn the mic back over to (Nadine) to read the recommendations one, two, and three for the people that are just joining the call now.

(Nadine Doyle):  Thank you Dr. (Dow). For those who can see the slides, I’ve backed us up just a touch so everyone can stay on the same page. I think what we will do is I will read draft recommendations one, two, and three very slowly so those of you who can’t read it can follow.

To keep us on track, we’ll continue with verbal comments beginning with recommendation four. And for those of you that did not get the chance to comment on the first three, we ask that you submit comments to Opioidcomments@cdc.gov. That’s O-P-I-O-I-D. Comments is C-O-M-M-E-N-T-S at cdc.gov.
The beginning was draft recommendation one. Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks. That’s draft recommendation one.

Moving to draft recommendation two -- before starting long-term opioid therapy, providers should establish treatment goals with all patients including realistic goals for pain and function. Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

And draft recommendation three -- before starting and periodically during opioid therapy, providers should discuss with patients risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy.

So for those of you who haven’t had the chance to comment on these first three recommendations verbally or via the webinar comment box, you still can comment by sending an email to Opioidcomments@cdc.gov.

And we will repeat that email address as well as a URL that you can go to for some additional information multiple times during this webinar so that everyone can write that down and ensure you can get your comments to us.

Thank you and apologies again for these issues. We continue to work to resolve them. With that, I’m going to move us along to draft recommendation four, at which point we’ll open up the lines again for verbal comment.
Draft recommendation four reads: when starting opioid therapy, providers should prescribe short-acting opioids instead of extended-release or long-acting opioids. Operator, we’re ready for the verbal comment period.

Coordinator: If you would like to make a comment, please press star one. Unmute your phone and record your first name clearly. Please stand by as the comments come in. One moment, please. The first comment comes from (Ellie). Your line is open.

(Ellie): The comment is more of a question. Is this about starting opioid therapy at the acute stage or only after the pain has reached chronicity? It’s unclear.

Coordinator: I’m showing no further comments at this time. If you would like to make a comment, please press star one. One moment, please. The next comment comes from (Randall). Your line is open.

(Randall): Thanks. Assuming that this is for chronic pain management and not for acute pain management, there might be more benefit to using long-acting opioids to prevent an escalation of dependence.

Coordinator: One moment, please. The next comment comes from - I believe she said (Carrie). Your line is open.

(Carrie): Yes. My comment is that this statement seems to be more relevant to noncancerous pain. It’s not uncommon to start simultaneously a long-acting and short for those patients with cancer. So I think making the distinction that this applies to acute injury, noncancerous type situation would be relevant.

(Nadine Doyle): Thanks everyone for your comments so far. We have time for one, maybe two additional comments if there are any.
Coordinator: The next comment comes from (Burl). Your line is open.

(Burl Beasley): Hello again. (Burl). There’s no timeframe specified, maybe, when starting opioid therapy. It should prescribe short-acting for the shortest time period or relevant time period. There’s no - I know that many patients do require longer, but some type of reference to timeframe, especially with - you’re shoring goal at the beginning of therapy, you want to express those goals to the patient - what the timeframe is. Thank you.

Coordinator: I have two more comments. The next comment is (Jeremy). Your line is open.

(Jeremy): Hello. This is (Jeremy). My comment is a question whether this is a strong or a weak recommendation. Thank you.

Dr. (Debbie Dow): This is (Debbie Dow). This is a strong recommendation.

Coordinator: Excuse me, speakers. Do we have time for one more comment?

(Nadine Doyle): We do, Operator. Thank you.

Coordinator: The last comment comes from (Robert). Your line is open.

(Robert): Hi, good afternoon. I just wanted to comment stating that we have to recognize this is starting opioid therapy, whether it’s acute or chronic. The need to safely titrate a patient - so starting a short-acting is appropriate. Thank you.

(Nadine Doyle): thank you everyone for your comments. Again, for those of you on the webinar, if you would like to make additional comments, please consider
using the comment box on your screen or send an email to Opioidcomments@cdc.gov.

I’ll now move to draft recommendation five. When opioids are started, providers should prescribe the lowest possible effective dosage. Providers should implement additional precautions when increasing dosage to fifty or greater milligrams per day in morphine equivalents and should avoid increasing dosages to ninety or greater milligrams per day in morphine equivalents.

Operator, we’re ready for verbal comment.

Coordinator: If you wish to make a comment, please press star one on your touchtone phone. One moment, please. The first comment comes from (Stephen). Your line is open.

(Stephen): Yes. Seeing you’re focused on dosage of fifty or ninety milligrams, there’s no (unintelligible) of polypharmacy, polysubstance abuse formulations, genetics, et cetera.

Coordinator: The next statement comes from (Chuck). Go ahead. Your line is open.

(Chuck): Is the CDC recommending that cancer patients with chronic pain who are in active treatment or with advanced disease, or who are survivors but not at end of life be limited to ninety mEq’s per day?

Coordinator: The next comment comes from (Jim). Your line is open.
(Jim): I’m not exactly sure what’s meant by additional precautions. Are we suggesting naloxone or - and I guess I’m just puzzled by additional precautions means. It’s a little bit ambiguous. Thank you.

Coordinator: One moment, please. The next comment comes from (Ellie). Your line is open. (Ellie), your line is open.

(Ellie): I apologize. I was one of the people locked out at the beginning for quite a while. So could you clarify whether the scope of these guidelines - do they pertain to hospice care, to cancer care? Or are those excluded?

Dr. (Debbie Dow): This is (Debbie Dow). Just to clarify, these guidelines are for opioid-prescribing for adults eighteen and older with chronic pain by primary care providers in primary care settings. They do not pertain to end of life or hospice care.

Coordinator: The next comment comes from (Robert). Your line is open.

(Robert): Hi. I agree with the additional precautions for the dose dependent risk, but also need to acknowledge that these additional precautions apply to any dose when risk warned. Thank you.

Coordinator: The next comment comes from (Ray). Your line is open.

(Ray): Yes. I was wondering if there was any thought to having patients over ninety milligrams of morphine seen by a pain specialist as I believe Washington had the cutoff of 120 milligrams.

Coordinator: One moment, please. The next comment comes from (Joel). Your line is open.
(Joel): Hello. Hopefully you can hear me. Obviously from some of the comments I think there needs to be more clarification about the recommendations being for non-cancer, non-end-of-life pain management situations.

But my other comment is that you may want an additional recommendation or comment about patients who come to physicians who are already on greater than ninety milligrams per day morphine equivalents, and what should be done in those situations; in other words, immediate conversation about the risks of the high dose and recommendations for immediate tapering. Thank you.

Coordinator: The next comment comes from (Marjorie). Your line is open. (Marjorie), please check your mute function.

(Marjorie): This is (Marjorie). I would caution the CDC that putting these dosage limits in here caused problems for patients as the previous comment was related to people who are already on ninety or greater that are not end of life, but who have long term chronic pain issues from any number of sources -- in our family's case, a genetic mutation. And the consternation that it caused in Colorado State policy was doctors would not take patients that were over the limit in the policy.

And this causes great problems for patient when they have a current primary care doctor that retires or has to cease practice for his own illness or cessation of practice for a temporary time. In our family we were five and a half months without a qualified chronic pain doctor.

We were fortunate that another specialist stepped forward to help our family member when the retirement of his doctor occurred and none of the
recommendations resulted in a pain management doctor that would take this particular patient who suffered from a genetic mutation.

So these recommendations have severe ramifications even though they are recommendations and not rules of law or whatever you call them in the federal area and the state area. You go through rulemaking. Even though these are policy guidelines, they have ramifications for patients. Thank you.

(Nadine Doyle): Thank you for your comments. Unfortunately, our time for verbal comment on recommendation five is up. For those of you who didn’t get the opportunity to provide verbal comment, again, please consider either typing your comment into the comment box on the webinar screen or sending via email to Opioidcomments@cdc.gov.

I’ll now move us to draft recommendation six, which reads: Long term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, providers should prescribe the lowest effective dose of short-acting opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three or fewer days will usually be sufficient for non-traumatic pain not related to major surgery.

Operator, we can now open the line for comments.

Coordinator: If you wish to make a comment, please press star one. One moment, please. The first comment comes from (Jim). Your line is open.

(Jim): I just wondered if there was going to be some additional emphasis, perhaps, on using non-opiates before opiates are used. Thank you.

Coordinator: The next comment comes from (Amy).
(Amy): For those of us who don’t have access to the slides, can you please repeat that one?

(Nadine Doyle): Sure. I will repeat draft recommendation six. Long term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, providers should prescribe the lowest effective dose of short-acting opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three or fewer days will usually be sufficient for non-traumatic pain not related to major surgery.

We can keep the line open for about another three minutes.

Coordinator: The next comment comes from (Kent). Your line is open.

(Kent): Yes. This comment has to do both with draft six and draft five. A table with morphine equivalents for other opioids would make this much more usable. And some of the people that are using them may not be using them with opioid equivalents.

Morphine orally in the seventies was thought to be poorly absorbed from the GI tract, so it wasn’t something that some of the doctors of my generation used orally. So it would be helpful to have - knowing what oxycodone and hydrocodone and codeine and hydromorphone equivalents were rather than just morphine. Thank you.

Coordinator: The next comment comes from (Linda). Your line is open.
(Linda): This comment is relevant to both recommendations five and six. In the determining the lowest effective dose under both situations is a significant challenge given the individuals’ variation in response to opioids. Thank you.

Coordinator: The next comment comes from (Robert). Your line is open.

(Robert): I agree with the three or fewer days usually will be sufficient for non-traumatic pain not related to major surgery, but when necessary, the amount and duration should be tied to the anticipated tissue recovery.

Coordinator: We currently have no more comments in the queue.

(Nadine Doyle): Thank you. We’ll then move on to draft recommendation seven.

I’ll read this slowly. It’s a bit longer. Providers should evaluate patients within one to four weeks of starting long term opioid therapy or of dose escalation to assess benefits and harms of continued opioid therapy. Providers should evaluate patients receiving long term opioid therapy every three months or more frequently for benefits and harms of continued opioid therapy.

If benefits do not outweigh harms of continued opioid therapy, providers should work with patients to reduce opioid dosage and to discontinue opioids when possible. We’ll now open up the lines for comments.

Coordinator: If you wish to make a comment, please press star one on your touchtone phone. One moment, please. The first comment comes from (Joel). Your line is open.

(Joel): Hello, yes. I have a concern about this recommendation. Our review of the evidence and, I believe, from the Cochran collaboration makes note of what
we recognize as a ninety-day cliff. In other words, patients who are on chronic opioids continuously daily for greater than ninety days are at increased risk of addiction and tolerance.

And so this frequency of reevaluation would not mitigate or avoid approaching this ninety-day point. So I would urge reevaluation of the evidence and a relook at this recommendation. Thank you.

Coordinator: The next comment comes from (Ellie). Your line is open.

(Ellie): This comment - this recommendation would be an opportunity to provide some guidance about how to evaluate risks and benefits. The data are fairly clear and compelling that people who at higher risk of addiction are actually at greater risk of being prescribed opioids.

So clearly there’s a disconnect in terms of understanding the matter of risk pertaining to behavioral health histories and mental health histories. So supplementing this point would be very useful.

Coordinator: The next comment comes from (Chardonnay). Your line is open.

(Chardonnay): Hello and thank you. I am a chronic pain patient myself and I have been marked at; not within the first three months. It was in the first week, second week, first month. Now I’m at the once every three months.

As far as chronic pain patients go, since I am one and I can say from my view I have been on and off opiates for a few years. I don’t have cravings for opiates. I am not addicted to opiates. I do think there is a (unintelligible) of opiates among the medical community as well as the CDC, possibly, and definitely the DEA.
My question is how do you decide which patients to continue to really benefit from this? And how do you decide the patients that are just needing to get high?

Coordinator: The next comment comes from (Mark). Your line is open. (Mark), please check your mute function. Your line is now open for comments.

(Mark): Okay, (Mark Stephens). I would recommend that the follow-on period after the first month be reduced to one month as opposed to three months. I think part of the problem we’re in at the moment is that there’s not been close monitoring of improvements and pain and function. And to have a period of three months I think perpetuates this problem that the providers are not closely monitoring whether there’s improvement in the patient’s conditions. Thanks.

(Nadine Doyle): Operator, we have time for one more comment.

Coordinator: The next comment comes from (Janet). Your line is open.

(Janet): Yes, hi. I want to emphasize what somebody had said previously. When we’re assessing benefits and talking about those that are looking to get high and those that really need it, I think the function is what needs to be evaluated and the increase in the - it is much more objective than asking someone about what their pain level is.

And frequently for those that are drug-seeking -- and I work in the work comp field -- we see patients that say their pain is nine or ten or nine and a half of ten and it’s - they’ve been on tons of opioids. And what’s the point of giving them more if they’re on that many and it’s still that high? I think it needs to be assessed by function and much more objectively.
(Nadine Doyle): Thank you for your comments. We are now out of time for verbal comment on recommendation seven. For those of you who were in the queue and not able to provide comment, please consider entering your comment on the screen or sending an email to Opioidcomments@cdc.gov.

I’d like to reiterate -- most of you are doing this -- but please indicate which recommendation your comment refers to for ease of our review. We’ve just completed recommendation seven.

I’ll now move to recommendation eight. Before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid related harms. Providers should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risks for OR related harms are present.

Operator, we’re ready for comment period.

Coordinator: If you wish to make a comment, please press star one. One moment, please. The first comment comes from (Nick). Your line is open.

(Rick): I think that’s (Rick). I think it’s very important that, again, recommendation eight cannot apply to cancer patients. One of the biggest problems with cancer patients is people are afraid to start narcotics when they’re clearly indicated.

Coordinator: The next comment comes from (Robert Jay). Your line is open.

(Robert Jay): My comment has to do with receiving patients that are already on opiates, whether it be morphine equivalency greater than ninety or whether it be two or three Vicodin per day. I think it’s important to note that a long term history
of opiate prescribing is not an indication to continue that therapy as folks transition between doctors, specifically.

Also, if a patient has an indication that’s receiving opiates for, I think it’s important that they comply with the current evidence-based recommendations for physical therapy or adjunctive therapies. And if they’re unable or unwilling to do those adjunctive therapies, it should adversely affect their ability to receive opiates if they’re opiate-focused, specifically. Thank you.

Coordinator: The next comment comes from (Ellie). Your line is open.

(Ellie): With regard to number eight, personally I agree with the previous commenter. And I would make this stronger considering the high risk of diversion of opioids for anybody who’s being treated for chronic pain. Chronic opioids should always come with a prescription for naloxone even if the particular patient is not seemingly at risk of addiction and overuse.

Coordinator: The next comment comes from (Ivan). Your line is open.

(Ivan): This is (Ivan). I want to add that some of these recommendations also take into consideration people that have chronic pain - nonmalignant pain and then get to the point where they are diagnosed with cancer. So we should also look at how do we cover those people that now we have on top of their nonmalignant pain a malignant pain as well. Thank you.

Coordinator: There are no further comments in the queue at this time.

(Nadine Doyle): Thank you and thanks to everyone for your comments. Again, if you would like to make a comment on draft recommendation eight at this time, please write it in the comment box on the webinar screen or send an email to
Opioidcomments@cdc.gov indicating that your comment is on recommendation eight.

I will now move us to draft recommendation nine. Providers should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program data to determine whether the patient is receiving excessive opioid dosages or dangerous combinations that put him or her at high risk for overdose.

Providers should review prescription drug monitoring program data when starting opioid therapy and periodically during long term opioid therapy, ranging from every prescription to every three months.

Operator, we’re ready for verbal comment.

Coordinator: If you wish to make a comment, please press star one on your touchtone phone. The first comment comes from (Ivan). Your line is open.

(Ivan): Thank you. One question I want to ask is how is this monitoring going to be done? Are we doing drug testing and doing the various opioids? Or how do you recommend the monitoring should be done?

Coordinator: As a reminder, if you would like to make a comment, please press star one.

(Nadine Doyle): Okay. If there are no further comments on recommendation nine...

Coordinator: Excuse me. We did just have two just come if you would like to take them.

(Nadine Doyle): That’s okay. That’s alright. Please...
Coordinator: The first is from (Burl). Your line is open.

(Burl): Hi. I think to the previous caller, maybe within this you would have a link to the state’s database with - that lists each state’s monitoring program with ah link to log into it. The other thing on this comment - it doesn’t address the issue of doctor shopping. I know the PMP is useful for that. Thank you.

Coordinator: The next comment comes from (David). Your line is open.

(David): Good afternoon. Thanks for a great program. My recommendation is that states should consider using population health reports to specific providers so that they can see their entire population of opioid users as a whole and be able to manage them rather than one by one.

Most monitoring programs only allow access on a per-patient basis. It makes it very difficult to manage a larger number of patients. And I would suggest that the group consider carrying that conversation forward.

Coordinator: We have one more comment if you’d like to take it.

(Nadine Doyle): Yes. We have time for one more.

Coordinator: (Keith), your line is open for comment.

(Keith): Can you hear me? Hello?

Coordinator: Yes, sir. We can hear you.

(Keith): Okay. The PMP’s are - because of all the data hacks and the - with healthcare providers and hospitals and insurance companies, multiple ID’s and fake ID”s
are becoming more and more prevalent. And the PMP’s will be full of those who are diverters and addicts - will have multiple ID’s, fake ID’s.

And so the people that you’re really after will be subverting the system. We need to have access to the state’s driver’s license motor vehicle bureau online database to validate a driver’s license against what’s being presented to us as healthcare professionals.

(Nadine Doyle): Thanks to everyone for your comments on draft recommendation nine. We’re out of time for verbal comment on this recommendation, but feel free to use the comment box on your screen or email Opioidcomments@cdc.gov for further comments.

I’ll now move us to draft recommendation ten. Providers should use urine drug testing before starting opioids for chronic pain and consider urine drug testing at least annually for all patients on long term opioid therapy to assess for prescribed medications as well as other controlled substances and illicit drugs.

We’ll open up the line for comment on draft recommendation ten.

Coordinator: If you wish to make a comment, please press star one. One moment, please.

The first comment comes from (Robert F.). Your line is open.

(Robert F): Yes, I absolutely agree, at least annually. But we should clarify and address and emphasize the greater the real or perceived degree of risk, the greater the frequency of the urine drug screens. As with the PDMP, mention of range of every prescription to every three months as with the UDS -- the greater the risk, the more frequent the use of these necessary monitoring tools. This really
is housed in universal precautions and should be -- and are by many --
considered standard of care. Thank you.

Coordinator: The next comment comes from (Michelle). Your line is open.

(Michelle): Thank you. I just wanted to expound upon what (Robert) had to say. Urine
drug testing schedule really needs to be established based on the patient’s risk
level, which could include the PDMP. It could include a pervious laboratory
report that comes back with an inconsistent outcome.

Consistent results - if you’ve got a patient who’s doing everything correctly, I
can agree with the annual testing. But for someone who is not compliant with
treatment and demonstrates that with previous drug tests, there needs to be
more ongoing frequent testing until compliance can be established.

I’m in the work comp space and several states do have mandated guidelines
for frequency of testing based upon patient risk level. And that should
probably be examined as part of this process. Thank you.

Coordinator: The next comment comes from (Lee). Your line is open.

(Lee): Thank you. Urine drug testing is an essential component to monitoring opioid
analgesic therapy. The definition of UDS needs to have a little bit more
granularity -- qualitative and quantitative. It’s important.

In addition, considerations for other biological fluid monitoring as well as
blood testing should be considered for the chronically administered
medication patients. Frequency, again, should be as is clinically indicated and,
importantly, the UDS should be a true random test. Thank you.
Coordinator: The next comment comes from (Dana). Go ahead. Your line is open.

(Dana), please check your mute function. Your line is now open and conferenced.

(Dana): Thank you, sorry. The comment has already been made that I was going to point out. Thank you.

Coordinator: The next comment comes from (Ivan). Your line is open.

(Ivan): Thank you. I think most of the comments I wanted to make have been made. The only addition I’ll add is that it should also be random. If a patient comes in and suspects something, do the urine drug tests. Also do a blood test.

Coordinator: We currently have no further comments in the queue.

(Nadine Doyle): Thank you Operator. I’ll move us along from draft recommendation ten to draft recommendation eleven. Again, for those of you who wish to comment, please do so on your screen or send via email.

Moving on to recommendation eleven. Providers should avoid prescribing of opioid pain medication and benzodiazepines concurrently whenever possible. Operator, we’ll now open up the line.

Coordinator: If you wish to make a comment, please press star one. One moment, please. The first comment comes from (Laura). Your line is open.

(Laura): Thank you. My comment is that this is not strong enough. Patients taking opioids with medications such as benzodiazepines and other sedative-hypnotics are at increased risk. Co-prescribing of opioids with sleeping pills,
muscle relaxants, and other benzodiazepines raises the risk of respiratory depression and can cause death. Thank you.

Coordinator: The next comment comes from (Joel). Your line is open.

(Joel): Yes, two comments if you can hear me. One is these medications may not be prescribed by the same provider. So the wording, I think, should be looked at so as not to suggest that only the one provider’s prescribing the opioid and the benzodiazepines. The provider should avoid prescribing opioid pain medications with benzodiazepines that were prescribed by any provider.

And then secondly, I can hear myself online too. Secondly, I second the last comment. Muscle relaxants, especially Soma, Carisoprodol in combination with opioids and benzos are higher risk. And I think this recommendation should be expanded to include all those other sedatives. Thank you.

Coordinator: The next comment comes from (Patty). Your line is open. (Patty)...

(Patty): Yes, hi. Okay, sorry. See, I’m a - I have fibromyalgia and GAD and back and neck problems since 2008 with fibromyalgia and back and neck problems. And I was diagnosed with depression and GAD, which is generalized anxiety disorder in 2002. And I’ve actually - I have taken - I’m not sure if Vicodin is also considered an opiate pain medication. And I’ve taken a benzodiazepine.

And since I was dropped from those two medications last year I do not feel like myself. I tried to get some rest just so that I could join in the conversation but I have made the comment in the comments section and I am - I think it just depends on the certain patient.
And my family doctor also knew of both medications that I was taking. So that’s just, I think - avoid prescribing both - I mean, I had a muscle relaxer as well. so I think doctors are now scared to be arrested for this.

And also, I was seeing a therapist or a psychiatrist for the benzodiazepine. And I was knocked off of that. So I had to try to get everything situated with my life and it’s been very difficult. Thank you.

Coordinator: The next comment comes from (Burl). Your line is open.

(Burl): Thank you for a great seminar. I would agree with the previous statements that this one is more of a generalized statement. It possibly could be a little bit more specific, especially when you talk about benzos as far as prescribing that for generalized anxiety disorder. Maybe additional resources on this or other therapies besides saying don’t prescribe benzos to guide our clinicians in the right direction. Thank you.

Coordinator: The next comment comes from (Rachel). Your line is open.

(Rachel): Hi. And I just want to thank the previous caller for sharing her experience. That was really moving.

One thing that I like to keep in mind when I’m looking at recommendations is there’s two sides to the story. There’s the population health story and then there’s the patient specific story. And I’ve heard a couple of times in this seminar very specific patient instances where I would completely agree with the exception.

But also, I think we need to keep in mind that these are for the greater population as well. So along with the wording in this one, if we could just
make it clear that this is the general recommendation for the general population, but definitely patient-dependent and specific situations may impact that decision. Thank you.

(Nadine Doyle): Thanks everyone for your comments. We have reached the end of the comment period for recommendation eleven. I’d also just like to add I think some participants may be experiencing a little bit of feedback through their computer audio. If that’s happening to you, I’d recommend muting your computer speakers so that you’re only hearing the audio via your phone line.

If you’re using a regular computer, you’ll likely see a little icon on the bottom of your screen that looks like a speaker. You should just be able to scroll over that and mute your speakers. Again, we apologize for this and hopefully everyone has been able to continue to hear.

With that I’m going to move us to the twelfth and final draft recommendation. If there are any who were in the verbal queue for verbal comment on recommendation eleven and didn’t get a chance, please enter your comment on the comment screen on the webinar or send it via email to OpioidComments@cdc.gov. Again, please indicate that it’s in response to draft recommendation eleven.

Moving on to draft recommendation twelve -- providers should offer or arrange evidence-based treatment, usually opioid agonist treatment in combination with behavioral therapies for patients with opioid use disorder. Operator, we’ll open up the line now.

Coordinator: If you wish to make a comment, please press star one on your touchtone phone. One moment, please. Our first comment comes from (Steve). Your line is open.
(Steve): This is a general statement about all twelve recommendations in that we need to remember that the so-called addicts we're dealing with are mental health patients and need to be treated for the mental health disease of addiction that they have, and not try to - being - having a mental health disease of addiction is not and should not be a crime in and of itself.

Coordinator: The next comment comes from (Armando). Your line is open.

(Armando): Thank you very much. Please comment for both draft number eleven and draft number twelve. Please comment on the link between this strong recommendation and the low quality of evidence found.

Coordinator: The next comment comes from (Lee). Your line is open. (Lee), please check your mute function. Your line is now open and conferenced.

(Lee): Sorry. I agree with using an agonist antagonist whenever possible. They're probably referring to buprenorphine. The problem is increasingly patients are having to pay out of pocket for these type of medications. Buprenorphine in California is very expensive relative - much more expensive relative to lower priced hydrocodone. In the context of a chronic pain patient, sometimes cost becomes very important.

Therapeutically, if you can use opiate antagonists, we'd obviously prefer to do that. Sometimes it's a better drug for chronic pain management anyway. But cost is the main consideration. Thank you.

Coordinator: The next comment comes from (Ellie). Your line is open.
(Ellie): This is a general comment about the guidelines as a whole. My question and request is that you circulate all of these to all the participants on the call in writing and to post them on the Web as well. It’s been pretty hard to keep up since I don’t have access to the slides.

Coordinator: The next comment comes from (Patty). Your line is open.

(Patty): Yes, hi. Sorry, it’s me again. I have a comment on the first person who spoke on this draft recommendation twelve about - to drug addicts and mental health. I have some mental health issues but I’m not a drug addict. I’m a chronic pain patient in pretty much pain.

And I know my one friend or ex-friend, I should say, who has an addictive personality. And yes, mental health issues should be looked at, but not all people who are in pain have a mental health issue. Or people who are looking for pain relief don’t necessarily have a mental health issue. Thank you.

Coordinator: The next comment comes from (Amy). Your line is open.

(Amy): Yes, thank you. I just strongly encourage the CDC to make these draft recommendations as widely available and transparent as possible. It was very difficult to get information about today’s webinar and to register, those of us who were locked out. So since this does impact millions of patients and also providers, as much information and as transparent a process as possible and additional time to provide feedback is strongly encouraged. Thank you.

Coordinator: The next comment comes from (Trish). Your line is open.

(Trish): Hi. Thank you very much. I would just say that I think that all of these recommendations are great, but I don’t think we’re really being strong enough
with the comorbid or mental health issues. And I would think there would be one on just that and the necessity of having psychologists or behavioral health therapists involved in this process. Thank you.

Coordinator: One moment, please. The next comment comes from (Paul). Your line is open.

(Paul): Hi. Thank you very much. Excellent presentation. I would like to see the names of the expert panel and their conflict of interest statements before the final document is done. Thank you.

(Nadine Doyle): Operator, we have time for one final comment.

Coordinator: There are no comments in the queue at this time.

(Nadine Doyle): Thank you.

Thank you so much to everyone for your participation today and for your very thoughtful feedback. Given the technological difficulties experienced today and several of the comments that we’ve received recently, CDC will reconvene the same presentation tomorrow, which is September 17, beginning at twelve noon Eastern Daylight Time and ending at 1:30 PM Eastern Daylight Time.

A new link and additional information will be circulated to all registrants later today via email. So for those of you who were unable to view the slides or otherwise would like the opportunity to hear the statements again, please join us again tomorrow. You can look for that information from CDC in your inboxes later today.
Thank you and, again, our apologies for the inconvenience that our technical difficulties caused.

In terms of next steps, CDC’s next steps are to revise the guideline in response to stakeholder review, peer review, and public comments. The guideline will then undergo review by CDC and the Department of Health and Human Services, and be published in the morbidity and mortality weekly report in or around January of 2016.

Again, for those of you who did not get the chance to comment verbally or via the comment box, please join us tomorrow and/or email any comments to Opioidcomments@cdc.gov by September 18 at five PM Eastern Daylight Time.

I’ll spell out that email address for those of you who aren’t able to see the screen. It’s O-P-I-O-I-D-C-O-M-M-E-N-T-S at cdc.gov - dot G-O-V.

As mentioned also, please consider joining us tomorrow for a repeat of this presentation and associated comment periods. You can also find additional information about the CDC’s guideline for prescribing opioids for chronic pain online at www.cdc.gov/drugoverdose/prescribing/guideline.html.

Thanks again to everyone and have a wonderful rest of your day.

Coordinator: That concludes today’s conference. Thank you for participating. You may disconnect at this time. Speakers, please allow a moment of silence and stand by for your post conference.

END
Coordinator: Welcome and thank you for standing by. At this time, participants are in a listen-only mode until the comment session of today’s conference. At that time, you may press star 1 on your touchtone phone to make a comment.

I would like to inform all parties that today’s conference is being recorded for archiving purposes only. If you have any objections, you may disconnect at this time.

I would now like to turn the conference over to (Joann Kang). Thank you. You may begin.

(Joann Kang): Thank you. Good afternoon everyone and good morning to those of you who are joining us from the West Coast. Welcome to CDC’s Opioid Prescribing Guideline Webinar. My name is (Joann Kang) and I’ll be your moderator today.
Before we begin, for those you who experienced technical difficulties while trying to access the webinar yesterday, we sincerely apologize. In reconvening this webinar again today, we wanted to provide an additional opportunity for all registrants to have access to the slides to inform the comments that you wish to share with us.

For those of you joining us today who likewise were on the call and webinar yesterday, CDC would like to take this opportunity to thank all of you and we appreciate all the thoughtful comments and feedback that were shared with us over the phone, via comment box, and also via email.

In a moment, I will introduce Dr. (Debbie Dowell) who will provide an overview of CDC’s draft opioid prescribing guideline for chronic pain. First, I’d like to go through a few logistical items so everyone is on the same page with how today’s session will operate.

As the Operator has already stated, all attendees will be in listen-only mode throughout the duration of today’s webinar. During the comment period, which I will describe in more detail in a moment, you’ll have the opportunity to provide a brief verbal comment -- time permitting -- at which time your phone line will be unmuted.

To minimize feedback we may experience and to ensure the highest level of sound quality, those of you who are joining us by both computer and phone – we’d like to ask that you take a moment now and check the microphone icon on your webinar screen. Click the dropdown tab and please mute your speakers.

If you are having difficulty connecting to the webinar or viewing the slides and are unable to communicate that to us via the comment box, please email
Opioidcomments@cdc.gov. That’s O-P-I-O-I-D-C-O-M-M-E-N-T-S at cdc.gov.

You can also find a brief summary and instructions for how to provide comment on what is being presented today online at www.cdc.gov/drugoverdose/prescribing/guidelines.html. Please note that this URL will be provided for you in written form in a later slide during today’s presentation.

Now I’ll walk quickly through today’s agenda. Following these welcoming remarks, I’ll provide a brief introduction to the process then turn it over to Dr. (Dowell) for an overview of the draft guideline. We will not pause for comments during the overview; however, following the overview we will move into the open comment period during which each recommendation will be brought up again.

The purpose of today’s webinar is to provide an opportunity for public engagement and the review of CDC’s draft opioid prescribing guideline. The target audience for the guideline is primary care providers such as family practitioners and internists who are treating patients aged eighteen and older for chronic pain in outpatient settings.

This webinar will be recorded to provide a complete and accurate record of the comments made. It will not be archived for public viewing and the slides will not be available after the webinar concludes. Please note that all feedback received will be carefully reviewed and considered by CDC scientists engaged in the guideline process.

CDC staff will prepare a written summary of the comments made during the webinar. The summary will not include names or affiliations of persons
making comments and the summary will be posted on a CDC public Web site in or around October 2015.

I will now move into an overview of the webinar comment process. First, CDC will review the guideline development process and present clinical recommendation statements after which we’ll move into the comment period.

During the comment period, participants may offer comments in response to each recommendation statement in one of three ways. First, verbally over the phone during the webinar, time permitting. Second, electronically via the webinar comment box in real time. And please note that only the webinar host will see your written comments. They will not be published to all participants. Or third, via email sent to Opioidcomments@cdc.gov before five o’clock PM Eastern Daylight Time tomorrow, September 18.

If necessary, CDC may provide minor clarifications at the end of the comment period today, but will not otherwise respond to comments. For those commenters who ask a question, please note that we are taking note of your question asked which will be instructed to us as we consider if and where further clarification is needed for any of the draft recommendation statements.

CDC will record all comments and they will be used to inform CDC’s ongoing revisions and also to provide to peer reviewers for consideration. This allows for the maximum feedback possible from all of you on the webinar today within the time period allotted for each recommendation statement.

Given the volume of individuals joining us today, we ask that you please treat this convening as you would any other business meeting and be concise, courteous, and professional when providing remarks.
This next slide provides CDC’s disclaimer language. This information is distributed solely for the purpose of pre-dissemination review. It has not been formally disseminated by the Centers for Disease Control and Prevention. It does not represent and should not be construed to represent any agency determination or policy. CDC provided funding for evidence synthesis and meeting support.

I will now turn the microphone over to Dr. (Dowell).

Dr. (Debbie Dowell): Thank you (Joann). Here is an overview of our guideline development process. An agency for healthcare research and quality sponsored systematic review published in 2014 on the effectiveness and risks of long-term opioid treatment of chronic pain served as a foundation for the evidence basis for the guidelines.

CDC conducted additional literature searches to update this evidence review as well as the contextual evidence reviews to help translate the evidence into recommendations. CDC convened a core expert group to assist in defining the scope of the recommendations, interpreting the evidence, and translating the evidence into recommendations.

These experts reviewed summaries of the scientific evidence and CDC’s draft recommendation statements, provided individual ratings for each draft recommendation statement, and discussed the draft recommendations with CDC during an in-person meeting in June 2015 in Atlanta.

CDC then revised the draft recommendations based on discussions and expert opinions expressed at the June meeting. CDC is now in the process of obtaining and reviewing comments on the revised draft recommendations. Comments have been or will be received from the core expert group, from
federal partners, from a stakeholder review group including representatives from professional and community organizations with interests in pain management and opioid prescribing, from peer reviewers, and from the public.

To obtain perspectives from the public, including healthcare providers and prospective patients, CDC has convened this public engagement webinar taking place yesterday and today. CDC will review comments from all of these groups, consider modifications, and revise the guideline as needed.

In addition, CDC will share a summary of comments received from the public with our independent peer reviewers in order to inform their review of the CDC guidelines. CDC anticipates sending the revised guideline to the Department of Health and Human Services for review in early November and publishing the guideline in January of 2016.

The Grading of Recommendations Assessment, Development, and Evaluation -- or GRADE method was used to rate the strength of the recommendations. In GRADE, the recommendations are rated as strong, meaning most patients should receive the recommended course of action, and that recommendation could be adopted as policy in most situations; or as weak, implying that different choices will be appropriate for different patients, the clinicians must help patients decide based on the clinical situation and on patient values and preferences, and that policymaking requires much debate and stakeholder involvement.

In GRADE, four factors influence the strength of recommendation ratings. First, is the recommended course of action effective in improving patient outcomes? Second, does the recommended course of action do more good
than harm? Third, how much do values and preferences vary about the recommended course of action? And fourth, are the benefits worth the cost?

A recommendation is likely to be rated as strong when the anticipated benefits are expected to be great relative to the likely harms.

The GRADE method was also used to rate the quality of evidence from the clinical evidence review. Quality of evidence could be rated high, moderate, low, or very low. Many factors influence this rating, such as study design, number of patients included in studies, and variation and findings across studies.

In GRADE, low quality evidence signals uncertainty, not an absence of evidence. Recommendations can be confidently made and are frequently made with low quality evidence. For example, for patients with septic shock it is standard of care to promptly administer fluids and medications in order to increase the patient’s likelihood of survival. When the Surviving Sepsis campaign used GRADE to develop the international guidelines for managing septic shock, the panel strongly recommended this practice while rating the quality of evidence for it as low.

The twelve draft recommendations are categorized into three conceptual areas -- determining when to initiate or continue opioids for chronic pain outside of end of life care; opioid deletion, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use.

When published, CDC’s opioid prescribing guideline will include both recommendation statements and supporting rationales for each recommendation. The supporting rationales will explain the reasons behind
each recommendation, citing supporting evidence, and will offer considerations for implementation.

I will now review all twelve draft recommendation statements without pausing for comments. After that, each draft recommendation statement will be brought up again, allowing the opportunity to comment. Please note that each of the twelve draft recommendation statements is intended to be easily understood, digestible, and implementable by providers as our primary target audience. Your feedback to help us determine whether those aims have been met is much appreciated.

Recommendation one -- non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks.

Recommendation two -- before starting long term opioid therapy, providers should establish treatment goals with all patients, including realistic goals for pain and function. Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risk to patient safety.

Recommendation three -- before starting and periodically during opioid therapy, providers should discuss with patients risks and realistic benefits of opioid therapy, and patient and provider responsibilities for managing therapy.

Recommendation four -- when starting opioid therapy, providers should prescribe short-acting opioids instead of extended-release, long-acting opioids.
Recommendation five - I’m sorry. I realize I skipped a slide here so I’m going to go back to recommendation four and read it with the slide.

Recommendation four -- when starting opioid therapy, providers should prescribe short-acting opioids instead of extended-release, long-acting opioids

Recommendation five -- when opioids are started, providers should prescribe the lowest possible effective dosage. Providers should implement additional precautions when increasing dosage to fifty or greater milligrams per day in morphine equivalents and should avoid increasing dosages to ninety or greater milligrams per day in morphine equivalents.

Recommendation six -- long term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, providers should prescribe the lowest effective dose of short-acting opioids and should prescribe no greater quantity than needed for the affected duration of pain severe enough to require opioids. Three or fewer days will usually be sufficient for non-traumatic pain not related to major surgery.

Recommendation seven -- providers should evaluate patients within one to four weeks of starting long term opioid therapy or dose escalation to assess benefits and harms of continued opioid therapy. Providers should evaluate patients receiving long term opioid therapy every three months or more frequently for benefits and harms of continued opioid therapy.

If benefits do not outweigh harms of continued opioid therapy, providers should work with patients to reduce opioid dosage and to discontinue opioids when possible.
Recommendation eight -- before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid related harms. Providers should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid related harms are present.

Recommendation nine -- providers should review the patient’s history of controlled substance prescriptions using C prescription drug monitoring program data to determine whether the patient is receiving excessive opioid dosages or dangerous combinations that put him or her at high risk for overdose. Providers should review prescription drug monitoring program data when starting opioid therapy and periodically during long term opioid therapy, ranging from every prescription to every three months.

Recommendation ten -- providers should use urine drug testing before starting opioids for chronic pain and consider urine drug testing at least annually in all patients on long term opioid therapy to assess for prescribed medications as well as other controlled substances and illicit drugs.

Recommendation eleven -- providers should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

Recommendation twelve -- providers should offer or arrange evidence-based treatment, usually opioid agonist treatment in combination with behavioral therapies for patients with opioid use disorder.

I’ll now turn the microphone back over to (Joann), who will bring up each recommendation again while allowing the opportunity to comment.
Thank you Dr. (Dowell). We will now move into the comment period. During this period I will present each recommendation one at a time and open up a five minute comment period for each. As I shared earlier, there are three comment options.

First, follow the phone operator’s instructions to make a verbal comment. Second, type a comment into the webinar comment box on the screen. And third, submit comments via email by five PM Eastern Daylight Time tomorrow to OpioidComments@cdc.gov.

When making a verbal comment, please keep your comment brief to allow time for others to participate. Also, when making a written comment via the comment box or by email, please note the specific number of the recommendation about which you are commenting to ensure CDC’s understanding of the reference which will help to inform the response.

As noted earlier, during the webinar CDC may provide minor clarifications as needed, but to allow maximum comment time we will not otherwise respond to comments. Also, please note that these slides of the draft language are for purposes of today’s discussion only and will not be available upon conclusion of the webinar.

Draft recommendation one -- non-pharmacologic therapy and non-opiod pharmacologic therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks.

Operator, can you please provide instructions to participants on how to queue up for verbal comments?
Coordinator: Thank you. We will now begin the comment session. If you would like to make a comment, please press star 1 on your touchtone phone. Unmute your phone and record your first name clearly. If you need to withdraw your comment, please press star 2.

It will take a few moments for those comments to come through. Please stand by.

One moment, please.

The first comment comes from (Ann). Your line is open.

(Ann): Actually, I was wanting to comment on number five. I thought it was all for the ones that we didn’t see and just wanted to comment. I apologize.

Coordinator: As a reminder, if you would like to make a comment, please press star 1 and record your first name only. One moment, please.

The next comment comes from (David). Your line is open.

(David): Yes. Will the panel of experts consist of ten professionals with opposing views? I guess I should say - I should have put this in the form of a recommendation that they should have opposing views as to get to a logical conclusion on this matter.

Coordinator: Thank you. There are no further comments in the queue at this time.

(Joann Kang): Thank you Operator. With that, I’d like to remind everyone that if you would still like to comment on recommendation number one, you can do so via the comment box or also by sending an email.
Draft recommendation number two -- before starting long term opioid therapy, providers should establish treatment goals with all patients including realistic goals for pain and function. Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

As a reminder, Operator, can you please provide instructions to participants on how to queue up for verbal comment at this time?

Coordinator: Thank you. If you would like to make a comment, please press star 1 on your touchtone phone and record your first name only. Thank you. One moment, please.

One moment please for our first comment.

Our first comment comes from (Ada). Your line is open.

(Ada), please check the mute function on your phone.

The next comment comes from (Kristin). Your line is open

(Kristin): Your recommendation two fails to explain what you mean by clinically meaningful improvement in pain and function that outweighs risk to patient safety. Also, your recommendation does not acknowledge that there are patients who suffer from very rare pain conditions who have already failed standard therapies and who require treatment by a pain specialist.

As stated, your recommendation implies that opioid treatment is generally negative, and that is not necessarily always the case.
Coordinator: Thank you. If you would like to make a comment, please press star 1.

There are currently no more comments in the queue.

(Joann Kang): Thank you Operator. As a reminder, also feel free to provide a comment via the comment box or by email, designating draft recommendation number two.

Draft recommendation number three -- before start and periodically during opioid therapy, providers should discuss with patients risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy.

Operator, can you please open up the lines and identify the first commenter in queue?

Coordinator: There are currently no comments in the queue. Please stand by.

Our first comment comes from (Kristin). Your line is open.

(Kristin): Again, recommendation three fails to in any way acknowledge that there are rare pain conditions suffered by some individuals. Your recommendation should in some manner acknowledge the World Health Organization’s three step ladder for pain care and should indicate that primary care providers should refer patients for specialized treatment by a pain specialist when the first and second steps have failed.

It leaves us feeling that opioid therapy is almost always bad and that is incorrect implication.
Coordinator: Thank you. If you would like to make a comment, please press star 1 and record your first name.

Please stand by.

There are no further comments in the queue at this time.

(Joann Kang): Thank you Operator. As a reminder, any follow-up comments can be sent via the comment box or by email designated draft recommendation number three.

Moving on to draft recommendation number four -- when starting opioid therapy, providers should prescribe short-acting opioids instead of extended-release, long-acting opioids.

Operator, can you please open up the lines and identify the first commenter in queue?

Coordinator: Please stand by. There are currently no commenters in queue.

There are no commenters at this time.

(Joann Kang): Thank you, Operator. Any additional comments can be shared via the comment box or by email with reference to draft recommendation number four.

Moving on to draft recommendation number five -- when opioids are started, providers should prescribe the lowest possible effective dosage. Providers should implement additional precautions when increasing dosage to fifty or greater milligrams per day in morphine equivalents and should increasing dosages to ninety or greater milligrams per day in morphine equivalents.
Operator, can you please open up the lines and let us know when the first commenter is in queue?

Coordinator: Please stand by for comments.

The first comment comes from (David). Your line is open.

(David): Yes. I was just - I guess I should make this in a referral, but I ask that they look at the difference in metabolism and how people and patients metabolize different. One human - it may take a less than another human. And I just wonder if they have considered this fact.

Coordinator: Thank you. The next comment comes from (Ann). Your line is open.

(Ann), please check your mute function or pick up your handset. Your line is now open for comments.

(Ann): Yes. I feel that recommendation number five does not account for patients who do require high dose opioids. Currently, prescribers are so careful to prescribe at all that they refuse to treat patients such as myself who have been stable and compliant on high dose opioids for over a decade with good benefit, no side effects, no endocrinopathy, and no aberrant behavior.

These patients should not be punished for the differences in their own metabolism. My physician of nine years post (unintelligible) buprenorphine only practice in preparation for retirement due to the stress of regulatory environment is imposing. There needs to be a specific pathway for physicians to follow if they feel a patient needs high doses and not simply pass these patients off to suffer.
Coordinator: Thank you. The next comment comes from (Kristin). Your line is open.

(Kristin): I would like to say that I agree with the concerns expressed by both of these prior commenters on recommendation five. I firmly, strongly agree that individual differences must be considered and there must be consideration given to genetic anomalies, absorption, malabsorption issues, and many other reasons why some people require higher doses.

Again, I would suggest that your recommendations need to be supplemented by some reference to the World Health Organization’s three-step ladder for pain treatment. We need to acknowledge that there are already many severe pain patients out here who are on greater doses than ninety and what I think you need to do is explain in your guideline - again, you have set these with a primary care.

But, you have not in any way indicated the existence of rare pain conditions which unfortunately befall many individuals. They have already or will probably fail standard treatment and they require treatment by specially trained pain specialists. You need to acknowledge that these people exist and they must be afforded consideration in this guideline before you put this out for primary care doctors.

Coordinator: Thank you. The next comment comes from (Dustin). Your line is open.

(Dustin) removed his comment. There are no further comments in the queue.

(Joann Kang): Thank you Operator. For any additional comments, please feel free to send them via the comments box or email and reference draft recommendation number five.
Draft recommendation number six -- long term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, providers should prescribe the lowest effective dose of short-acting opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.

Three or fewer days will usually be sufficient for non-traumatic pain not related to major surgery.

Operator, can you please open up the lines and let us know when the first commenter is in queue.

Coordinator: Thank you. Please stand by for comments.

One moment, please.

The first comment comes from (Kristin). Your line is open.

(Kristin): Regarding recommendation six, I think it is, again, very important to address the fact that some patients have DNA abnormalities that require them to have higher doses for the pain relief that another person might get with a small dose. Similarly, there are individuals with malabsorption problems who do not readily absorb opioids and therefore may not get sufficient treatment from a low dose.

Coordinator: Thank you. If you would like to make a comment, please press star 1 and record your first name only. Please stand by.

One moment, please.
The first comment comes from - I believe it was (Cynthia). Go ahead. Your line is open.

(Cynthia): Yes. Regarding number six, I understand the need for the lowest dose for the shortest duration. But how can you arbitrarily add three or fewer days when you don’t know exactly what condition you’re treating? And you’re again not accounting for patient individuality. If you were to do this with somebody that had hypertension or another medical problem, it would be ridiculous. I think the three or fewer days needs to completely be deleted from that particular recommendation. Thank you.

Coordinator: Thank you. The next comment comes from (David). Your line is open.

(David): Yes. I was just - in the current atmosphere, most trauma doctors are actually scared to treat. There are some that are actually scared to treat their patients whatsoever. And we’ve heard many stories of people going untreated because of this fear doctors have of the DEA and other agencies.

And I just wish I could see something in their terminology here that would show - give them a specified regulation. And again, like they have said earlier, with metabolism I just don’t’ understand how you can - they can set a number on this. Thank you.

Coordinator: Thank you. The next comment comes from (Matt). Your line is open.

(Matt): Yes. These sound more like rules rather than guidelines. They really kind of sound absolute and as some of the other speakers have mentioned, there are going to be cases where it’s going to be reasonable to use longer than, say, three days. That’s all.
Coordinator: Thank you. Please stand by.

There are no further comments in the queue at this time.

(Joann Kang): Thank you Operator. Additional comments can be sent via the comment box or by email with reference to draft recommendation six.

Moving on to draft recommendation number seven -- providers should evaluate patients within one to four weeks of starting long-term opioid therapy or of dose escalation to assess benefits and harms of continued opioid therapy. Providers should evaluate patients receiving long-term opioid therapy every three months or more frequently for benefits and harms of continued opioid therapy.

If benefits do not outweigh harms of continued opioid therapy, providers should work with patients to reduce opioid dosage and to discontinue opioids when possible.

Operator, can you please open up the lines and let us know when the first commenter is in queue? Thank you.

Coordinator: Please stand by.

Our first comment comes from (Kristin). Your line is open.

(Kristin): Thank you. I want to point out with regard to recommendation statement as well as other recommendations that you say for each one that you have strong recommendations -- all but one of them, I believe -- but low quality evidence.
I would like to point out that there are professional panels such as the NIH Opioid Panel that convened in September of 2014 and published its reports somewhat later indicating that there are certain patients who benefit from long term opioid therapy. And there is nothing in any of your recommendations that would acknowledge that these medications can be extremely helpful and may be the only option for some pain patients.

Again, I think it is imperative that you speak to the World Health Organization’s three step pain treatment ladder and indicate that individuals who fail standard treatment must be referred to a pain specialist for appropriate dosing, appropriate care. I believe that along with other commenters the tendency is going to be to - your guidelines are going to continue to generate that fear and will cause prescribers to not prescribe dosages that patients need and the outcome of that is going to be people in pain unnecessarily. Thank you.

Coordinator: Thank you. The next comment comes from (Matt). Go ahead. Your line is open, sir.

(Matt): Yes, just a couple things on this. One, benefit versus harm -- that’s really kind of vague. If you ask a philosopher, they might say - a physician trying to measure benefit versus harm would be like asking a rabbit to try to guess what a jellyfish would want.

And defining benefit versus harm I think is probably important to maybe have a panel of patients who are chronic long-term pain patients. I realize that the thing that’s probably stimulating development of these guidelines - number one is the widespread prescribing of opiates, and number two is the overdoses that we’re seeing.
But that means also the way to - there’s a substantial risk of suicide in people with long-term chronic pain that should be looked at against that. That’s it.

Coordinator: Thank you. There are no further comments in the queue at this time.

(Joann Kang): Thank you Operator. As a reminder, you can send additional comments via the comment box or via email with reference to draft recommendation number seven.

Moving on to draft recommendation number eight -- before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid related harms. Providers should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid related harms are present.

Operator, can you please open up the lines and let us know when the first commenter is in queue? Thank you.

Coordinator: Thank you. Please stand by.

Our first commenter is (Ann). Your line is open.

(Ann): Yes. While we’re focusing mainly on opioid harms in this webinar, I think we’re failing to acknowledge the harm of uncontrolled pain or blood pressure causing a patient to be inactive and literally decimating an individual’s quality of life. Please (unintelligible) essentially take away everything a person has, it seems, in chronic severe pain while they have done nothing wrong in taking their medications as prescribed.
I realize there’s a few aversions from nature (unintelligible) but we cannot punish patients that have done exactly as they are supposed to in an effort to protect other people from their own bad choices. Addiction is a disease and there was a choice initially to misuse medications prescribed or take medication that was not prescribed. And I think that needs to be acknowledged.

Coordinator: Thank you. The next commenter is (Kristin). Your line is open.

(Kristin), please check your mute function. Your line is open for comments.

(Kristin): Sorry. This is (Kristin). I would like to indicate that I agree with the previous commenter and I think there should be great focus put on the fact that there are serious health risks associated with being in a long term state of constant severe pain to include cardiovascular risk, high blood pressure, depletion of hormones that may alter body functions in many ways, and ultimately death.

Your recommendations tend to make no mention of long term severe chronic pain. You need to address the World Health Organization’s three step ladder and you need to acknowledge that there are also serious risks associated with not treating pain.

Coordinator: Thank you. The next commenter is (Matt). Your line is open.

(Matt): Yes. The naloxone thing - I would be cautious. Certainly industry probably wants to sell naloxone in a select group of patients who are at risk for overdosing. It might be an okay thing, although I’m not really aware of any good evidence on that.
The first thing whenever someone is found unconscious and not breathing is to start chest compressions and call 911. I’m afraid that widely publicizing and making available the naloxone - that stuff is going to be forgotten while someone runs for the naloxone.

And that’s all.

Coordinator: Thank you. There are currently no further questions in the queue.

(Joann Kang): Thank you Operator. Additional comments can be sent via the comment box or via the email address with reference to draft recommendation number eight.

Moving on to draft recommendation number nine -- providers should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program data to determine whether the patient is receiving excessive opioid dosages or dangerous combinations that put him or her at high risk for overdose.

Providers should review prescription drug monitoring program data when starting opioid therapy and periodically during long term opioid therapy, ranging from every prescription to every three months.

Operator, can you please open up the lines and let us know when the first commenter is in queue? Thank you.

Coordinator: Please stand by.

One moment, please.

Our first commenter is (Kristin). Your line is open.
(Kristin): I would like to state again that individual variation in response to opioid medications and other medications as influenced by genetic variations and other factors clearly make it important to consider the patient’s individual characteristics and history.

And this recommendation as stated suggests to me that individuals can perhaps have prescriptions denied, treatment denied based on a rather routine or cursory review of information in the prescription drug monitoring program. Looking at what is in there is not going to be sufficient to tell exactly what dose or what combination medications will put an individual patient at high risk for overdose.

Coordinator: Thank you. The next commenter is (Matt). Your line is open.

(Matt): Yes. The drug monitoring program has been useful. Once every month or every three months -- that would just be too high of a time constraint. The other problem is not everybody uses that. The VA - they don’t often times report to the drug monitoring program. A lot of mail order pharmacies don’t. There is nothing that prevents someone from going from one state to another and us not being able to see that they’re getting drugs over the state line. If it’s our goal to prevent these people from doctor shopping they’re not dumb people. They can get online and do a Google search and find a script to tell a physician, you know, exactly what they have to to get - or another practitioner what they have to to get a prescription of a narcotic. This just seems like every three months it’s going to add a lot of extra work without really being that helpful in address those other problems. That’s all.

Coordinator: Thank you. There are no further comments in the queue at this time.
Woman: Thank you operator. Additional comments can be shared by the comment box or via email with reference to draft recommendation number 9. Moving on to draft recommendation number 10. Providers should use urine drug testing before starting opioids for chronic pain and consider urine drug testing at least annually for all patients on long-term opioid therapy to assess for prescribed medications as well as other controlled substances and illicit drugs. Operator, can you please open up the lines and let us know when the first comments are in queue? Thank you.

Coordinator: Please stand by. The first comments are with (Matt). Your line is open.

(Matt): Yes, I think the drug screening is a good thing. It is very expensive - I think around $200 for the good test. I think a five year old could probably figure out how to beat them by saving a few pills to take a couple of days before their appointment. So I would probably recommend that if doing urine drug testing that it be done randomly by a phone call to call the person in for a pill count and a urine test. And not on every visit because that would get extremely costly. That’s all.

Coordinator: Thank you. The next commenter is (Kristin). Your line is open.

(Kristin): I would like to point out that in your earlier slide where you showed all of the twelve (unintelligible) recommendations, I believe this particular one was supported only by weak recommendations and very low quality of evidence. I would therefore question why it’s on the list at all if that’s all the support that it got. Certainly it is common practice to screen - do drug testing before starting opioid therapies. I believe that is standard. To the extent that some receipt may be necessary, that is possibly appropriate, but a focus on frequent testing or consistent testing, which the test can be beaten by people who want to do that. First you really undermine the (unintelligible) relationship between
a legitimate long-term pain patient and there are many of them and their
doctors. We need to build trust and communication between doctors and
patients and rely on things other than drug tests to assess whether somebody is
doing what they’re supposed to do.

Coordinator: Thank you. There are no further commenters in the queue at this time.

Woman: Thank you operator. Additional comments can be shared via the comment box
or via email with reference to draft recommendation number 10. Moving on to
draft recommendation number 11. Providers should avoid prescribing opioid
pain medication and (unintelligible) concurrently whenever possible.
Operator, can you please open up the lines and let us know when the first
commenter is in queue? Thank you.

Coordinator: Thank you. Please stand by. One moment please. The first commenter is
(Kristin). Your line is open.

(Kristin): That’s recommendation 11 fails to point out that there are, just as
(unintelligible) a pain medication, there are short acting and long acting
(unintelligible) medications. It may be in many cases that long acting
(unintelligible) are helpful to long term pain patients who suffer other
concurrent symptoms such as anxiety and use appropriately extended relief
long acting (unintelligible) may be very helpful to those who require long
term (opioid) treatment as well.

Coordinator: Thank you. The next commenter is (Matt). Your line is open.

(Matt): Yes, I’m a family doctor - (unintelligible) care doctor and I agree the overdose
risk is higher with the (unintelligible) and opioids, but at least in the end the
wise patients COPD or lung failure is probably the king of bad ways out of
this world and less than half of those people - folks are well controlled with their symptoms through the dying process where cancers and various other things, you know, well over 90% of them are controlled to their satisfaction. COPD is a very long drawn out way to go. I mean sometimes 10 years that they’re symptomatic and the constellation of symptoms is that they get the chest wall pain, the air hunger. You pretty much need an opiate for that, but they also get anxiety from those things and in my experience a lot of the times those folks will benefit from like a long acting (unintelligible) long a (unintelligible). Of course, my folks are usually the end of lifers, but, you know, that’s just the past six months. But I could certainly see someone sub-acute before they’re ready to enter a hospice program where they might benefit from something like that. And, again, this is an absolute statement. You know, a person should avoid prescribing as in it’s a rule rather than a guideline. That’s all.

Coordinator: Thank you. There are no further commenters in the queue at this time.

Woman: Thank you operator. Additional comments can be shared via the comment box or by email with reference to draft recommendation number 11. Moving on to draft recommendation number 12. Providers should offer or arrange evidence based treatment - usually opioid treatment in combination with the behavioral therapy for patients with opioid use disorder. Operator, can you please open up the lines and let us know when the first commenter is in queue? Thank you.

Coordinator: Please stand by. One moment please. The first commenter is (Kristin). Your line is open.

(Kristin): I would like to say, with regards to recommendation 12 and other recommendations as well that although they are (unintelligible) guidelines we see too many patients where guidelines are interpreted as rules and your
guidelines make no acknowledgement of their long-term pain patients who have already failed lower steps on the World Health’s Organizations three step pain ladder. Your recommendations (unintelligible) critically basically offer - they provide a negative implication about the use of opioids (unintelligible) chronic pain at all going back to your very first one where you said non-(unintelligible) therapy and non-opioid therapy are preferred for chronic pain period. There is insufficient attempt given here or instruction given to primary care doctors to let them know that there are individuals who suffer very rare pain conditions for whom long-term opioid therapies will be the only option. And I think it is a disservice to chronic pain patients to go forward with your recommendations until they can be re-worked to better address this issue.

Coordinator: Thank you. The next commenter is (Anne). Your line is open.

(Anne): I have not heard anything in these guidelines that provides support for the chronic (unintelligible) improvement without variance behavior, which was (unintelligible) focus of those guidelines. These are the patients our medical system should give priority and focus to rather than punishing them in an effort to (unintelligible) addiction. The guidelines support low quality evidence, strong recommendation (unintelligible) example (unintelligible), yet when groups of this (unintelligible) an injury prevention website use the fact (unintelligible) low quality evidence as a reason that chronic opioid therapies should be avoided. I find this to be a bit (unintelligible), but I just ask that you not forget patients that are in chronic pain that have benefited from opioids, including high doses like myself. (Unintelligible) quality of life stolen from me over the past two months (unintelligible) tapper from medication and I (unintelligible) suffer withdrawal from a significant dose in just a few days and a solution to this has not been found and I have done nothing to deserve being punished in this way. Thank you.
Coordinator: Thank you. The next commenter is (Marie). Your line is open. Please check your mute function. Please stand by. The next commenter is (Greg). Go ahead, your line is open sir.

(Greg): Hello, I agree that we cannot wait to publish guidelines until research is supported every single recommendation. The fact that 7 in the 12 recommendations are supported by only very low quality of evidence and by merely low quality evidence flies in the fact of the fact that 11 of the 12 recommendations are considered strong recommendations. Clearly this is the epitome of imminence based rather than evidenced based medicine and should be embarrassing to every pain and addiction clinical researcher and or research funding agency if this is truly a national epidemic that has emerged over the last couple of decades as many believe. It would be a shame if these guideline opinions were seen as answers rather than questions to be evaluated.

Coordinator: Thank you. The next commenter is (Matt). Your line is open.

(Matt): Yes, a couple of things. As far as the level of evidence that, you know, it’s quite a task that you folks have because I look at these opiates as an all or none. You know, kind of like not taking someone’s appendix way back in the day. Universe was the ones where you took their appendix out and, you know, it was so dramatic the survival benefit that, you know, it was an all or none situation. And it’s kind of like that with an opiate. You know, someone with moderate to severe pain like the lady mentioned about the World Health Organization pain ladder, you know, moderate and severe pain, you know, opiates are it. You have adjuncts, you know, helper drugs to give, you know, to help out.
So, you know, I think that’s why it’s hard that there’s really no good studies, you know, on opiates versus (unintelligible) pain. You couldn’t make a study like that. I mean how would you handle the dropouts? That just said I’m not going to take this pill. It’s not working and they left. The other issue I think we really should look at is pathways. You know, probably the most robust data in all of medicine I’ve seen in the past 20 years came from anesthesiologists. You know, how they got pathways because injuries from this type of medication in the OR was terrible, you know, 20 something years ago. And so they got pathways and they’ve dropped their risk of overdose and things like that in the OR by - it’s like 100s of times. It’s something absorbed.

I don’t think I’ve seen data that robust anywhere in the past 20 years, but I think that would probably be a nice way to go would be to have a template visit, you know, that we go down as like a little preflight. You know, you check your plane before you take off and make sure you’ve done all the things. And it can be tested and, you know, watch for improvements on overdoses and, you know, kind of tweak it as time goes. That’s all.

Coordinator: Thank you. There are no further comments in the queue at this time.

Woman: Thank you operator. As a final reminder, you can provide additional comments via the comment box for the duration of the webinar, which will be concluding shortly or via email. Please reference draft recommendation number 12 when doing so.

Our sincere thanks to everyone for your participation and thoughtful feedback. CDC’s next steps are to revise the guideline in response to stakeholder review, peer review and public comments. The guideline will then go under review by CDC and the department of health and human services and will be published in the morbidity and mortality weekly report in or around January 2016.
Again, for those of you who did not comment verbally, but would like to do so please send an email to opioidcomments@cdc.gov by tomorrow, September 18, at 5:00 PM Eastern daylight time. That’s opioidcomments@cdc.gov. You can also find additional information about CDC’s guidelines at the website that’s provided on the slide. Thank you again to all our participants and we hope you have a great rest of your day.

Coordinator: That concludes today’s conference Thank you for participating. You may disconnect at this time. Speakers, please allow a moment of silence and standby for your post-conference.

END