

Moderator: Bill Finerfrock
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1:00 p.m. CT

Operator: Good afternoon and welcome to the rural health clinic proposed rule review part two. This call is being recorded.

At this time, I'd like to turn the conference over to Mr. Bill Finerfrock. Please go ahead.

Bill Finerfrock: Thank you, operator. And I want to welcome all of our ((inaudible)) today to our presentation on the rural health clinic proposed rule review. Our presenters today are Captain Corinne Axelrod, who is the RHC coordinator with CMS, and she'll be joined by Mary Collins and Scott Cooper who are with the Office of Clinical Standards and Quality within CMS.

I am Bill Finerfrock. I'm the Executive Director of the National Association of Rural Health Clinics, and I'm the moderator of today's call. Our speakers today will review background and highlights on the proposed rule, covering the parts that were not covered in our first call.

Today, we'll be dealing with staffing, waivers, contracts, some of the payment issues, the quality assurance program improvement initiative, questions about hours of operation, emergency and patient health records. Today's program is scheduled for an hour and a half and the majority of the time will be devoted to speaker presentations with breaks for questions during the call.

This series is sponsored by the Health Resources and Services Administration Federal Office of Rural Health Policy in conjunction with the National Association of Rural Health Clinics. The purpose of the call series is to provide Rural Health Clinic staff with valuable technical assistance in RHC specific information.

Today's call is the 26th in the series which began in 2004. As you know, there is no charge to participate. We encourage you to refer others who might benefit from this series to sign up to receive announcements regarding call dates, topics and presentations. To do that you can go to www.ruralhealth.hrsa.gov/rhc.

During the question and answer discussions we request that you please provide your name as well as the location you're calling from before asking your question. In addition, for future reference you can e-mail questions in ahead of time to info, that's I-N-F-O, at [NARHC.org](mailto:info@NARHC.org) and put RHC teleconference question in the subject line. All questions and answers will – we will try to get to them.

I want to remind you that we did make the slides available via e-mail and they are posted on that ruralhealth.hrsa Web site address I provided you with.

At this point, I'd like to turn the call over to Corinne Axelrod with CMS. It's all yours Corinne.

Corinne Axelrod: Thanks Bill and thanks to everybody else for taking the time out of your busy schedules to join this call.

On the last call I went over the background of the Rural Health Clinic program, some highlights of the proposed regulation, and then spent the rest of the time talking about location requirements and the proposed exceptions to those requirements.

As Bill mentioned, we're going to go over staffing, payment and quality issues. But before we get started I want to emphasize again that this is a proposed rule. Nothing in here is final until the rule is published as a final rule. Let us know what may need to be changed or what can be improved.

As I said on the last call, we have tried our best to develop a set of regulations that are clear and reasonable and strike a good balance between the statutory requirements and providing as much flexibility as possible. But if we missed the boat on anything please let us know.

Our goal is to make sure that rural beneficiaries get the care they need by giving you as much support and flexibility as possible while implementing the requirements of the law. So if you have any specific recommendations to improve the program please let us know.

I will again stop after each section for some questions and then hopefully at the end we'll have time for any other questions you may have.

So let's start with the staffing requirements. There are a couple of special statutory requirements for Rural Health Clinics. The first one is that Rural Health Clinics must have a nurse practitioner, physician assistant or a certified nurse midwife at least 50 percent of the time that the clinic operates. The second one is that the RHC must employ one or more nurse practitioners for physician assistants.

These are two separate but obviously related requirements. Let's talk about the first one, the NP, PA or CNM at least 50 percent of the time the clinic operates. This does not include the time that the RHC is open solely to address administrative matters or provide shelter - that was addressed in a Survey and Certification letter that was sent out about a year and a half ago.

Existing rural health clinics would be able to apply for a one year waiver of this requirement. This waiver is not available to new RHCs, only to existing RHCs. To be granted a waiver rural health clinics would have to demonstrate a good faith effort to recruit and hire and NP, PA, or CNM within the past 90 days.

I know some of you have asked what does it actually mean “a good faith effort”, and we have given some examples. For instance, advertising in a newspaper or professional journals, conducting outreach at an NP, PA, or CNM school; things like that.

But we recognize that situations may vary in different locations so these are just examples and you may actually come up with some other good ways to demonstrate your recruitment efforts.

Rural health clinics that submit a waiver request would be granted a one year waiver unless they are notified within 60 days that the request is denied. You would be able to reapply for another waiver six months after the expiration of the last waiver and RHCs that do not meet this requirement and do not request a waiver would be decertified.

The second staffing requirement is that the RHC must employ one or more nurse practitioner or PA. A CNM or other practitioner does not fulfill this requirement. It must be a nurse practitioner or a physician assistant. Employ is a term that I think we all know what it means and it's usually evidenced by the employer's provision of a W2 form to the employee.

The NP or PA must be employed at all times but the NP or PA, would not be required to be a full time employee. That leads into the topic of contracting. We are proposing that the regulation prohibiting rural health clinics from contracting with non-physician providers would be removed and that the RHCs would be allowed to contract with non-physician providers as long as at least one NP or PA is employed.

I'm going stop here and ask if anybody has any questions on the staffing requirements, the waivers or the ability to contract with non-physician providers. So operator would you open the lines for any questions?

Operator: Thank you. The question and answer session today will be conducted electronically. If you would like to ask a question, please do so by pressing the star key followed by the digit one on your touchtone telephone. If you're using a speakerphone, please make sure your mute function is turned off to allow your signal to reach our equipment. A voice prompt on your phone line will indicate when your line is open and we do ask that you please state your name and location before asking your question. We will proceed in the order that you signal and we'll take as many questions as we can.

Once again – once again, please press star one. We'll pause for a moment to give everyone an opportunity to signal.

Bill Finerfrock: While we're waiting operator, Corinne, I'd like you to clarify something. On your slide you said that to be granted a waiver RHCs would have to demonstrate a good faith effort to recruit and hire an NP or PA or CMN within the past 90 days.

The 90 day time period is when you – but if you have initially 90 days to replace your PA or NP at which point do one year waiver would kick – opportunity would kick in, correct?

Corinne Axelrod: Yes, that's correct.

Bill Finerfrock: And throughout the period of the waiver you have to demonstrate that you've made a good faith effort, not just simply for 90 days.

Corinne Axelrod: Well the waiver is in affect for one year. So hopefully the NP or PA or CNM that you hire will want to stay for more than one year once they're hired.

Bill Finerfrock: Right. So let's say that I did my initial 90 days and I applied for the waiver and it's now 12 months later. I haven't hired a PA or an NP during that 12 month period so I can't extend – but, as I understood it that you would go back and verify that during the time period of the waiver I was continuing to make a good faith effort to fill that position, or is that not what you're saying?

Corinne Axelrod: I don't think that's exactly right. Let's say that it's July 1st and your NP has just quit. So you have 90 days to make a good faith effort to recruit another NP, PA or CNM.

Bill Finerfrock: Right.

Corinne Axelrod: Let's say that you are not successful so you apply for a waiver – you will be notified within 60 days – well, if you're not notified within 60 days that your request has been denied than you will be granted a one year waiver.

As of July 1st you're without an NP, PA or CNM, you have 90 days, so that's July, August, September, you apply, that's October and November is the 60 days. Let's say you get the waiver, that would begin December 1st and go through December – that would go through November 30th of the following year.

Bill Finerfrock: But – yes, but what I'm questioning is what is the – what do I have to be doing during the period of the waiver? I can just do nothing.

Corinne Axelrod: Well you can. It wouldn't be advisable because the waiver can only be for one year. If you don't hire somebody by the end of that one year then you're going to have a problem.

Bill Finerfrock: I would agree that you would at that point loose your rural health clinic certification but there had always been a expectation that during the period of the waiver you had to be actively recruiting to fill that position and if CMS determined that you had done nothing during the waiver period they could resend your rural health clinic designation retroactive to the initial end of the 90 days.

So you're saying that that's no longer the policy.

Corinne Axelrod: Whether you do any recruiting or not, if you have a one year waiver and you're at the end of that waiver and you have not hired somebody then the clinic would be then decertified.

Bill Finerfrock: OK. All right, let's move on to the questions from the audience.

Operator: OK. We'll take our first question. Please go ahead.

(Brian Banchowder): On the – this is (Brian Banchowder) from Ohio, Morro County. The very last slide you showed, slide number eight, I guess I'm having a bit of trouble distinguishing employment from contracting. I assume that employment means you directly employ the person but contracting, the other possibility would be as an independent contractor would be considered not employed.

Can you – can you clarify that a bit?

Corinne Axelrod: Thank you. I'll certainly try to. The term employ, as I mentioned, is usually evidenced by the provision of a W2 form. So whatever mechanism you are employing your other staff with would be the same for the NP or PA that's employed.

I'm sure there's reams of paper defining the term employ but I think just a common sense approach is that however your other staff is employed would apply to this person versus contracting. I don't know if I'm answering your question very well but without getting into all the legalities, is there – can you be a little more specific?

(Brian Banchowder): Well I guess everybody – I think everybody inherently knows what employment means. I guess the other term is what do you mean by contract? What is – what do you mean is not employed? How can a person work and not be employed?

Corinne Axelrod: There are a lot of places that – for instance physicians in a lot of clinics work under a contract. They're not employees of the clinic per say but they do have a contract to work X number of hours at X salary et cetera.

I'm not sure that I can really give you more detail on that. You might want to send in a question on that and perhaps we can answer it better later.

Operator: We'll take our next question.

Female: Hi. I think Mr. Finerfrock in his question he answered my question.

Corinne Axelrod: OK, great. Thank you. What I'm going to do is go on and we can come back to any other questions on the ...

Female: Hello.

Corinne Axelrod: I'm sorry. Go ahead.

Operator: That caller would have to re-queue.

Bill Finerfrock: OK. Go ahead, Corinne. Just get ((inaudible)).

Corinne Axelrod: OK, the next area that I want to talk about are payment issues. The first one is regarding the exceptions to the payment limit. I think all of you know that an exception to the payment limit is available to RHCs that are an integral and subordinate part of a hospital with less than 50 beds determined by either of two methods.

The first method is the bed count as described in 412.105(b), and the second one is for sole community hospitals, the average daily census does not exceed 40 and the hospital is in a RUCA nine or 10. I know there's been some confusion on this. Several people have called me about it and I actually now understand where in the preamble some of the language might have been confusing.

Let me just say that if you are using the first method there is no change. This proposed rule makes no changes to the methodology used in the first method. If you are using the second method, that is if you're a sole community hospital, in the past that used urban influence codes, that is being changed to RUCAs which are rural urban commuting areas.

As we talked about last time, we believe that the RUCAs are a more precise measurement of rurality and they're more consistent with other CMS programs such as the hospital and ambulance payment systems.

I believe that most of the RHCs who are provider based to a hospital are using the first method. So this really is not going to affect very many RHCs but I just wanted to make that clear because I think there is a little bit of concern about that.

OK. The payment methodology. There are some revisions to the payment methodology which I want to now go over with you. The Social Security Act states that Medicare payment can not exceed 80 percent of reasonable costs and that coinsurance can not exceed 20 percent of reasonable charges.

Under the current methodology Medicare pays rural health clinics 80 percent of reasonable costs. This does not take into account coinsurance payments and it allowed, in some cases, the rural health clinics – and this also applies to federally qualified health centers, FQHCs, it allows them in some cases to receive more than 100 percent of reasonable costs.

What we are proposing is that Medicare pays rural health clinics reasonable costs minus coinsurance and deductibles based on the facility charges not to exceed 80 percent of reasonable costs. We have some examples here that I'm going to go through with different clinic charges of \$100, \$80 and \$70. I'll go through these for both rural health

clinics with the per-visit payment limits and RHCs with an exception to the payment limit.

In the first example, which is an RHC with the per-visit payment limit, the clinic charges \$100 for the service. Under the current methodology Medicare would pay 80 percent of \$75.63 which is the 2008 upper payment limit. The patient's obligation, which is 20 percent of the clinic charge of \$100, is \$20. The clinic revenue would then be \$80.50 which is higher than the upper payment limit.

The proposed method would take the upper payment limit of \$75.63 and deduct the \$20 that the patient has paid for their co-pay and the Medicare payment would then be \$55.63. If you add that with the \$20 that the patient has paid the clinic revenue is \$75.63 which is the 2008 per visit limit.

For RHCs that have an exception to the per visit payment limit in this example we're going to say that the clinics allowable cost per visit prior to the application of the beneficiary obligation is \$80 and the clinic charges \$100.

Under the current method Medicare payment would be 80 percent of the \$80, which is \$64, plus the \$20, which is the 20 percent of the clinic charge, and the total revenue would be \$84 which again is higher than the clinics allowable cost per visit.

Under the proposed method the Medicare payment would be \$80, which is the allowable cost per visit for this clinic, minus \$20, which is \$60, plus the \$20 for clinic revenue of \$80.

In the next example the clinic charges \$80. For the RHC with the per visit payment limit the Medicare payment is 80 percent of \$75.63, which is \$60.50, plus the \$16, which is 20 percent of the \$80, that's the patient obligation, and the clinic revenue is \$76.50.

Under the proposed method the Medicare payment would be \$75.63, the upper payment limit minus the patients co-pay, which is \$16, and that comes out to \$59.63. The \$59.63 plus the \$16 ends up being \$75.63 which is the clinics revenue.

In these examples the co-pay is less than in the previous example because the charge is lower, so the Medicare payment is higher but the revenue would be the same.

Bill Finerfrock: But in each one of those instances the RHC and the aggregate is getting less money, anywhere from \$1.13 per visit up to \$5 per visit based on the way you would propose to do the calculation compared to current methodology.

Corinne Axelrod: That's correct. And as we'll see when we go through these examples, that for RHCs who have a payment limit there won't be any change to their revenue if the charges are at or below the payment limit. For RHCs with the exception to the payment limit there won't be any change if the charges are at or below the allowable cost per visit but if they're higher than there would be changes.

Bill Finerfrock: Corinne, just if I could stop you a second.

Corinne Axelrod: Sure.

Bill Finerfrock: Did you provide us – did you – do you actually have – I don't have these slides and I don't think – we therefore didn't provide them to anybody. I don't – I don't – unless I'm missing them.

Corinne Axelrod: You should have them. This is part of the slides that I sent. The examples begin on slide 16. Can we ask if other people have them?

Bill Finerfrock: I don't – if we can open up the line, operator, does anybody else have these slides? I don't know that we got these.

Operator: We had several people queue up so do you just want me to open one of the lines?

Bill Finerfrock: Yes, just open one of the lines. Go ahead. Who ever opened their line up, did you get a copy of these slides? Do have the financial examples?

Female: Actually I was queued up for a question about a previous one.

Bill Finerfrock: Oh, OK. Did you – we can put you back in the queue but did you get – did you get any slides showing financial examples?

Female: Yes.

Bill Finerfrock: You did.

Female: Yes.

Bill Finerfrock: All right, then my bad. OK. Continue on Corinne.

Bill Finerfrock: I'll try and find them.

Corinne Axelrod: I know this is hard to follow even with the slides so thankfully, hopefully everybody else has the slides.

Bill Finerfrock: OK.

Corinne Axelrod: If we look at a rural health clinic with the per visit payment limit that charges \$70 for a visit, the Medicare payment would be 80 percent of the \$75.63, which is the upper payment limit, and that would be \$60.50, the patients obligation would be \$14, which is 20 percent of the \$70, and the clinic revenue than is \$74.50 which is the \$60.50 plus the \$14.

Under the proposed method it would be 80 percent of the \$75.63 and 20 percent of the \$70 is \$14 and the clinic revenue would be \$74.50. So in this case, because the clinic charges are less than the payment limit, the revenue would be the same.

For an RHC with an exception to the payment limit that charges \$70 for a visit, the current method, again, 80 percent of 80 is \$64 minus – plus the \$14, which is 20 percent of the \$70, for a clinic revenue of \$78. Under the proposed method it would be \$80, which is in this example the clinics allowable cost per visit, minus the \$14, which is the patients obligation, which equals \$66.

However, that would exceed 80 percent of the allowable cost so even though that comes out to \$66 it would still – the Medicare payment would be \$64 on that plus the \$14 for a clinic revenue of \$78.

I know this is an awful lot of numbers, it's very confusing but again this is to comply with the statutory requirement that Medicare not pay more than 80 percent. And again, if the RHC that has a payment limit charges the same as the payment limit or less than the payment limit there will not be any change to the revenue.

If the clinic charges are higher than there would be a change. And the same with the RHCs that have the exception to the payment limit, if the charges are at or below the allowable cost per visit, there would not be a change.

I'm sure that's a mouthful. Let me just quickly mention a couple other things in this section and then we'll open it up for questions again.

When the 2003 final rule was published we got a lot of questions about commingling. What we tried to do in the preamble to this proposed rule is to add some language to hopefully clarify when comingling is permissible and when it is prohibited.

I'm not sure if we helped it or not but that certainly was what we tried to do. Commingling is the sharing of RHC space, staff, supplies, records and other resources with an onsite Medicare Part B or Medicaid fee for service practice operated by the same RHC practitioners.

Commingling is prohibited is when it results in duplicate payment either due to the inability of the RHC to distinguish its actual costs from those that are reimbursed on a fee for service basis or for any other reason.

It's also prohibited if the RHC and a Medicare fee for service practice operate simultaneously to select patient encounters for enhanced reimbursement.

Situations when it may be allowed are when, for instance, the RHC shares some resources with a non-RHC entity, such as in a multipurpose clinic, and maintains accurate records to assure that the RHC costs are only for those resources used for RHC purposes.

Another example of when it may be allowed is when the RHC shares its practitioners with the emergency room of the hospital in an emergency or provides on-call services for an emergency room and continues to meet the conditions for certification and allocates appropriately the practitioner's salary between RHC and non-RHC time.

I am not going to be able to answer questions on specific situations on this call. If you have specific situations that you want clarification on you may contact your MAC, your FI, carrier or regional office. We encourage you to talk about the permissible resource sharing situations and proper cost reporting methods.

Finally in this section we did want to mention high cost drugs because we know that that's an issue for a lot of rural health clinics. The rural health clinics reimbursement includes the cost of drugs provided incident to a patient visit and high cost drugs, as you all know, certainly can pose a financial risk to the clinic.

So we are soliciting comments on this. We are hoping that people might have some good ideas that are consistent with the legislative requirements, commingling policies and administrative accountability. We will certainly consider any of those ideas that you send in. So please let us know if you have any ideas on how to help RHCs provide high cost drugs to your patients.

So I know that was a lot of stuff. And what we'll do now is open it up to your questions.
Operator ...

Operator: The next question please go ahead.

(Amy Johnson): This is (Amy Johnson), ((inaudible)) Family Health Center in Washington State. I have a question about how the proposed rules will affect our state operations. For example, in our state operations manual we are located on an island so we don't have to meet the requirement for the PA, NP or CNM staff.

Corinne Axelrod: So can you tell me specifically what your question is?

(Amy Johnson): Will the proposed rule affect our state operations manual? So the proposed rule of the 50 percent rule for the physician assistant or the nurse practitioner, we're exempt from that ...

(Amy Johnson): ... because we're on an island.

Corinne Axelrod: OK. Well I think that question is something that you might want to send in as a comment and then that way we can address it in the final rule.

(Amy Johnson): OK. And ...

Bill Finerfrock: The exception for island – rural health clinics located on an island is a statutory exception.

Corinne Axelrod: Yes.

Bill Finerfrock: And I don't think that there's anything in the rule that addresses that nor changes what is part of the law, nor can a rule overturn what is in the law. So I mean I think you should still put a letter in or put that in a comment but that is a statutory exception that a rule can not overturn.

(Amy Johnson): OK. Thank you.

Operator: Next question, please go ahead.

Bill Finerfrock: Go ahead, caller.

Operator: Caller, your line is open.

Female: New council, Indiana, Henry County. My answers – my question's been answered. Thank you.

Corinne Axelrod: Thank you.

Operator: Next question, please go ahead.

Bill Finerfrock: Go ahead, caller. Make sure your mute button's not pushed.

Operator: Caller, your line is open. Please go ahead. We'll go next to – we'll go on to the next question.

Bill Finerfrock: Go ahead, caller.

Operator: Please go ahead, your line is open. We'll go forward.

Bill Finerfrock: Do you want to remind them what they should be listening for so they know when they're in the queue and when they're next.

Operator: Absolutely. A voice prompt on your phone line will indicate when your line is open. Please state your name and location before posing your question. Next caller, your line is open.

Bill Finerfrock: Well I don't know whether we're having technical difficulties – is there a way we can ...

Operator: Actually I think a lot of people queued up when you asked if they had the slides. So they may just not be ready to ask a question. Are you ready next caller?

Bill Finerfrock: OK. Can you tell them how – if they – if that was the case and they want to cancel their question, prompt ...

Operator: They can ...

Bill Finerfrock: ... how they do that?

Operator: One moment. Star two to remove yourself from the queue.

Bill Finerfrock: OK. Do we have questions now caller – or operator?

Operator: They're still – yes, they're still dropping. Just give it one more second.

Bill Finerfrock: OK.

Operator: OK. We'll go ahead to the next question.

Bill Finerfrock: Go ahead caller.

Female: My question's been answered. Thank you.

Corinne Axelrod: OK, thank you.

Operator: We'll keep going.

Bill Finerfrock: OK.

(Gail Nickerson): Hello. This is (Gail Nickerson). I'm calling from Roseville, California. I actually had a question from the last time but I was technically challenged and didn't get to ask it. I'm wondering whether this rule covers contracting – whether an RHC could contract with an M.D. group to provide the services of NPs or Pas.

When you say contracting are you talking about direct contracting or any contracting?

Corinne Axelrod: OK, that's a great question. And I'm sorry but I think that's one that you'd need to send in as a comment for us to answer.

(Gail Nickerson): OK. My next question has to do with this change in the payment. You know historically we've gotten 80 percent from Medicare and we reconcile that through our cost supporting process. So my understanding when you're talking about all this is that it's really a change interim payment but not a change in ultimate reimbursement. Is that correct?

Corinne Axelrod: Actually no. This is a change in your final reimbursement.

(Gail Nickerson): Well what about all the times when the 20 percent of charge doesn't actually equal 20 percent of our rate? You know you're fixing it so that when it goes over you're going to take that money but we don't get the money when it goes the other way. Scott ...

(Randy Rector): Yes. The provisions are – this is (Randy Rector) in CMS. The provision is applied in the aggregate. In other words, at the end of a cost reporting period we look into clinics overall reasonable costs and all of the coinsurance charges. So if you have some charges where for an individual service it's less and some are more those are all aggregated and subtracted from reasonable cost to derive what Medicare would pay.

Our examples are just that, examples trying to illustrate on an individual – you know on an individual service how it – how it works in principle.

(Gail Nickerson): Well I understand that. It's just that there's always been a difference between what happens in the interim payment and what happens ((inaudible)).

(Randy Rector): Oh sure. And that will continue.

(Gail Nickerson): And I'm trying to select that out in the ...

(Randy Rector): OK.

(Gail Nickerson): ... I understand you.

(Randy Rector): Yes. You're interim payment is always going to be based on the – yes, the best information available which is usually the cost report from the prior year. So – or other information. So assuming this provision, for example, would get – would become part of the final, that could be something that might adjust your interim rates slightly for your – for the upcoming year.

But interim payments are always reconciled with final payment. I'm not sure if that's your question or not or if that answers your question. I hope it does.

Bill Finerfrock: (Randy), ((inaudible)) perhaps others so that what I get from Medicare – let's say I have 10 rural health clinic visits during the course of you know a week and my rate is \$80. Medicare is going to pay me \$80 times 80 percent times 10, that the – regardless of what the charges were this isn't going to be reconciled on a claim by claim basis but it will be reconciled at the end of the year.

(Randy Rector): It will be reconciled at the end of the year.

Bill Finerfrock: It's not on a claim by claim basis.

(Randy Rector): No. The ...

Bill Finerfrock: So even though the clinic – the examples you gave were specific ...

(Randy Rector): Right.

Bill Finerfrock: ... encounter claim examples ...

(Randy Rector): Correct.

Bill Finerfrock: It's not an example of how it would work. It's going to be done in the aggregate.

(Randy Rector): It's going to be done in the aggregate at the end of the year. And then the last point that I was trying to make, to the extent that the aggregate at the end of the year changes what Medicare payment is, the following year what might be the clinics interim rate would be – would reflect that.

Bill Finerfrock: So it might – take next year, let's say you determined that I was overpaid by \$1,000 and my rate next year instead of it being \$80, as it was this year, might be reduced to \$79.

(Randy Rector): Yes. The base – the whole – yes. The whole basis or the whole last point I'm trying to make is that we're setting – we set the year on an interim rate as an amount for a particular clinic that will most closely approximate what the – what the final payment will be.

In a lot of cases where the clinics are above the limit, you know close to the payment limit, but in some cases it's not or clinics are under the payment limit and that's based on their actual cost. So the only point I was trying to make in the end there is that we're trying to approximate as closely as possible in the interim rate what payment will ultimately be.

And this provision that's in the law is a provision that affects final payment and it's basically a change that instead of paying 80 percent of cost, ((inaudible)) like we had in the past, we basically take reasonable cost and subtract out the aggregated coinsurance – well deductible for RHC amounts to arrive at Medicare payment.

Corinne Axelrod: I just want to add that Randy is our resident expert on reasonable costs and cost reimbursement. So this is a good time, if people have questions on this, to ask them.

Operator: And we'll go to our next question.

(Tanya Kristofferson): Yes. My name's (Tanya Kristofferson). I'm from the ((inaudible)) Valley Clinic in Idaho. And on that – this is a question on the high cost drugs and this is kind of specific. We have patients wanting the ((inaudible)) vaccine and we've been approached by some pharmaceutical companies to use, I think it's called, E-dispense or

something where we order the vaccine in and give it to the patient. We kind of act as a pharmacy.

Is that a – is that going to go against some of these RHC rules or is – maybe the ((inaudible)) vaccine, because it's like \$160, going to become part of the vaccines we are reimbursed for on our cost report?

Corinne Axelrod: You know that's another great question that is a little bit complex so that may be something that you want to send in a comment on.

(Tanya Kristofferson): OK.

Corinne Axelrod: Thank you.

Operator: Next question.

(Rosemary Kernel): Hi. My name is (Rosemary Kernel) and I'm calling from Iowa. I have a question about – two questions – on page “A” of the slides where a rural health clinic would be allowed to contract with non-physician providers as long as at least one NP or PA is employed. Would this apply to multiple location clinics? For example if a hospital has four rural health clinics and they have one NP or PA then they could contract with a non-physician provider as long as they have one NP or PA at a different clinic or is this all on the same clinic?

Corinne Axelrod: That would apply to each clinic.

(Rosemary Kernel): So that's separate for each location.

Corinne Axelrod: That's correct.

(Rosemary Kernel): OK. And then I know we talked a little bit about the line above that, regulation prohibiting RHCs from contracting with non-physician providers would be removed. My understanding currently is that for physician providers it's not allowed to contract with third party providers, for instance a company that provides local tenants physicians.

But it is acceptable to contract with a physician provider individually. And is that what we're talking about for mid level or non-physician providers, OK to contract with an individual but not necessarily with a third party provider that ...

Corinne Axelrod: Yes, that's correct. It's always been allowable to contract individually with a physician. We're now proposing to allow RHCs to contract individually with a mid level as long as there's one that's employed.

(Rosemary Kernel): OK. But not with a third party company; is that correct?

Corinne Axelrod: You know I feel bad not answering your questions and telling you to send in a comment but if its not actually in the rule right now it's not something that I'm allowed to address.

(Rosemary Kernel): OK.

Corinne Axelrod: I can really only comment on what's in the rule and other things you're going to have to send in a comment and then we will address it in the final rule. I apologize for that.

(Rosemary Kernel): OK. Well thank you. It did – you did answer one of my questions.

Corinne Axelrod: Oh good.

Operator: And we do have several more questions. Please go ahead.

(Jim Dixon): Yes. This is (Jim Dixon) from Copper Queen Hospital in Bisbee, Arizona. And the section on bed count as described in 412.105(B), that means there will not be a – you will be – we now operate three rural health clinics who are not – do not have caps on them in their payment methodology.

And when I look at the federal register I can't see what you're saying about 412.105(B). Can you tell me what that is and if we're a clinical access hospital with less than 25 beds?

Corinne Axelrod: I don't have a copy of the regulation with me but I certainly would be happy to e-mail that to you if you'd like. But the important thing to know here is that if you are operating as in a provider based RHC with less than 50 beds using this method to count your beds there is no change from the current method.

It's only if you're using the other method that there's a proposed change in this rule. But I would be happy to e-mail you that regulation if you would like.

(Jim Dixon): Yes. Do you know what that – OK, I would – I would really appreciate that. How do I get my e-mail to you?

(Randy Rector): Corinne, I might be able to just clarify that a little bit. The reasons there's two definitions or two methods is that the – you know the law says you know 50 beds, so if you're ((inaudible)) and you've got 25 beds that's not an issue with you, your under 50.

The alternative definition was out there and I can tell you the history on that was some rural health clinics that were located in some areas where there was great fluctuation and since this might be in a hunting area or a ski resort area where you have a large amount of beds for those peak times and then not many for other times. And we were trying to afford some flexibility in those areas where some clinics are teeter tottering around 50

and might be slightly over 50 but most of the year they might only have a patient census of 10 or 11.

So that's the whole reason for the second methodology or this alternative methodology. So in summary it doesn't apply to you but that explanation is for the benefit of perhaps some other people out there that might be wondering why or ...

(Jim Dixon): So you're really not proposing a big change in provider based clinics that are operated by clinical access hospitals under 25 beds.

Bill Finerfrock: You know when this provision was initially put into the statute, as (Randy) said, the statute says ((inaudible)) 50 beds and a question was raised well what constitutes a bed. Now you may have a hospital that is licensed for 60 beds but as a practical matter only staffs 40 of those beds. So for purposes of considering any section to the cap would this hospital be considered a 60 bed hospital because it's licensed for 60 beds and wouldn't qualify for the cap or is it a 40 bed hospital because it only staffs 40 beds and for intents and purposes only has 40 beds available at any given time.

What the particular regulatory reference this is included in the rule tells you is what does it mean to be a bed in a hospital, and essentially there's some specific criteria but when you get through it all it means that the bed is available to be occupied.

And so you could be a 60 bed – licensed 60 bed hospital but if you're staffing, if your utilization – if your use of those beds is only that you're only actually using 40 beds than that hospital would be considered a 40 bed hospital for purposes of the cap exception not a 60 bed hospital.

So you need to look at that particular definition if you're a hospital that you know may have more licensed beds than you're actually staffing to see how you would calculate. But as a critical access hospital you're already statutorily restricted to fewer than 50 beds so for you it's actually – it's a moot point as (Randy) was saying.

(Jim Dixon): So – and then I could infer from that – and for the people in the state of Arizona if you're a critical access hospital operating an RHC this is not going to make you ineligible ...

Bill Finerfrock: Correct.

Bill Finerfrock: ... critical access hospital, as you know, you're already limited to 25 beds but I think, what additional 10 beds that are swing beds?

(Jim Dixon): Yes.

Bill Finerfrock: So you're no bigger than ever 35 beds so you wouldn't ever exceed the 50 bed threshold.

(Jim Dixon): That's great news. Thank you so much.

Corinne Axelrod: I think we just have time for one more question because I want to allow enough time for the health, safety and quality issues. If we have time at the end we can come back and take any additional questions.

Operator: Next question, please go ahead.

(Carol Frost): Hi. This is (Carol Frost) from the Mile Bluff Clinic in Mauston, Wisconsin. I have two questions to ask. The first is regarding dual entitlement ((inaudible)) with the Medicare and Medicaid situation. When you look at the payment methods you're looking at, how are you going to determine the patient obligation? Is – or what is Medicaid going to do in this situation?

Corinne Axelrod: Why would it be any different?...

(Carol Frost): Well if you're ... using the charge currently we get 80 percent of our encounter rate and then the 20 percent is picked up by Medicaid.

Female: ((inaudible))

(Carol Frost): But – 20 – no, 20 percent of the encounter rate. So – but going forward if you would happen to adjust that say in the future years because you overpaid us, because of the patient coinsurance determination, than what would happen at that point?

(Randy Rector): Patient obligation is unchanged by this rule. It's always 20 percent of the reasonable cost on charge. So that does not change. That was – that would be, I think, what would – for ((inaudible)) Medicaid today ...

(Randy Rector): ... paid under those provisions. I'm not real familiar with how that works but the patient obligation ...

(Carol Frost): OK. Then the question – the other question I have is – or my concern is – probably is if you look at the typical RHC charge – I shouldn't say typical, our typical RHC charge, it's probably a lot more than – no, not a lot more but more than the \$75.63 upper payment limit.

(Carol Frost): So then in essence we would be losing, as Bill pointed out, significantly more than the \$1 per encounter because you're limiting us to a maximum between the patient's coinsurance and what Medicare is going to reimburse to \$75.63. Is that correct?

Corinne Axelrod: That is correct.

(Carol Frost): And so – and so at the end of the year we could – in fact if you're going to always pay us 80 percent of the counter rate, particularly for the first year, we could end

up owing you money back because the patients would have paid us more on the 20 percent level.

(Randy Rector): It's possible.

Corinne Axelrod: Yes. And it's possible ...

Bill Finerfrock: Yes.

(Carol Frost): Very possible.

Bill Finerfrock: I think it's likely.

(Carol Frost): Yes. Right, because it's just like you said Bill, the ((inaudible)) of the charge and I don't know if it is. And is there a reason why you're changing this whole method of – is there a significant dollar impact to the government budget the way we're currently getting reimbursed?

Corinne Axelrod: The reason for the change is to comply with the statutory requirements.

(Carol Frost): Well ...

Bill Finerfrock: What – Corinne could you review again what those statutory requirements are? And when did the statutory requirements change?

Corinne Axelrod: I can give you the citations; sections 1833(A)3 of the Social Security Act was amended by the Medicare Modernization Act and stated that except for pneumococcal and influenza vaccine and their administration Medicare payment can not exceed 80 percent of reasonable costs.

Bill Finerfrock: And how – just out of curiosity, how is this – how have you ever paid more than – Medicare paid more than 80 percent of reasonable costs?

(Carol Frost): Because my reasonable cost is greater than the encounter rate.

(Carol Frost): ... reasonable cost than I'd have more ...

Bill Finerfrock: You've always paid – Medicare's always paid 80 percent of reasonable cost. Nothing since the MMA has changed.

(Randy Rector): Yes, the statute hasn't changed since the MMA. You're right.

(Randy Rector): The provision has always been in there, this provision. It was not implemented properly on the costs report by just paying ...

(Randy Rector): ... 80 percent of reasonable cost. And this change is to comply with the statute. So ...

(Carol Frost): But what you – but what you've done is for independent clinics ...

(Carol Frost): ... you've put a cap on our costs. You haven't ...

(Carol Frost): ... our reasonable costs.

(Randy Rector): Well yes, congress did. I mean ...

(Carol Frost): Yes.

(Randy Rector): And that cap is equivalent to what – that's basically saying what is reasonable cost, the cap. And that – that's not something we can change I guess is what I'm ...

(Carol Frost): Yes, right. I understand. But that's the concern we as independent clinics, rural health clinics, have. The majority of – two statistics that I have at conferences majority of rural health independent clinics have reasonable costs – their costs – the encounter costs for encounter is greater than \$100.

(Randy Rector): Right.

Corinne Axelrod: We understand your concern and we're sympathetic to it but we don't feel like there's a whole lot we can do.

(Carol Frost): Wiggle room. OK.

Corinne Axelrod: Yes. I'm sorry about that.

(Carol Frost): OK.

Corinne Axelrod: I think what we'll do now is I'm going to turn this over to my colleagues Mary Collins and Scott Cooper to talk about health and safety requirements. Hopefully we'll still have a little time at the end to take any additional questions.

Mary Collins: OK. Thanks Corinne and thanks to everyone for calling in to participate in this call. Again, my name is Mary Collins. And Scott Cooper and I will summarize the proposed health and safety standards.

I will discuss the proposed quality assessment and performance improvement requirements, here after referred to as QAPI, for rural health clinics, the infection control requirements, and the requirements for RHCs and FQHC's to post their hours of operation. Scott Cooper will summarize the emergency services and training in patient health sectors.

For those of you who are new to the RHC program I would like to provide a brief history or an evolution of the QAPI requirement. And for those who have been with the program since 1997 this will be quick refresher.

Congress, by way of the 1997 BBA Act mandated that rural health clinics have a quality assessment and performance improvement program. With very little instructions from congress we began back in '97 researching the industry trend in light of what rural health clinics currently did to evaluate their programs for quality assurance.

The trend for the healthcare industry had moved beyond the remedial problem solving approach of quality assurance to focusing on the systemic quality improvement. In addition to ensuring patient safety, CMS has devised it's quality initiatives to focus on stimulating and improving the quality of care and health outcomes for our beneficiaries.

In addition to publishing quality standards for hospitals, we're in the process of revising quality standards for a number of providers. The revised standards are directed at improving outcomes of care and satisfaction for patients while eliminating unnecessary prescriptive requirements.

The revised standards will replace the responsibility on the provider to develop and evaluate an effective data driven program.

Since 1997 we have encouraged rural health clinics to begin looking at its operation and to think about how they can restructure its current evaluation process to incorporate an outcome approach to improving care and patient satisfaction.

On February 2008, CMS published a proposed rule to implement the BBA requirement the rule was finalized and published December 2003. Due to the restrictions in the 2003 MMA that a final rule has to be published within three years after the proposed rule, CMS published a notice in September of '06 that suspended the December 24th, 2003 rule.

However, after the publication of the 2003 rule, CMS staff participated with HRSA's Office of Rural Health Policy to provide technical assistance to rural health clinics with developing the new QAPI requirements. Currently rural health clinics are required to conduct an annual evaluation of its total operation; including the overall administration, policies and procedures and patient care areas.

The proposed QAPI requirements will replace the annual evaluation requirement. Quality assurance versus the QAPI: The QA standards were designed to ensure a minimum level of quality. Standards focused on the meaning and documentation of the clinics evaluation of its care.

The QAPI standards were designed to ensure a process for continuous measurement and improvement of care and this will enable the clinic to systematically review its operating systems and processes of care and identify and implement opportunities for improvement.

And when we talk about measures and data we mean that the rural health clinics should use objective means of tracking performance that enables the clinic to identify the difference in performance between two points in time and that the data only needs to be as sophisticated as the individual needs it to be to measure from point “A” to point “B”.

We’ll move on to the proposed QAPI standards. The program must be appropriate for the complexity of the rural health clinics organization and services. I want to, again, emphasize that the QAPI standard will replace the current program evaluation standard and the resources used to comply with the current requirements can be used for the QAPI standard.

The components of a QAPI program: Overall we have proposed three standards under the QAPI requirement. The first standard discusses the component of a QAPI program. The program must include objective measures to evaluate organizational processes, functions, services and the utilization of clinic services.

The second standard discusses the program activities. So the areas discussed on the program components, which is the organization processes, functions and et cetera, the rural health clinics must adopt or develop performance measures that reflect processes of care and rural health clinic operations that are shown to be predictive of desired patient outcome or be the outcomes themselves. Clinics should use the measures to analyze and track the performances.

Also, the clinic should set priorities for performance improvement, considering either high volume, high risk services, or the care of acute and chronic conditions, patient safety, coordination of care, the convenience and timeliness of available services and grievances and complaints.

Rural health clinics must also conduct improvement projects. We’ve stated that the number and frequency of distinct improvement projects must reflect the scope and complexity of the clinic services and available resources.

At RHC we’ve also allowed here for information technology projects. An RHC that develops and implements an information technology system explicitly designed to improve patient safety and quality of care would meet the requirements for a project under this section.

It is not a requirement that clinics develop an IT project. This IT provision is listed in the proposed rule because we recognize that it is important for clinics to identify opportunities to improve and expand the use of information technology to prevent medical errors and improve quality of care.

We also state that the rural health clinics must maintain records on its QAPI program including quality improvement projects.

The next standard is program responsibility. The RHCs professional staff , administrative officials, and governing body (if applicable) are responsible for identifying or approving QAPI priorities and ensuring that the QAPI activities that are developed to address identified priorities are implemented and evaluated.

Resources that are available: Guidance and examples of QAPI related activities are available from professional and governmental organizations and also from some state offices of rural health. The Department previously contracted with the NARHC to develop technical assistance materials that provide guidance for rural health clinics in complying with QAPI requirements.

Materials that were developed for the 2004 technical assistance calls and other resource materials are provided at HRSAs Web site. We proposed in the preamble that we would deem an RHC that chose to utilize a QAPI model program provided by the Department as being compliant with the QAPI requirement, provided that the model program chosen was one that was in compliance with the provisions of the proposed rule.

Now with that I will stop and answer questions on the QAPI requirements. Operator, can you open the phone lines for questions?

Operator: As a reminder, it's star one to pose a question; star two to remove yourself from the queue. First question, please go ahead.

(Rich Armitron): Yes. Am I on?

Mary Collins: Yes.

(Rich Armitron): Yes.

Mary Collins: Go ahead.

(Rich Armitron): Well I've been in the queue for so long that my question actually referred – goes back to some of the payment issues. So ...

Bill Finerfrock: Identify yourself please.

(Rich Armitron): (Rich Armitron), CFO, Mount Saint Raphael Hospital.

Mary Collins: Sure.

Bill Finerfrock: Where are you from, (Rich)?

(Rich Armitron): Mount Saint Raphael in Trinidad.

Bill Finerfrock: Trinidad?

(Rich Armitron): Colorado.

Bill Finerfrock: OK. Thank you.

(Rich Armitron): Yes. My question goes back to some of the billing issues as it relates to concerns involving you know the high cost of drugs and things and it's surrounded by there. So if the question is off base I can submit it in writing.

But we are – we continue to struggle with different advice on the place of service code. And I don't have the slides. I don't know if that is addressed in your – there will be changes in that but some of our advice stems from the fact that because we're a provider based rural health clinic and the public awareness Medicare regulations would identify us as an integral part of the hospital and an outpatient part of the – outpatient department of the hospital that many of these type of charges to non-Medicare, non-Medicaid payers that are submitted on a 15 – a form 1505 are submitted with a place of service code 22 because we're an outpatient department of the hospital.

The negative impact to the patient is that then gets applied to their deductible and their coinsurances even though the injection or the drug is given in the clinic and it doesn't get applied as part of their office visit. We have other advice that says that we should be using a place of service code of 11 instead because we are still a physician office even though we are a part of the hospital but we have a separate Medicare regulation – we have a separate Medicare number.

So we struggle back and forth with different advise on whether our place of service code on non-Medicare, Medicaid payers should be an 11 or a 22 for professional fees ...

Corinne Axelrod: Excuse me. If I – if you don't mind, I'm sorry to interrupt you but ...

(Rich Armitron): Yes.

Corinne Axelrod: This might be something you might want to send in to Bill because we just want to deal right now with what's in the proposed regulation.

(Rich Armitron): OK.

Corinne Axelrod: I know people have some other questions on the proposed regulation so if you don't mind sending that in, that would be great.

(Rich Armitron): OK.

Bill Finerfrock: You want to send the question to me. Send it to info, I-N-F-O, at NARHC.org and we'll try and get you an answer.

(Rich Armitron): Info@NAR ...

Bill Finerfrock: HC.org.

(Rich Armitron): NARHC.org. OK.

Bill Finerfrock: Thank you Rich.

(Rich Armitron): Yes.

Bill Finerfrock: Next question.

(Debbie Johnson): Hi. This is (Debbie Johnson) with the Arizona Hospital and Healthcare Association. I also have a patient related question that had come up earlier in the description of the regulation. Hopefully it wasn't covered on a previous call.

But under 404.2411 could you clarify the phrase that RH services are not covered in a hospital or a critical access hospital? We're discussing that here and we really don't know what exactly that means.

Bill Finerfrock: Corinne, did you want to take a crack at that?

Corinne Axelrod: Actually I just put you on mute and we were talking about that here.

(Randy Rector): Lead the way. I think – I think it's addressing the hospital bundling provision, if I'm not mistaken, that you can't provide services to patients who are inpatients of hospitals. That's another part of the Medicare statute that ((inaudible)) to the rural health clinic area in terms of where services can be provided.

I think I'm answering your question. I hope I am.

Corinne Axelrod: Is your question about hospital bundling?

(Debbie Johnson): I guess what we want to make sure is that this doesn't prohibit a hospital, for example a critical access hospital, from operating a rural health clinic on the campus of the hospital. I mean they may – they're not providing services to inpatients of the hospital.

(Randy Rector): Right.

(Debbie Johnson): You know it's an outpatient center.

(Randy Rector): Yes.

(Debbie Johnson): But we just want to make sure that they can still do that because the way the rule is drafted that's not very clear.

Corinne Axelrod: Yes. They should still be able to do that and if there's a particular area that leads you to believe otherwise please let us know.

(Debbie Johnson): OK. It just – it's just that the language on the service – but we'll go ahead and put that in a comment letter. I do have one question related to the QAPI provisions. Would a rural health center be able to meet this requirement if they're a hospital based rural health center and they participate in a hospital QAPI program that includes the standards that are in the rule?

Mary Collins: By all means, yes.

(Debbie Johnson): OK, good. Just wanted to make sure. Thank you.

Mary Collins: Correct.

Operator: Next question, please go ahead.

(Brian Banchowder): This is (Brian Banchowder) again from Ohio. The question I have is on the QAPI. It talks about setting priorities for performance improvements considering high volume, high risk, organization.

It addresses a lot of different areas and I just want to make sure one thing, that you don't necessarily have to have QI programs going on in each of the individual areas you mention but that you could have a program going on in one area such as chronic care for diabetes or falls or something else of that nature.

Mary Collins: That's correct because often times when you go through and evaluate areas where you want to make improvement you're going to find that you might have more than one area and then you will begin to prioritize based on what you feel is your most crucial area to begin.

No. We're not requiring that you have a project in all of these areas but improvement projects should be prioritize based on this criteria.

(Brian Banchowder): And then that would make sense for smaller rural health clinics where organization is not really a problem. You know if you've got a solo practice doctor or one or two docs then organization – you know who's at the top and who's controlling things but maybe care would be areas to look at, like NCQA recognition in diabetes or double MPs metric program or the ((inaudible)) program through the federal government will all be potential problems; maybe even the Patient Center of Medical Home would qualify for this.

Mary Collins: Whatever area that the rural health clinic would take a look at and deem a priority for an improvement project. Basically these guidelines are here to guide clinics in selecting improvement projects after they conduct their assessment. Clinics should select projects that will have the most impact on health outcomes and patient satisfaction.

Bill Finerfrock: OK. Operator, do you want move on to the next question? Thank you (Brian).

Operator: Next question, please go ahead.

Female: OK. This will be the last QAPI question.

(Charlene Pump): This is (Charlene Pump) out in Montana. Do you have a Web site that has some specific examples of what are being done so we could have say a starting point for what we might want to work with?

Bill Finerfrock: Yes.

Mary Collins: Right. That's an excellent question and we do have a web address of the resource materials on the slides. The resources are available at www.ruralhealth.hrsa.gov

(Charlene Pump): Right.

Mary Collins: ... they have a lot of examples and additional resources that could be helpful.

(Charlene Pump): OK. Thank you.

Mary Collins: Sure.

Bill Finerfrock: That's the same Web site that you go to for the rural health clinic technical assistance. If you scroll all the way down this – as we mentioned at the outset this initiative on technical assistance calls have been going on for several years and the first few calls were all on QAPI and those calls, the transcripts and examples are listed. You just have to scroll down to the rural health clinic technical assistance bottom of that page and you'll see those and links to other information as well.

Mary Collins: OK. Thanks Bill. So I want to go ahead and just cover a couple of more on standards before Scott Cooper speaks. The next one is infection control.

Currently the current CFC requires rural health clinics and FQHCs to keep their premises clean and orderly. There's no Medicare standard addressing infection control. And in light of this environment we felt it would be prudent to do so.

So we proposed updating the requirements to add an infection control standard that will require rural health clinics and FQHCs to follow and document an infection control

process that follows the accepted standards of practice to prevent the transmission of infectious and communicable disease.

Although we believe the clinics and centers are currently following industry guidelines for infection control, we wanted to formalize a standard here. And if clinics or centers are currently complying with infection control standards for outpatient healthcare facilities they would most likely meet or exceed this proposed standard.

And we are also proposing to require that the infection control activities be integrated into the QAPI program. Whatever areas you find that you need to improve on with infection control can be incorporated into your QAPI program.

Any questions on infection control requirements?

Operator: We do have two questions in the queue. I'll go to the first question.

(Eric Jurgens): Hi. This is (Eric Jurgens). I'm with ((inaudible)) clinic is ((inaudible)) Texas. My question actually had to do with the QAPI requirements. Originally you could do one or the other, the program eval or choose a QAPI style – you know for the clinic standard. Is it now one or the other? Is it the QAPI program is going to replace the ((inaudible))?

Mary Collins: The QAPI program will replace the yearly evaluation.

(Eric Jurgens): OK.

Mary Collins: Since the proposed rule was, finalized and suspended, a lot of clinics had gone ahead and incorporated a QAPI program and the instructions were if they had done that then they exceeded the current requirement of the annual program evaluation.

If this proposed rule is finalized, the QAPI requirement will replace the annual program evaluation requirement.

(Eric Jurgens): All right.

Operator: Next question.

Female: Hello. I was just wondering if you could give us that whole Web site again. I didn't get the slides. So if you could repeat that Web site I would appreciate it, with the examples on.

Mary Collins: OK.

Bill Finerfrock: You're going to do it, Mary?

Mary Collins: Well, yes. I have it here; it's www.ruralhealth.hrsa.gov.

Bill Finerfrock: Right. Now if you want to go – that – you’ll see there on it it says rural health clinic technical assistance. You can click on that or for the web address, what Mary’s just given you put then forward slash RAC and that’ll take you directly to that page.

Female: Thank you so much.

Operator: And we have one more question.

(Nancy Ness): Yes. This is Dr. (Nancy Ness) from Mile Bluff Clinic in Wisconsin. I have concerns about the infectious disease standard. I do appreciate the flexibility that you’ve incorporated into the QAPI plan. And I really believe that that kind of flexibility needs to be put in an any kind of infection control standard.

I am puzzled however if you believe that the rural health clinics are following industry standards why there is any need to document or create something unless there were some – there was some evidence that rural health clinics are failing to use reasonable methods of preventing transmission of infectious disease.

In other words if it isn’t broke, why fix it? The concern that I have with the standards as written is that it is entirely less up to the rural health clinic surveyors discretion to make decisions about what kind of unquote – quote unquote standards the rural health clinic would be subjected to.

And most of those surveyors come from either the inpatient hospital or the nursing home environment which is a far cry from an outpatient clinic, especially one in a rural area, when it comes to worrying about what things you need to worry about transmission of.

The – certainly if there are evidence based standards for what constitutes reasonable infection control measures in a rural outpatient clinic environment than it is a requirement, I believe, of CMS to provide us with those references as to what those standards are otherwise we are going to be subjected to all kinds of craziness on the part of surveyors.

One surveyor who came to one of our clinics wanted to site us for having Christmas decorations in boxes that were on the floor, for example, as being somehow that was an infection control problem. If you leave it up to the discretion of the surveyors there is just going to be a gigantic mess and it is certainly not going to improve anybody’s quality.

Mary Collins: Thanks for that question. And you make a good point. What we do is list some of the sites here in the preamble proposed rule in terms of guidelines and industry standards – the resources for those guidelines and industry standards are here in the proposed rule.

And actually some of this has been as a result of CDC's recommendation that there should be a formal requirement or for outpatient providers to have an infection control standard. And the other piece about the surveyors is something that we would need to definitely deal with in terms of guidelines and training. So that's – you know that's a good point and I understand but if you follow the industry standard for this particular type of facility ...

(Nancy Ness): Well what industry standards are you citing? I mean where are there industry standards that apply specifically and only to rural outpatient clinics? We're not talking about hospital standards. We're not talking about nursing home standards.

... standard for what constitutes adequate and sufficient infection control program. And it has to be evidence based. In other words, it's got to be based in scientific inquiry, not just in an administrative opinion.

Scott Cooper: Right. What we drew from was – and I don't know if you had a chance to read the preamble for the rule-

(Nancy Ness): I read the whole rule.

Scott Cooper: OK. And we mentioned the – it was the – actually two articles, the one from CDC and then also the one from – that involved APIC and SHEA, the epidemiology and infection control groups and organizations that really looked outside the hospital setting with regard ...

It wasn't just specifically aimed at rural health clinics but physician offices, ambulatory surgical centers and the like, and home health agencies in addition to that. So their recommendations, while they weren't necessarily specific in what– you know step-by-step guidelines and rules for what it looked like, but the conclusions were that there needed to be some formalized infection control program in place for these providers.

I think the problems you're talking about with surveyors kind of going outside the parameters of the rule maybe because the current regulations are so not there in terms of infection control. They talk about clean and orderly premises which certainly boxes of Christmas ornaments sitting around could– technically they could site on something like that. It's not orderly. So we want to ...

(Nancy Ness): Well those ...

(Nancy Ness): They were in a closet.

Scott Cooper: OK. But again, it's – you know the way they're written now, the current regulations, really do leave a lot of room and we wanted to move more toward an infection control focus.

(Nancy Ness): Well it is very – it is going to be imperative that when you formulate this rule you cite some things that you make it very clear that the surveyor does not have the latitude to automatically apply standards from surgical centers, for example, or hospitals or nursing homes ...

(Nancy Ness): ... outpatient clinics.

Mary Collins: That's a good point and thank you.

Corinne Axelrod: Yes. We're going to have to move on. By the way, that was Scott Cooper speaking and that's a good segue because Scott actually has the next section and we don't have a whole lot of time left.

I do want remind everybody to send in formal comments on anything that you would like addressed in the final rule. And Scott would you like to go ahead?

Scott Cooper: Sure. I will. And just to add to that, the interpretive guidelines, which will be developed after the rule is finalized, will certainly bring out – will give surveyors the interpretive guidance that they need. So we'll certainly be looking at that.

The next area I'm going to be talking about is just two small areas that are in the CfCs for the provision of services, CfC, under that the direct services standard, specifically emergency and then also the CfC for patient health records- the record systems standard and a small provision under that.

I think, as both Corinne and Mary pointed out earlier, for those of you familiar with the 2003 proposed and final rules you'll notice that neither one of these provisions that we're proposing here were included in that – the 2003.

So these are in one regard a revision of the current regulation with some new language and in the other regard with the patient health records an entirely new provision.

And if you could hold your questions until the end, I'm going to go through both of these provisions and then go ahead and take questions. The first one is the emergency services under the provision of services CfC.

It's required for both RHCs and FQHCs. The change here was to really clarify what was contained under one provision. We've broken it into three smaller provisions, the first of which is that the clinic or center needs to provide medical emergency procedures as a first response to common life threatening injuries and acute illnesses. So that's really no change from what's currently there.

Also, that they have available the drugs, biologicals, equipment and supplies appropriate to patient population and which are commonly used in emergency first response procedures, and finally, to provide training for all staff in the provision of emergency procedures.

In addition to breaking it into three smaller provisions the differences are we're eliminating the prescriptive list of drugs and biologicals that are – that is included in the current regulations right now. However, we are specifying that equipment and supplies for emergency procedures must be available and the training for staff is also a new provision to that.

As I said, we were looking really to clarify the role of the clinic or center and the staff when they're providing a first response to medical emergency, specifically you know they're looking to assess, treat and stabilize patients until emergency transport or an advanced level of care becomes available.

We're looking also to make these consistent with current standards of practice and care, particularly with regard to training of staff. And even though the language does not specify this, in the preamble we talked about it and we would like comments on it that you know the – we feel like it's really appropriate to the role and there's a discussion in the preamble that we would not require support staff of the clinic to do the same as the mid level practitioner obviously but that we feel that its essential that they're trained in the policies and procedures that the clinic or center set up.

We feel like this proposed rule is really no different than what the clinics and centers have been doing all along – and you know since they've been required to be a first response to emergencies. And moving on with that – actually that's that.

Now next, the under 491.10(a)(3)(v), under patient health records; as I said, this is an entirely new provision. It would require entries in the health records to be legible, complete, dated, timed and authenticated by the person responsible for ordering, providing or evaluating the service.

The authentication may be in written or electronic form, however it must be done promptly. With regard to that, it's – you know the intent there is that at the next available opportunity, though in a clinic it's a bit different then a hospital setting where there are a lot of verbal orders and the physician or midlevel practitioner may not be there. So we don't really expect that that's going to be much of a problem. The authentication would be occurring when they're writing in a patient's health record.

I want to point out also unless there's a state laws specifying a specific timeframe, that that authentication must be done within 48 hours. Again, we don't expect that to be really a burden to clinics where the providers are right there.

Again, this is a requirement for both RHCs and FQHCs. We looked to reflect current standards of practice along with some of the technological advances with regard to electronic health records. We're not requiring that clinics have electronic health records but if they do they're certainly – we're leaving it open that they can authenticate records with E-signatures.

It's also reflecting our other requirements for other providers with regard to electronic medical records and E-signatures. And we believe that the proposed requirements here would really help to promote safety and quality of care by requiring that entries be complete and legible and that there's verification by the staff who are responsible for the care of the patient with regard to their entries.

And if anyone has questions now on both of those areas I'd be glad to answer.

Corinne Axelrod: Bill, we're a little bit over time. Can we still take questions?

Bill Finerfrock: We can still take questions. If you have the time, we can go over. I have one that was submitted in via e-mail for someone who wasn't able to be on the call with regard to the authentication. This comes from a (Sharon Overton) from Saint Mary's Regional Medical Center.

They say currently our nurse practitioner and medical director sign or initial all entries in the medical record. Is this what authentication is referring to?

Scott Cooper: Yes.

Bill Finerfrock: And then she goes on, will these signatures or initials have to have the time and date written by them.

Scott Cooper: Yes. All entries need to be timed and dated.

Bill Finerfrock: And is she also to understand that entry in the medical record dictation, nurses notes et cetera will also have to have time and date written by it and the authenticated by the practitioner within 48 hours of that time

Scott Cooper: Yes.

Bill Finerfrock: OK. Thank you.

Scott Cooper: Sure.

Bill Finerfrock: All right, operator, any questions?

Operator: Yes. We have three questions. First question please go ahead.

(Brian Banchowder): This is (Brian Banchowder) in Ohio once again. Your next to the last slide at the bottom, unless there's a state law designating everything has to be done with 48 hours. The one problem I see with that is that if I do a biopsy in the office, in which I totally excise a lesion and then I try to do coding for it, which automatically happens on my electronic medical record, I do not know whether to code that as a benign lesion or as a cancerous lesion which then affects the coding that then goes on for reimbursement.

So I would, I guess, be hard pressed to try to close a note that I can't put a final diagnosis on until I get a biopsy report back which typically takes about a week later. So that's the one exception that may be difficult to comply with within your proposal.

Scott Cooper: Right. Yes, actually – and if you could submit that as a written comment so we can take that into consideration.

Mary Collins: Yes.

(Brian Banchowder): Thank you.

Scott Cooper: Thank you.

Operator: Next question, please go ahead.

(Nancy Ness): Yes. This is Dr. (Nancy Ness) from Mile Bluff Clinic in Mauston, Wisconsin again. The – for those of us who do not yet have or have only partially affective electronic medical record systems a burden of authentication of every single entry, including just initialing lab work that you've seen it, initially other things, first of all putting the date and time is an enormous burden that almost no physicians are in the habit of doing so it's a huge problem in terms of changing peoples work habits.

Further more, there is absolutely no evidence what's so ever that the date and time that something is initialed has anything to do with the quality of care. The only purpose of the time and date is to give ammunition to lawyers who want to sue you later on.

Therefore, I would politely ask that there be some proof given that this will actually improve something in terms of our ability to provide healthcare as opposed to just wasting more practitioner time. Thank you.

Scott Cooper: Thank you.

Operator: Next question.

(Heather): This is (Heather) from California.

Bill Finerfrock: Go ahead, (Heather).

(Heather): And the previous two questions really did get up the point that I'm having my question regarding. And that has to do with you know dating and timing, even signing off on transcriptions and all of that. It really is something that I've worked with our practitioners around and changing those work habits is next to impossible to enforce on every sheet of paper that goes through. And we're currently on all paper charts at the moment.

Scott Cooper: OK. Well thank you. Yes. And again, if you could submit that I have a feeling we're going to get a lot of comments ...

Mary Collins: Yes.

Scott Cooper: ... about time and dates.

Mary Collins: Please submit your comments and we will certainly take a look at that and ...

Bill Finerfrock: OK. Are there any other questions on the line operator?

Operator: We have two more questions.

Bill Finerfrock: OK. If you guys have time let's – if we can try and clear these out.

Corinne Axelrod: Yes.

Scott Cooper: Sure.

Mary Collins: We have time. We'll be here as long as you want us.

Bill Finerfrock: OK. Go ahead.

(Lisa): Hi. This is (Lisa) with Emmett in Idaho. And I was just going to follow up again with the timing. I haven't the problem so much with the dating any time you make an entry in a medical record but to put the time stamp on every one of those as well I can definitely see is going to be a burden.

Scott Cooper: OK. Thank you.

(Lisa): So just another comment about ...

Scott Cooper: OK.

(Lisa): ... that section again.

Scott Cooper: It's helpful. Thank you.

(Lisa): Thank you.

Mark Collins: Send in your formal comment to us please.

(Lisa): Yes. Thanks.

Operator: And the final question in the queue.

Bill Finerfrock: Go ahead caller.

(Leah): This is (Leah) from Parsons, Kansas. On the authentication of the entry, for the PA's they have to be signed off by an M.D. or D.O.. Is that within the 48 hours as well?

Scott Cooper: You know I think we haven't considered that because that's on a state by state basis.

(Leah): OK.

Scott Cooper: Required to signing off. So if you could – if you wouldn't mind sending that in and the particulars of it, because I think that would be – I think you know would be very relevant to a lot of other providers out there and clinics.

(Leah): OK. All righty, I will.

Bill Finerfrock: First I want to thank all of our presenters from CMS, Corinne, Mary and Scott and (Randy). You guys did a great job and I know this is not a particularly easy ((inaudible)) responding to comments versus questions and so I appreciate your ((inaudible)) as we work our way through this.

I do want to remind folks that the National Association of Rural Health Clinic's next meeting will be November 18th to the 20th in Saint Louis, Missouri. And we will be devoting a fair amount of time to discussion of these issues at that meeting.

we've invited Corinne to come and be a speaker there to try and delve a little bit more, as much as legally we're able to given the process of proposed rules and comments. But I would encourage you all to visit our Web site, www.NARHC.org and try and plan on attending that meeting in Saint Louis. I think it's going to be one of the more significant rural health clinics meetings we've had in a long time.

I do want to again thank our callers and thank you office of rural health policy for their support for this initiative. This is Bill Finerfrock, your moderator ...

Corinne Axelrod: Bill ...

Bill Finerfrock: Yes.

Corinne Axelrod: May I just say something before we end?

Bill Finerfrock: Yes.

Corinne Axelrod: I don't want to interrupt you but I didn't want you to hang up either. I just want to remind people that the CMS rural open door forum will be on July 29th, 2:00 p.m. Eastern Time and we will do a summary of the rule on that open door forum.

The following week we're going to have a special Open Door Forum specifically on this regulation which will be two hours. So for people who did not get their questions answered today that will be another opportunity. That will be on August 5th.

Just a reminder as well, that the comment period for this regulation will close on August 26th. So please send us your comments. The more specific your comments can be the more helpful that will be in terms of making any revisions. I also want to thank you Bill for this opportunity to talk about the regulation and we really appreciate the opportunity to do this.

Bill Finerfrock: Well thank you again. You preempted me. I was going to encourage folks to keep in mind the – that this is a proposed rule and to please submit comments to CMS at the web address that's been provided to you previously.

It is absolutely critical that you comment on this. A number of – there have been a number of questions slash comments today which are extremely relevant to the outcome of this final rule. And don't presume that simply because something was put out there as a proposed rule that it's set in stone or that you can't change it or have an impact.

You absolutely can. So please, please everyone take the opportunity to provide comments, to provide insight. If you think something is bad say that it's bad. If you think it can be fixed tell them how they can fix it if you think it can be fixed. And if you think something is good tell them that you think something is good.

But at the end you must comment, you must take this opportunity because if they don't hear from anybody then they will be trying to develop policy in the dark and that's never going to be good for the – for this particular program.

Again, I want to thank everybody for participating today. We will be putting out information on the next rural health clinic technical assistance call in the near future. This being the summer month, I know many folks are on vacation, so if you haven't had your vacation yet I hope you have a great vacation and we'll probably be talking to you in the fall.

Thank you and that concludes today's call.

Operator: That does conclude today's conference. Thank you for your participation. You may now disconnect.

END