

CENTERS FOR MEDICARE & MEDICAID SERVICES
Special Open Door Forum:
Prior Authorization of Non-Emergent Hyperbaric Oxygen Therapy
December 10, 2014
1:30-2:30 pm Eastern Time
Moderator: Jill Darling

Operator: Good afternoon. My name is (Dan) and I will be your conference facilitator today. At this time, I would like to welcome everyone to the Centers for Medicare and Medicaid Service Prior Authorization Non-Emergent Hyperbaric Oxygen therapy Special Open Door Forum.

All lines have been placed on mute to prevent any background noise. After the speaker's remarks there will be a question and answer session. If you would like to ask a question; during this time simply press star and then the number one on your telephone keypad. If you need to withdraw your question, simply press the pound key. Thank you.

Ms. Sheila Mulligan, you may begin your conference.

Sheila Mulligan: Hi, thank you. Good morning and good afternoon everyone. Thank you for joining today's call which is the Special Open Door Forum Prior Authorization of Non-Emergent Hyperbaric Oxygen Therapy.

We apologize for the delay in the start of the call. We wanted to get as many folks on the line as we can and we have much to cover today, so we will begin. First, we have Connie Leonard speaking.

Connie Leonard: Thank you for joining our Special Open Door Forum today on Prior Authorization of Non-Emergent Hyperbaric Oxygen Therapy. This is our second call and we last had a call in about a month ago and early – this early November and since that time, we have been able to clarify some of the jurisdictions impacted. This is one of the big questions that was raised by participants last time, so Jennifer and Angela will talk about that and we also

announced a start date of the federal register on November 21, 2014. So we will discuss the start date too.

So with that, I will turn it over to Jennifer.

Jennifer:

Thank you. The purpose of this model is to establish a three-year prior authorization process for non-emergent hyperbaric oxygen (HBO) therapy and to ensure that beneficiaries continue to receive medically necessary care while reducing expenditures and minimizing the risk of improper payments to protect the Medicare trust fund by granting provisional affirmation for a service prior to the submission of the claim.

Prior authorization is a process through which a request of provisional affirmation of coverage is submitted for review before a service is rendered to a beneficiary and before a claim is submitted for payment. Prior authorization helps ensure that applicable coverage, payment, and coding rules are met before services are rendered.

Some insurance companies such as TRICARE, certain Medicaid programs and the private sector already use prior authorization to ensure proper payment before the service is rendered. HBO therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure.

The National Coverage Determination, NCD, can be found in the Medicare National Coverage Determinations Manual Chapter 1, Part 1 sections 20.29. Of the 15 covered clinical conditions listed in the NCD, 6 will be available for prior authorization.

The six conditions available for prior authorization are – preparation and preservation of compromised skin grafts not for primary management of wound; chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management; osteoradionecrosis as an adjunct to conventional treatment; soft tissue radionecrosis as an adjunct to conventional treatment; Actinomycosis only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment; Diabetic wound of the lower extremities in patients who meet the following three

criteria, patient has type 1 or type 2 diabetes and who has a lower extremity wound that is due to diabetes. The patient has a wound classified as Wagoner Grade 3 or higher and patient has failed an adequate course of wound therapy as defined in the NCD.

Who and where: providers that submit HBO claims with bill type 13-Hospital Outpatient are included in the prior authorization model. It will occur in Illinois for those serviced by MAC J6 NGS, in Michigan for those serviced by MAC J8 WPS, and in New Jersey for those serviced by MAC JL Novitas.

The MACs will begin accepting prior authorization requests on March 1, 2015 for HBO treatments with one of the six included conditions for dates of service on or after March 15, 2015. All HBO treatments with one of the six included conditions and a date of service on or after March 15, 2015 must have completed the prior authorization process or the claims will be stopped for pre-payment review.

The following HBO HCPCS code is subject to prior authorization. The HCPCS code subject to prior authorization is G0277 – hyperbaric oxygen under pressure, whole body chamber for 30 minute interval. This HCPC code replaces C1300 on January 1, 2015. Prior authorization is only needed for the facility payment part of the HBO therapy service.

However, if a facility does not have prior authorization or has a non-affirmed prior authorization, the associated physician claim with the following code will be subject to medical review. The code is 99183- Physician attendance with supervision of hyperbaric oxygen per session.

Coverage and documentation requirements: Under this model Medicare coverage policies are unchanged. Documentation requirements are unchanged and timeframe for HBO therapy are unchanged. The model does not create any new documentation requirements. It simply requires the information be submitted earlier in the claims process. Current requirements can be found on the MAC website.

Existing coverage requirements The NCD can be found in the Medicare National Coverage Determinations Manual Chapter 1, Part 1 Section 20.29.

HBO therapy is covered as an adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard healing care. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days.

Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

Also unchanged is that the MACs will be conducting the reviews. All advanced beneficiary notice policies and claim appeal rights.

What has changed: the facility will know before the service is rendered whether Medicare will pay for the service. Also upon request, the beneficiary will be notified before the service is rendered whether Medicare will pay for the service.

Prior authorization request content as of December 1, 2014: The request needs to identify the beneficiary's name, Medicare number, date of birth and gender, the physician's name, national provider identifier (NPI) and address, the facility's name, NPI and address, the requestor's name and telephone number, procedure code, submission date, start of the 12-month period, number of treatments requested, diagnosis codes, and indicate if the request is an initial or resubmission review and indicate if the request is expedited and the reason why.

The request also needs to include documentation from the medical record to support the medical necessity and other relevant document as deemed necessary by the contractor to process the prior authorization.

I will now turn the presentation over to Angela to continue through the slides.

Angela: Thank you, Jennifer. A provisional affirmation prior authorization decision may affirm up to 36 courses of treatment in a 12 month period. If additional

sessions are needed in excess of the 36 treatments, a new prior authorization request may be submitted.

The facility or the beneficiary may submit the prior authorization request. It can be mailed, faxed or submitted to the esMD system. For the initial request, the MAC makes every effort to review requests and postmark decision letters within 10 business days.

Resubmitted requests are requests submitted with additional documentation after the initial prior authorization request was non-affirmed. The MAC makes every effort to review these requests and post mark decision letters within 20 business days.

Expedited circumstances are when the standard time frame could jeopardize the life or health of the beneficiary. The MAC will make reasonable effort to communicate a decision within two business days.

Decision letters are sent to the facility and to the beneficiary upon request. Decision letters that do not affirm the prior authorization request will provide a detailed written explanation outlining which specific policy requirement was not met.

When a prior authorization request is submitted but not affirmed, a submitter can resolve the non-affirmative reason described in the decision letter and resubmit the prior authorization request or provide the service and submit the claim, that claim will be denied but all appeal rights are available.

For non-affirmed prior authorization requests, unlimited resubmissions are allowed. These requests are not appealable, however for denied claims all normal appeal rights apply.

The Medicare Administrative Contractors will list the prior authorization unique tracking number on the decision letter. This tracking number must be submitted on the claim.

When submitting an electronic 837 institutional claim, the unique tracking number should be submitted at the 2300 claim information level in the prior

authorization reference segment where REF01 equals G1 qualifier and REF2 equals UTN.

When submitting a paper CMS 1450 Claim form the unique tracking number should be submitted in Form Locator 63. The UTN should be submitted on the same line (A, B, or C) that Medicare is shown in Form Locator 50(Payer Line A, B, or C). The UTN should begin in position 1 of Form Locator 63.

If a facility has not requested prior authorization the claims will be stopped for prepayment review. The MAC will send an additional request letter and wait for 45 days for a response. The MAC then reviews submitted documentation within 60 days.

Without a prior authorization decision, the facility or the beneficiary will not know whether Medicare will pay for the service and the facility or the beneficiary maybe financially liable. CMS strongly encourages providers to use the Medicare Prior Authorization process.

This slide summarizes the different scenarios that can occur. Scenario 1, the prior authorization request is submitted, the MAC decision is affirmative, the facility chooses to render the service and submit the claim. The MAC will then pay that claim as long as all other requirements are met.

Scenario 2, the prior authorization request is submitted but the MAC decision is not affirmative. The facility can either A. submit the claim, the MAC will deny that claim or B. The facility can fix and resubmit the prior authorization request.

Scenario 3, the prior authorization request is not submitted therefore there is no MAC decision, the facility can then render the service and submit a claim, the MAC will stop that claim for pre-payment review. Please note that if a facility has no prior authorization or a non-affirmed prior authorization, the associated physician claim will be subject to medical review.

As for the beneficiary impact, the service benefit is not changing. Beneficiaries upon request receive a notification of the decision about their

prior authorization request. Dual eligible coverage is not changing and private insurance is not changing.

The MACs have additional information on HBO services on their websites. Illinois is in jurisdiction J6 NGS, Michigan is jurisdiction J8 WPS, and New Jersey is jurisdiction J11 Novitas.

You can also find additional information on the CMS HBO prior authorization model website at <http://go.cms.gov/PAHBO>. There you can find frequently asked questions, background information, and information on open door forums including the slides for today's presentation.

So in summary, the HBO Prior Authorization model will begin on March 1, 2015 in the states of Illinois, Michigan and New Jersey.

Requests can be submitted by the facility or the beneficiary and it will last for three years. You can also e-mail questions to the prior authorization team at HBOPA@cms.hhs.gov and now I will pass it back over to Connie for some additional information.

Connie Leonard: Thank you, Angela. On the last call in early November participants commented on a few of the conditions that we have included in the model, these specifically there were comments about the diabetic limbs of the lower extremities and the compromised skin graft and if those should be considered non-emergent given the importance of beginning the HBO therapy.

And we said we would take those back and try to determine if we wanted those to remain in the model. We have determined that we do want diabetic wounds of the lower extremities and the uncompromised skin graft to remain in the hyperbaric oxygen therapy model. However, we are still exploring options on how we could make the prior authorization model work and still be – still ensure; that the beneficiaries are going to get access to their care in a timely manner.

We are considering modifying the length of time that a MAC or a contractor has to review the prior auth decision. We are exploring options to issue a conditional or a provisional affirmative approval based on you know records

submitted at day 20 so that on day 31 for the lower diabetic wounds to the lower extremities for those therapies could begin on day 31 with the remainder coming in after the records are received from day 31.

So we are exploring lots of different options of how we might be able to tweak this process to get it to work more effectively. I do want to remind everyone that participation in the model is voluntary so a physician, a facility does not have to submit a prior authorization request. However, if they don't, that claim will get reviewed pre-payment.

So if there ever is a situation that a facility or a physician feels that a particular beneficiary needs to have that care begun right away and it's not – they didn't have time to wait for the prior authorization request. They could go ahead and provide the treatment and have the claim stopped for prepayment review.

Now if everyone did that, we would not necessarily test our model for that condition and so that is one of the reasons why we are looking for other options. We are exploring. Talking with the MACs, talking with the physicians and in CMS, hoping to talk a few associations, you know to get their thoughts to then say – to come to some sort of a compromise that we can then make sure the treatment is available as soon as necessary but also to allow the prior authorization process to go through.

Those discussions are still occurring and we will have further details at the next open door forum which we expect will be in mid to late January that will probably be the last open forum before the MACs begin their educational effort so if needed we will have another open door forum in February also right before the March start day.

I suspect that the MACs will have their targeted educational sessions, webinars, or onsite sessions in the month of February leading right up to the start of the model. So today, I don't necessary know. Obviously we are more than willing to hear your comments about the six conditions and if they're not emergent you know – if you would just give us one more month to provide some additional feedback and we're always interested in comments that you

might have and with that I will open it up to the participants for the Q&A sessions.

Operator: As reminder ladies and gentlemen, if you would like to ask a question please press star then the number one on your telephone keypad. If you would like to withdraw your question, please press the pound key. Please limit your question to one question and one follow-up to allow other participants time for questions. If you require any further follow-up, you may press star 1 again to rejoin the queue. I'll pause for a moment now to compile today's Q&A roster.

Your first question comes from the line (Ellen Deli) from Georgia. Your line is now open.

(Ellen Deli): Hello. I would like to address the issue of the number of treatments that the Medicare recipient will be preauthorized for. So currently, is 36 the number of treatments that you're authorizing per authorization?

Connie Leonard: That is correct, 36 is the number of treatments. Now there is an ongoing discussion and we hope to have some more clarification next month about exactly what does that 36 treatment mean. The G-code, the G0277 is billed in 30-minute increments.

I do not believe that one 30-minute increment equals a treatment. If that was the case, I think a lot of beneficiaries would exceed their 36 treatments in one week and so one of the things that we are fine tuning and we will have more information for you in February, what does the treatment mean?

I believe a treatment is going to equal the time – the time going into the chamber, the time in the chamber and then the time coming out of that chamber so it's going to be one session but we will – that is something that we are going to define for everyone way before the model begins in January so more to look for that.

(Ellen Deli): OK, could I ask or suggest that you also look at changing the number of treatments from 36 to 40 considering the two actual chronic indications that you have on your list, chronic osteomyelitis and radiation tissue damage/osteoradionecrosis, 40 is the minimum that those patients get.

And so, leading into the fact that the preauthorization request will have to be submitted before the 30-days to document improvement makes 40 a much more reasonable number.

Connie Leonard: Thank you, (Ellen). We will definitely take that back. Thank you.

(Ellen Deli): Alright, thank you.

Operator: Your next question comes from the line of (Kathleen Judge). Your line is now open.

(Kathleen Judge): Yes, hello and my question was exactly that same as the previous caller with the request that with those two diagnoses for chronic osteo and the radionecrosis the standard of care is 40 and sometimes up to 60 treatments. So with what the discussion was that we would need 20 days of business days for the reauthorization, that would really put that patient's previous hyperbaric treatments in jeopardy because as you should know, hyperbaric therapy is a successive treatment that builds upon the oxygenation of the tissue over succession, you know, successive treatments so if we were to have to stop the treatment of the hyperbarics and wait for 20 days or reauthorization, it might completely jeopardize that entire set of treatments that we had given the 36 treatments beforehand. So that is critical that that be analyzed and based on the standard practices of care that has been scientifically demonstrated in hyperbaric that this preauthorization should match the evidence.

Connie Leonard: Yes, thank you for that comment and that is definitely something that we will take back and see if we can modify in some way. We certainly in no way want treatment to stop, you know, certainly it's begin we certainly understand the need for the success rate is obviously much higher if it is continuous therapy.

(Kathleen Judge): Thank you so much.

Connie Leonard: Thank you.

Operator: Your next question comes from the line of (Jean Johnson) from Michigan. Your line is now open.

(Jean Johnson): Hi. I was just wondering for the MAC for Michigan, et cetera that you're referring to what are the mailing addresses and fax and phone for the authorization process?

Connie Leonard: Those will be available at a later time. They are not yet available now.

(Jean Johnson): OK.

Connie Leonard: MACs will have, you know, a fax number and e-mail address or an address specific for the prior authorization process that they will put up and we'll also ...

(Jean Johnson): OK.

Connie Leonard: ... put a link through our website. They're just not there, not yet.

(Jean Johnson): OK. So I'll wait into the – into the New Year some time probably late January.

Connie Leonard: Correct. I would suspect ...

(Jean Johnson): OK.

Connie Leonard: ... by January, early of February going into the March 1st start date.

(Jean Johnson): OK. Thank you.

Connie Leonard: Thank you.

Operator: Your next question comes from the line of (Tom Nord) from Missouri. Your line is now open.

(Tom Nord): Yes. I see that you said this will be applicable to the G0277 code and I think in our last open forum call they had also mentioned that it would be for centers that are subject to OPPS so my question is are Critical Access

Hospitals subject to this or are they part of this demonstration project since they do not use the G0277 code?

Connie Leonard: Critical Access Hospitals or facilities are not included in this model.

(Tom Nord): Thank you.

Connie Leonard: That's a great question. We will make sure that we put a frequently question up in our website just to make that distinction.

(Tom Nord): Thank you.

Operator: Your next question comes from the line of (Rebecca Leebrick) from Michigan. Your line is now open.

(Rebecca Leebrick): Just I am curious as to how whomever; came up with the number 36 for treatments.

Female: That was roughly ...

Connie Leonard: The 36 treatments was developed by a group of physicians here in CMS after they had done a pilot study of some hyperbaric oxygen claims. So we did do some research and actually reviewed some claims and came up with the average day of 36 so it's interesting to hear some of the feedback that we got today about the minimum requirements that we will certainly take back and see if we can make modifications to the design.

(Rebecca Leebrick): Thank you.

Connie Leonard: Thank you.

Operator: Again if you would like to ask a question, simply press star one on your telephone keypad.

Your next question comes from the line of (Karen Gilroy) from New Jersey.
Your line is now open.

(Karen Gilroy): Hi. I noticed in all of the (pronounced) that I have that they're stating that responses of authorization are going to be postmarked, not to disparage the post office, but sometimes by the time you get through the hospital mailroom and the post office, you're looking at a 7- to 10-day delay for when something is mailed until it's received. Isn't there in this day and age sort of a more efficient way to communicate that authorization electronically via e-mail and is that something we could consider?

Connie Leonard: Well I'm going to start with right at the beginning the only other way outside of mail is fax, but all of the MACs will fax back a decision if that's what the facility wants, which I would expect a lot of – a lot of them will want. Another ...

(Karen Gilroy): Yes.

Connie Leonard: ... option, I'm not so sure if it's going to be available in all three states, certainly probably not at the start date, but shortly after you'll see several portals, all of the MACs have a portal that they use in some way or another and at least some of them are looking to being able to accept documents through the portal ...

(Karen Gilroy): Yes.

Connie Leonard: ... and we will check on responses and the last way is the electronic submission of medical documentation. That is an electronic system that providers can use to submit documentation to CMS. We will not have them in March, but we will have them shortly after.

We will have what we call review result codes and reason codes and those codes actually come back through the esMD System to give providers the actual review decision in a much faster format and we do believe those will be in place hopefully by April or May timeframe.

(Karen Gilroy): OK. Thank you.

Connie Leonard: Thank you.

Operator: And there are no further questions on the line at this time. I'll turn the call back over to the presenters.

Connie Leonard: Well thank you very much everyone. I do appreciate everyone, being patient with us as we are, you know, trying to determine the best way that we can make this model work, not only with CMS, but also with the facilities so we are very much interested in our conversations that we've been having with the MACs and the associations as to some of the type of compromises that we can make.

I also thank you for some of the feedback that you guys gave today about changing the number of the treatments and just some of the minimum first for some of the conditions that's very, very helpful information that we will certainly take back and examine to see what changes we might be able to make for the design. Again, you know, we do not want to delay treatment for any beneficiary whereas we are just trying to test this model to see how this would have – prior authorization would have worked.

So we appreciate everyone's feedback and I would just, again, if you think of anything, any types of questions, feedback, comments that you'd like to give, the e-mail box is H, B as a boy, O as an oxygen, P as in prior and A as an authorization at cms.hhs.gov and we certainly have been trying to answer those questions we do get in the mailbox and we answer them as best we can and you will get an answer, you know, from us. Sometimes the harder questions take some days and we have to let you know that we're working on it, but we will get answers and will try to bring some of those up on the next call.

So, we will have another call in mid-to-late January and hopefully we'll have a lot more answers for you guys. One last chance; are there any questions in the queue?

Operator: As a reminder, if you have a question, please press star one now.

You have a question on the line from (Paris Gulley) from Michigan. Your line is now open.

(Paris Gulley): Hi. Yes. The question I have is the, you know, the continuity of care in diabetic patients with foot ulcers. If we get 20 treatments and then we have to submit to document there has been improvement, by the time we get a response, the patient's wound will definitely deteriorate and how are we going to assure, you know, definite continuity of care with these patients because some of them come with very large wounds, amputations and such we're trying to get to heal and some need up to 60 treatments to get them, you know, out of the, you know, in a – in a good state so how do we assure – how are we assured of this?

Connie Leonard: You know that's – that's a great point and as I mentioned we certainly do not want any therapy to stop. That is not the intent of any prior authorization and certainly not this prior authorization so that especially with that of the lower extremities and the diabetic wounds to the lower extremities as that is the one that we are trying to determine how we can best make it work, what changes to the design can we make so that you can continue providing the treatment necessary while still be able to provide us with the documentation necessary to keep prior authorizing the treatment.

So that is something that we have to have more information on at the next open door forum call, but we do understand and appreciate all the feedback everyone has given us and it has given us some great ideas and we think we're going to be able to come up with the solution and as soon as we can get back to you guys for feedback we will.

(Paris Gulley): And, you know, and one more point, you know, this also goes with, you know, some of the other callers with respect to patients with, you know, radiation, you know, therapy, let's say radiation cystitis who have severe hematuria and many of them again, they go from 40 to 60 treatments and we see an excellent response and basically we're trying to keep them away from the urologist, you know, scoping them, you know, cauterizing the bleeding, you know, increasing, you know, morbidity of these patients so again, you know, continuity of care, you know, is of the utmost in all of these indications and it's not just diabetic foot ulcers, but there is a definite morbidity with patients getting scoped, getting fulgurated and so on and we need to, you

know, be able to address the issue because we have the highest response rate with HBO with the lowest mortality – morbidity.

Connie Leonard: OK. You know that that – definitely thank you for that feedback. We agree that the continuity of care is very important not just for diabetic wounds, but also for all of these conditions then so I appreciate the feedback that I got today on some of the – some of the other conditions and we certainly will take that back and discuss some more with our physicians and again see what tweaks we can make. Again we want to ensure that this is going to be a process that does not impede the continuity of care or the ease of care that a beneficiary has access to. Thank you.

Operator: Your next question comes from the line of (Jewel Krieger) from Maryland. Your line is now open.

(Jewel Krieger): Connie, this is (Jewel), I want to thank you for your responsiveness to a number of the issues that were brought up over our meeting and the last call specifically on the concerns of the clinical indications and I appreciate all the group is doing to respond to the concerns to ensure that the patient care is not impeded.

One other issue I want to make sure stays on the list and that was a concern that we brought up with respect to needing guidance on exactly what paperwork is required for each indication.

Connie Leonard: Yes.

(Jewel Krieger): Again, our concern is that the amount of paperwork and documentation for each indication is voluminous and so we want to be able to ensure that hospitals are not in a position where they turned in to print – printing organizations to get all the documents there and that; MACs aren't turned into warehouses if you would of documentation. So we want to make sure we're getting exactly what's needed in the appropriate timeframe, so we'd ask that we keep that as a – as an open issue before we go live so that everyone knows exactly what documentation is required for each indication.

And then the last comment I'll make and I'll refer it back to (Helen Gelly) as she brought up concerns about the indications, the turnaround time for the prior authorization, but also the number of dives or treatment per indication.

UHMS has an indications manual that may be helpful to the medical team that is part of your group looking at the number of dives per indication so that they have reference not just to what has been provided in building the path, but more importantly to the clinical justification for what type of treatment should be applied to the specific diagnosis. Thank you.

Connie Leonard: Thank you, (Jewel). I'll take a look at that. We'll – I'll try to find that indication manual and we'll take a look at that just to make sure again we're keeping in line with the rest of the industry.

And as far as the paperwork that's expected, yes that we have been talking with the MACs about that and we would expect that they'll provide detailed information when they do their educational sessions and we have been talking with them about exactly what they're going to need in getting feedback to the facilities and I appreciate your association's willingness to work with us and then (inaudible) to contact you after the holiday just so we can continue our discussions and kind of get your feedback on, you know, some of the things we might be thinking so we'll be talking. Thank you.

(Jewel Krieger): Great. Thank you.

Operator: Your next question comes from the line of (Rebecca Leebrick) from Michigan. Your line is now open.

(Rebecca Leebrick): Hi thank you. Following up on the previous caller, we have a concern here regarding standard of care and what I heard what we were hearing was that this was based on a review by physicians of the claims. Is there any supporting documentation ...

Connie Leonard: Yes.

(Rebecca Leebrick): ... any studies, any ...

Connie Leonard: Oh yes.

(Rebecca Leebrick): Go ahead.

Connie Leonard: What happens, sorry I didn't mean to cut you off there. So what happened with our – we had a group of physicians in CMS who did a review of not only the claims, but also supporting documentations so these were from a contractor who had requested medical documentation and did a full-fledged post-payment medical review and those were the documents that were reviewed so it was just not claims information, it was also the supporting documentation behind the claim.

That being said, it doesn't mean that we can't go back and look at some of these other, you know, indication manuals and some of these other types, you know, really go back and say what type of claims, what type – what type of conditions did they look at, you know, in that study and just fill up to make sure that it was well represented with the six conditions, you know, that we have kind of put forth in the model.

(Rebecca Leebrick): OK because – that's good to hear because there are several – there are multiple reasons why patients do not complete their HBO treatments. To begin with, a lot of them are very sick when they go in to the chamber ...

Connie Leonard: Certainly.

(Rebecca Leebrick): ... and there's a lot of insinuating circumstances regarding your treatments.

Connie Leonard: You know we certainly understand that and we certainly understand that sometimes, you know, HBO therapy, you know, might be your – a last resort or the, you know, one of the last few things that you can do especially if you're trying to save a limb and so we certainly do do that and we'll take another look and we'll go back and talk to our physicians.

You know this type of feedback is always good as we're trying to, you know, roll it out, you know, in a perfect world, we'd be able to come out say and hold these sessions before we even had approval to do the model, it just

necessarily worked – always worked that way, you kind of want to go through the process and come up with the design and then kind of make it public – sometimes it may seem a little bit backwards, but we still are at the time period where we haven't started yet. It's still a model and we can still tweak it and so I appreciate everyone's feedback. It will – It really helps us to kind of make sure we wanted to kind of start this one slowly and two that successfully we want this to be a good process not only for Medicare, but also for the facility so I appreciate all this feedback.

(Rebecca Leebrick): OK. Thank you.

Connie Leonard: Thank you.

Operator: Just a reminder, to ask a question, please press star one on your telephone keypad.

Your next question comes from the line of (Helen Gelly) from Georgia. Your line is now open.

(Helen Gelly): Yes, thank you. On behalf of the industry in Hyperbaric Medical Society, I would like to offer at least an electronic version of the 13th edition of the Hyperbaric Oxygen Therapy Indications Manual so if I send an e-mail to the HBOPA e-mail address, would you all or we sent it electronically, would you receive it or would there be a filter?

Connie Leonard: I don't know. I believe ...

(Helen Gelly): That ...

Connie Leonard: ... it would receive it. If you get a message back that says it's – it could not go through because of size limitation or something else so we do allow usually a pretty large file to come through. If you could send me an e-mail, I'm pretty easy to find. It's just connie.leonard, l-e-o-n-a-r-d@cms.hhs.gov and then we can work out another way to get it.

(Helen Gelly): All right. Thank you very much.

Connie Leonard: Thank you, (Helen). I appreciate that.

Operator: Your next question comes from the line of (Sean Bonnet) from New Jersey.
Your line is now open.

(Sean Bonnet): To get back to an operational direction on this and I appreciate the depth of clinical experience we're hearing here, I have yet to see any mention on the Novitas site about this and just tangentially I've been in discussions with my friends in the ambulance preauthorization and I was told by them that the numbers and access were not released until the day of for instance in our case is we wouldn't see a thing until March 1st, I certainly hope that's not the case and I think that is something that's working on most of our minds that is of great concern to all of us I'm sure.

Connie Leonard: You know those are very big concerns. I do know that from an ambulance perspective and that the ambulance model just began December 1st so it's just last Monday that the form – the voluntary form that can be used was updated on the website as I believe was the 1-800 call number. They have a – Novitas actually has a dedicated customer service area set aside just for prior authorization so that was really – it is possible that the fax line and the address may not have been just to prevent cases coming in beforehand that does create unnecessary work, but I'm thinking it was there beforehand because we attended some of the trainings and such and we thought it had – it had been there, but I could be mistaken.

We would expect that at least by the time of the educational outreach up in New Jersey or at the other two states that the requisite information would be available meaning at least the draft form and the address, the fax number, you know, any information that you needed so that you can start your operational process in your facility so we'll make sure we talk with them on a weekly basis, sometimes more if need be so we'll make sure that that's going to get there.

It's not surprising to me that they don't have anything up there yet about HBO given that it's not going to begin until March, but I certainly would expect as we move into the January timeframe, you'll start to see more on the website.

(Sean Bonnet): Thank you.

Connie Leonard: Thank you.

Operator: If there are any further questions, please press star one now.

Your next question comes from the line of (Jean Johnson) from Michigan.
Your line is now open.

(Jean Johnson): Hi. I just want to make sure that the slides and everything from today will be available soon.

Connie Leonard: Yes, we actually placed them on the website now.

(Jean Johnson): OK.

Connie Leonard: They are on the CMS website; get it through our website so it's the go, the go.cms.gov/PAHBO and that's all capital letters, the P-A-H-B-O ...

(Jean Johnson): OK. Wait a second.

Connie Leonard: ... but the slides are up there.

(Jean Johnson): OK so the go.cms.gov/PAHBO, it's not the open door forum?

Connie Leonard: Correct. It is not the ...

(Jean Johnson): OK.

Connie Leonard: ... open door forum site ...

(Jean Johnson): OK. OK.

Connie Leonard: ... it is the prior authorization site.

(Jean Johnson): OK. Very good.

Connie Leonard: Thank you.

(Jean Johnson): Thank you.

Operator: And there are no further questions on the line at this time. I will now turn the call back to the presenters.

Connie Leonard: Well I would like to thank everyone for participating today. It's been very, very helpful as each of these calls are.

We will definitely take everything that you have said back and continue to discuss this with the associations and the physicians here in CMS and I just appreciate everyone's willingness to participate, give us feedback and help us to make that successful.

And with that, thank you and have a great afternoon and we'll talk again in mid-to-late January. Please e-mail the mailbox if you have any further questions.

Operator: This concludes today's conference call. You may now disconnect.

END