CENTERS FOR MEDICARE AND MEDICAID SERVICES

Special Open Door Forum on Rural Health Clinics:

Changes in Conditions of Participation Requirements and Payment Provisions for Rural Health Clinics and Federally Qualified Health Centers Proposed Rule

Conference Leader: Corinne Axelrod
Moderator: Natalie Highsmith
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2:00 pm ET

Operator: Good afternoon my name is (Laurie) and I will be you're conference facilitator today. At time this time I would like welcome everyone to the Centers for Medicare and Medicaid Services Special Open Door Forum.

Changes in Conditions of Participation Requirements and Payment Provisions for Rural Health and Federally Qualified Health Centers Proposed Rules.

All lines have been placed on mute terms of prevent anyone 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, then the number 1 on you're telephone keypad. If you would like to withdraw your question, press the Pound key. A time this time I'll turn the conference over terms of Miss Natalie Highsmith. Please go ahead.

Natalie Highsmith: Thank you Laurie and good day to everyone and thank you for joining us for this Special Open Door Forum when the changes and conditions of

participation requirements and payment provisions for RHC and FQHC proposed rule. Topics to be covered today include location requirements and exception criteria, staffing, waivers and contracts, payment issues and health safety and quality. The commit period for this proposed rule ends on August 26 of this year.

Some of the updates in this proposed rule include requirements on staffing, waivers and contracts, clarification of the methodology used to calculate RHC payments and updates the use of rural-urban community areas also known as RUCAs.

An agenda was posted on the special open door forum website, which is on www.cms.hhs.gov/opendoorforums with an S. If you scroll down on the left hand side you'll see a link for special open door forums and you will see the link for the agenda there as well.

I will now turn the call over to Corinne Axelrod who works in our Center for Medicare Management, Hospital and Ambulatory Policy Group. (Corinne).

Corinne Axelrod: Thank you Natalie. I want to welcome all of you to CMS' Special Rural Health Clinic Open Door Forum. I won't repeat our very long name of our title again.

We really appreciate you taking time out of your busy day to join us on the call and we also appreciate the opportunity to go over some of the provisions of the proposed rule with you. Our goal is to make sure that people in rural areas have access to high quality healthcare and we've tried to put forth regulations that implement the statute while giving you as much flexibility as possible.

Please let us know if there are areas that need to be clarified or changed in any way and as Natalie said the comment period is open until August 26th. You'll be able to send in as many comments as you like and we will address all comments that we receive.

We're going to, as Natalie said, follow the format that's actually the same format that's in the proposed rules and start with the RHC location requirements and exceptions.

The legislation that created the RHC program was the Rural Health Clinic Act of 1977. It requires that clinics be located in an area that has been determined by the Census Bureau to be non-urbanized and designated or certified by HRSA, the Health Resources and Services Administration, as a shortage area.

It also contained a grandfather clause that enabled an RHC to remain in the program even if it no longer met the location requirements.

If we move ahead 20 years, we have the Balance Budget Act (the BBA) of 1997, which amended the Social Security Act to require that the location requirements apply to existing RHCs, so in effect it removed the "Grandfather" clause. It also permitted exceptions to the location requirements for existing RHCs if the RHC can demonstrate that it is essential to the delivery of primary care in a service area.

We had to develop regulations in order to implement these provisions and so in February of 2000 we issued a proposed rule and in December of 2003 we published a final rule and in September of 2006 we suspended the final rule because the MMA (the Medicare Modernization Act) had just come out and said that no more than three years could elapse between a proposed rule and a

final rule. So, in June of 2008, as you all know, we have just issued a new proposed rule.

There are two location requirements and the first one is that, the RHC must be in a non-urbanized area as defined by the Census Bureau. I want to talk about that first.

An urbanized area according to the Census Bureau is basically one whose population is at least 50,000. If you are in an area that has been determined by the Census Bureau to be an urbanized area, known as a UA, than that does not meet the location requirements for rural health clinics.

There is also another category called Urban Clusters, which are known as UCs. Those are basically areas that have at least 2,500 people but fewer than 50,000 people. The Urban Clusters do meet the RHC location requirement.

I really want to draw attention to that because it can be very confusing on the Census Bureau's website if you're trying to determine if you're in a UA or a UC or neither. There are some other websites that also have this information, but if you have any questions about that you can certainly contact your regional office, you can contact us. But, be sure and delineate between the UAs and the UCs.

If you are neither in a UA nor a UC than you also meet the location requirement of not being in an urbanized area. I'm sorry for all these double negatives, but the Census Bureau doesn't actually define rural except that it's not in an urbanized area, so it makes the language a little bit clumsy.

If your RHC is in an urbanized area then you can apply for an exception and status as an essential provider. You can do this if your rural health clinic is

located in a level four or higher RUCA. A RUCA is a rural urban commuting area and I'll talk more about that in just a minute.

Also your clinic must demonstrate that at least 51% of its patients reside in an adjacent non-urbanized area and you must have a current shortage area designation. If you can demonstrate these three things - that your clinic has a current shortage area designation, at least 51% of the patients reside in an adjacent non-urbanized area, and you're located in a level four or high RUCA you can apply for status as an essential provider even if you're located in an urbanized area.

The RUCAs are, as I said, rural urban commuting areas. We are proposing to use those instead of Urban Influence Codes, which were used in the previous version of the regulation because they provide a more precise measurement of the degree of ruralness of an area and they're also more consistent with other CMS programs such as the hospital and ambulance payment systems.

There are several websites that you can go to, to determine the RUCA for your area. I don't want to read off all of these long websites to you on this call, so you might just want to do a Google search if you want to determine that. If you still can't find these websites, you can send me an email and I will email them to you.

Okay, the second location requirement is that the RHC must be in an area that has been designated or certified by the Secretary within the previous three years as having an insufficient number of needed healthcare practitioners.

I'd just like to note here that a bill has been introduced in Congress that would change the statute from three years to four years. It's currently in the Finance

Committee. If the bill is passed the requirement would be four years, which is consistent with HRSA's requirement for updating HPSAs.

It is still three years. If it changes then all of this would change to four years. I just wanted to make note of that and we'll see what happens on that.

Designation applications are usually prepared by the State. The rural health clinics are not responsible for preparing these applications and they are submitted to HRSA.

If you need to know the name or contact information of the person in your State, you can look that up on HRSA's website at hrsa.gov. They've been moving some things around, but I think it's still under the category of Grants. I'm sure that it's on there somewhere and again, if you can find that, let us know and we'll direct you to that website.

There are four types of designation that are acceptable for rural health clinic purposes. They are the geographic health professional shortage areas, which are known as HPSAs. The second one is population group HPSAs. The third one is Medically Underserved Areas and the fourth one is Governor - designated and Secretary- certified shortage areas.

Any other types of designations other than these four are not acceptable for RHC certification. So, if you have a designation that's a Medically Underserved Population designation, safety net facilities, dental or mental health, these will not satisfy the requirement for RHC certification.

Again, there are some websites to determine if your rural health clinic is in a designated area. HRSA has updated their website recently and it's really very

easy at this point to find that out. You can put your address in and it will pop up this screen and tell you if you're in a designated area.

You can also go to their site that's HPSAFind or MUAFind and look it up there. The one type of designation that is not on their website is the Governor-designated –Secretary- certified shortage area and if you are not one of the other three and you want to find out if you have that type of designation; you'll have to call the shortage designation branch in HRSA. I know they're planning on putting that on the website, but until they do you'd have to give them a call.

If your rural health clinic is not in a currently designated area, I would suggest the first thing is to contact your State primary care office to determine if an application to update the designation of the rural health clinic's area has been submitted.

If HRSA has received a complete designation application, either a new one or an updated one for the area where the rural health clinic is located before the end of the three year period since the last designation, no action is needed. Your clinic is protected from decertification as long as the application has been received by HRSA before the deadline.

Let's say that your rural health clinic is not in an urbanized area, but your designation is more than three years old. If HRSA has not received an application to update the designation before the end of the three year period or let's say they received an application to update the designation but they determine that area no longer qualifies for one of the designation types accepted for RHC certification, then you would need to apply for an exception to the location requirements.

Let's just talk for a minute about the process. If you are in an area that is not a non-urbanized area, you've applied for an exception because your rural health clinic is in an urbanized area, you would submit an application for an exception to the appropriate regional office within 90 days from either the date that the area is determined to be urbanized or the effective date of the regulation, which ever is later.

The regulations usually go into effect 60 days after the final rule is published. So in this case you would have 60 days from the time that the final rule is published, plus 90 days to submit your application to the regional office.

If you are applying for an exception to the location requirements because you are no longer in a currently designated area, you would also submit an application to the appropriate regional office within 90 days from the date that the designation is no longer current or the effective date of the regulations, again, which ever one is later.

The regional offices have 90 days to review the application for an exception for the location requirements and if the application is rejected then that can be appealed and the information on appeals is in Regulation 498.3(b)(5).

We want to encourage people in this situation to not wait until the end of the 90 days after the 60 days. We feel like it's to your benefit if you're in this situation to submit your application as soon as possible so that you can get a decision as soon as possible.

RHCs, as I mentioned, are protected from decertification if HRSA has received an application to update the designation before the end of the three year period. I want to also remind everybody that a clinic that is decertified as

a rural health clinic may apply to become another type of Medicare provider who would then bill Medicare under the fee-for-service system.

Our goal, and I know I don't have to say this, but our goal is not to close clinics, our goal is to make sure that clinics serving rural people get the enhanced reimbursement provided by this program. We want to do what ever we can to help that happen.

Anyway, decertification is effective on the last day of the month in which the 180 day limit was met. If for instance your clinic is no longer in a designated area and you've applied for an exception, you would have to get your application to the regional office within 90 days.

The regional office would then have another 90 days to make their determination and if that occurs in the middle of the month and if your application was not approved and you were going to be decertified it would not occur until the last day of the month.

We also are aware that for provider based clinics that do not meet the location requirements and do not qualify for an exception that they would in many cases be required to have a State survey for certification to become another type of Medicare provider. We have proposed that clinics in this situation would have a 120 day extension of their status as a rural health clinic while the application is being processed. That's120 days in addition to the 180 days.

Okay, I'm going to talk now about the proposed location exception criteria. There are four categories, sole community provider, major community provider, specialty clinic and extremely rural community provider. I'm not going to read the specific requirements for each of those, but I do want to just make note of a few things.

Specialty clinics do not have to provide every service within their specialty. For example if you're a pediatric specialty clinic, you have to provide pediatrics exclusively, but you do not have to provide every single pediatric service under the sun. Same thing with OBGYN clinics, if you for instance are providing prenatal care that would meet the requirements for an OBGYN specialty clinic. You don't have to provide every type of OBGYN service that's available.

The second thing I wanted to note is that in our 2003 proposed rule, we have another category under specialty clinics, mental health specialty clinics. We have asked for comments on this because the statute actually prohibits rural health clinic from being primarily a facility that provides mental health treatment.

We have asked for comments since the statute imposes a ceiling on mental health services and when the statute says primarily, we interpret that to mean more than 50%. Since the statute imposes a ceiling on mental health services, we'd like your comments on whether it is still appropriate to include rural clinics that provide mental health services for the purpose of an exception to the location requirements.

If you feel like it is still appropriate, please tell us if you feel like there should be a minimum level of mental health services in order to qualify for this exception and what that level should be.

The criteria that we have here, the sole community provider, the major community providers, specialty clinics and extremely rural community providers are based on comments that we got to the 2000 proposal rule and

were incorporated for the most part in the 2003 final rule and also comments that we got subsequent to that.

This is an area that we really value your comments and encourage you to look at these categories. If they seem fair to you, let us know. If you have other ideas, let us know. But this is one area that your feedback is especially important to us.

Okay, I'm going to stop at this point and open it up for questions. Before we do that though, I did get some questions on this topic and I just want to clarify a few things. I have been asked who is required to formally submit a request to the regional office for an exception, whether it's the rural health clinic or the State. It would be the rural health clinic that is responsible for submitting the request for an exception.

I've also been asked if there's a form or format used to submit a request for an exception. The answer to that is no, The rural health clinic will be responsible to choose whichever exception option they chose to use and then provide the information requested.

Okay, so if we can now open it up for any other questions.

Natalie Highsmith: Okay, (Laurie) if you can just remind everyone to - how to get into the queue to ask a question. And everyone please remember that we are taking questions just on this first topic, the location requirements and exceptions. I will take about five minutes worth of questions so we can quickly move through the rest of the agenda. (Laurie)?

Operator: Thank you. If you have a question, you may signal by pressing star 1 on your telephone keypad. We'll go to (John Riggs) from California.

(John Riggs): Hi, thanks for taking my question. The question about the essential provider exception that say at least 51% of the patient panel has to be from an area, not including an urbanized or an area that is not urbanized and yet is adjoining the RHC area.

We have some areas in the State of California in which we have a very large county that overlap multiple RUCA areas, some of which are inaccessible to the urbanized area of the county and yet are categorized as urbanized for the entire county, not even urbanized, whatever the sub-category of urbanized is, urban cluster, I guess it is.

So, I guess under this definition what is your understanding of what an urbanized area is? In other words, whose definition would we use for what constitutes an urbanized area? Would an urban cluster constitute an urbanized area? Or would that constitute an un-urbanized area? That 51% threshold, could it also apply to - and what exactly is an adjoining area? Thank you.

Corinne Axelrod: Thank you, those are great questions. We do accept urban clusters. If the adjoining area is an urban cluster that would be okay. It sounds like you have some special situations in that area and that actually might be something that you want to send a comment in on and if you have other suggestions about that, please let us know.

Adjacent areas have a contiguous border between the two areas, so if that’s not clear than you might want to send in a comment asking for more clarification on that.

Natalie Highsmith: Okay, next comment please.

Operator: Our next question comes from (Chris Coffon) in Virginia.

(Chris Coffon): Hi Corinne, thanks for the briefing, this has been great. I have two questions. One is could CMS clarify whether the requirements of this proposed rule would apply to FQHC look a likes?

And second, you (unintelligible) clarification regarding the location requirements for FQHCs, specifically HRSA states an FQHC site must serve in whole or in part in anyway but doesn't require that an FQHC site be physically located in an MUA and the proposed rule section .91582, the proposed rule states that an FQHC must be located in a rural or urban area designated as an MUA or includes an MUA.

The question is, is it CMS's intent to require FQHCs to be physically located in a MUA despite the fact that HRSA does not require a community health center's site to be physically located in an MUA?

Corinne Axelrod: Okay, thanks Chris for your question. I know that it's a little confusing because some parts of this proposed rule apply to both rural health clinics and federally qualified health centers and other parts apply to one or the other. These location requirements apply only to the rural health clinics. We are not proposing any changes to the location requirements for FQHCs.

(Chris Coffon): So, then it should be - so then 4915A2 should not be interpreted as requiring an FQHC to be specifically located in a MUA?

Corinne Axelrod: I'm trying to quickly look up 491. I don't have the file memorized yet!

(Chris Coffon): And just so you know the issue is if sometimes FQHCs have a separate administrated site that maybe outside an MUA or maybe just, you know,

across the road from a designated MUA. It doesn't necessarily always break down as being physically located in that particular site.

Corinne Axelrod: I think that if you want more clarification on that, it might be a good idea to send in a question, so that we can clarify that in the final rule.

(Chris Coffon): That's great. Okay, thank you Corinne I appreciate it.

Natalie Highsmith: Okay, let's take one final comment.

Operator: Our next queue (Covey LaBlue) in California.

(Covey LaBlue): Hi, I was just wanted some clarification on the shortage area designation timeframes. We're getting some conflicting information, our State office is telling us that it's required to be renewed every four years and yet, in your discussion you kept referencing a three year requirement.

Corinne Axelrod: Okay, thanks for that question. The legislative requirements for rural health clinic are a little bit different in terms of a designation than the legislative requirements that HRSA operates under for the HPSAs. Currently the requirement for rural heath clinics is three years, but HRSA has requirements for their designation to be updated every four years.

There is, as I mentioned, a Senate Bill that would change the rural health clinic requirements to four years, make them consistent with HRSA, but at this time they are different and that the requirement for rural health clinic is that they be in an area that has been designated or updated within the past three years.

(Covey LaBlue): Can I ask a follow up question to that then?

Corinne Axelrod: Yes, please.

(Covey LaBlue): What is the process then, I guess, just contact the State office and convince them that we need to follow the three year time frame?

Corinne Axelrod: Yes, I think it's helpful for people to know who their State primary care person is in their State Health Department. They are responsible for the designation in their State. I think that most States are aware that rural health clinics have this three year requirement.

I know that HRSA has informed them about it and but there's always turnover in State offices, so certainly not everybody is as aware as others. But, yes, you would be in contact with your State person and at this time the requirement for rural health clinics is that they be in areas that have been designated within the last three years.

(Covey LaBlue): Okay, thank you.

Corinne Axelrod: Okay, I think we'll move onto the next section and if we have time at the end and there are more questions on that, we can go back to that.

This section is on staffing. There are some special requirements for rural health clinics. Rural health clinics must have a nurse practitioner, physician assistant or certified nurse midwife at least 50% of the time that the clinic operates.

The second one is that rural health clinics must employ one or more nurse practitioner or a physician assistant. These are two separate requirements, they're obviously related, but they are separate requirements.

On the first one, that the clinic has an NP or a CMN at least 50% of the time, this does not include the time that RHC is open solely to address administrative matters or provide shelter. Existing RHCs would be able to apply for a one year waiver of this requirement. To be granted a waiver, an RHC would have to demonstrate a good faith effort to recruit and hire a nurse practitioner, a PA or CMN within the last 90 days.

We have gotten some questions about what we mean by good faith effort. We've given some examples in the proposed rule, but we recognize that communities are different, situations are different and we didn't want to make this so narrow and inflexible, we wanted to give you the opportunity to show that you've made a good faith effort. If people have suggestions about requiring certain items for that, you can let us know.

RHCs that submit a waiver request would be granted a one year waiver, unless they are notified within 60 days that the request is denied. They would be able to reapply for another waiver six months after the expiration of the last waiver. If a RHC doesn't meet this requirement and doesn't request a waiver, then they would be decertified.

The second special staffing requirement for RHCs is that an RHC must employ one or more nurse practitioner or a physician assistant. A certified nurse midwife does not satisfy this requirement. The term employ is usually evidenced by the employer's provision of a W2 form; or the employer providing benefits, things like that.

We've gotten a lot of questions about what do we mean by employed? And I would just say let's not make this more complicated then it is. It's just

however other people in the clinic who are employees are defined would be the same thing here.

The requirement is that a nurse practitioner or a PA must be employed at all times, but this person does not need to be a full time employee. We are proposing to remove the regulation that prohibits rural health clinics from contracting with non-physician providers.

We know that when the statute was first enacted 30 plus years ago, conditions were much different then and the idea was to require that a nurse practitioner or a PA be an employee because that would increase continuity of care. But the environment has changed and we want to provide you with more flexibility on this as long as the statutory requirements that an NP or PA is employed is met.

So an RHC would be allowed to contract with non-physician providers as long as at least one nurse practitioner or PA is employed. I'm going to stop and we'll take any questions on that section.

Natalie Highsmith: Okay (Laurie), please remind everyone again on how to the queue to ask a question and everyone please remember we are taking about five minutes worth of comments on the section for (classing) requirements right now.

Operator: Again if you have a question, please signal by pressing star 1, again that's star 1.

At this time we'll take our first question from (Tim Frye) in Washington DC.

(Tim Frye): Good morning and good afternoon it's Tim Frye with the National Rural Health Association. Something that I didn't even realize the question until

now, and I just want to clarify. The waiver, does that - that applies to both of the two separate non-physician provider requirements is that correct?

Corinne Axelrod: The waiver applies to the requirements that an RHC employ a nurse practitioner or physician assistant.

(Tim Frye): Does the waiver apply as well to the 50% they need to be given service?

Corinne Axelrod: Well, that's the part where the two are related because obviously if you don't have NP or PA then you can't meet that requirement, so in that sense yes, it would.

(Tim Frye): Okay, thank you.

Corinne Axelrod: Okay, did I answer your question?

(Tim Frye): Well, so in your way of - the way you feel the rule is written it would apply to both, it's not such a thing here where CMS is with the proposed rule waiving the requirement to have this person employed, but they still expect you to contract for the 50% of the time?

Corinne Axelrod: Oh, I see what you mean. Okay, you know we'll have to look at that so again, that might be a good comment.

(Tim Frye): Okay. But, just to clarify. In the way it's written in the rule, it only applies to the employed and so there might be questions here because of the contracting?

Corinne Axelrod: Well, I think you're bringing up a good point that we may well need to clarify, but obviously these two are very much related. So, if you wouldn't mind

adding that to your list of questions that you're planning on sending in, that would be great.

(Tim Fryer): Thank you Corinne.

Corinne Axelrod: Thanks Tim.

Operator: Next to (Angela Hogan) in Mississippi. Miss (Hogan), please go ahead with your question or check your mute button, we cannot hear you.

(Angela Hogan): Okay, can you hear me?

Operator: Yes, please go ahead.

(Angela Hogan): Okay, thank you. If you could again, cover quickly the waiver. You said it was a one year waiver if you are actively recruiting. Is that correct? Did I understand?

Corinne Axelrod: You are eligible for a one year waiver and you must demonstrate that in the past 90 days you have made a good faith effort to hire a nurse practitioner or PA.

(Angela Hogan): Okay. I didn't catch the 90 day, okay. Thank you.

Corinne Axelrod: Sure, thank you.

Operator: No further questions.

Corinne Axelrod: Okay, great. So, we'll go onto the next section, which is on payment issues. There's actually four areas here that I want to cover, exceptions to the

payment limit, the revised payment methodology, commingling and payment for high cost drugs.

The first one is the exception to the payment limit. An exception is available to rural health clinics that are integral and subordinate part of the hospital with less than 50 beds and the number of beds can be determined by either of two methods.

The first one is described in Regulation 412.105(b). The second one is for sole community hospitals, the average daily census does not exceed 40 and the hospital is in a RUCA 9 or 10.

The only change that we are proposing for the exception of the payment limit is that in the previous rule, or actually currently, the people who are using the second option, the sole community hospital, they would be required to be in a UIC 9 or 10 and we are proposing throughout this rule that where ever UICs, urban influence codes, are used, to use RUCAs instead.

I believe that most Rural Health Clinics use the first method, so this actually would not affect a lot of clinics, but I did want to just make note of that.

The next thing I want to talk about is the payment methodology. Section 1833(a)(3) of the Social Security Act as amended by the Medicare Modernization Act states that except for pneumococcal and influenza vaccine and their administration, Medicare payment cannot exceed 80% of reasonable costs.

In 1866(a)(2)(A)(ii), I don't if anybody can actually understand when I say that, but in any case that's the statutory reference, that states that co-insurance cannot exceed 20% of reasonable charges.

Currently Medicare is paying rural health care clinics 80% of reasonable costs. We are proposing that Medicare pay rural health clinics reasonable costs minus co-insurance and deductibles based on the facility charges, not to exceed 80% of reasonable costs.

If you're an RHC with the payment limit then there would be no change in your payment methodology if your charges are at or below the payment limit. If you are an RHC with an exception to the payment limit there would be no change if charges are at or below the allowable cost per visit.

I'm sure there will be a lot of questions on that, but I'm just going to go on to commingling right now, which 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, either physician or non physician.

Conditions when commingling is prohibited is when it results in duplicate Medicare or Medicaid reimbursement 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 Medicare Fee for Service practice operates simultaneously in order to select patient encounters for enhanced reimbursement.

Conditions when it may be allowed is when the RHC shares some resources with a non-RHC entity such as a multi purpose clinic and maintains accurate records to assure that the RHC costs are only for those resources used for RHC purposes.

It also may be allowed when the RHC shares a practitioner with the Emergency room of the hospital in an emergency or provides on call services for an ER and continues to meet the conditions for certification and allocates the appropriately the practitioner's salary between the RHC and non-RHC time.

There are probably an infinite number of possible scenarios regarding commingling, so we want to encourage people that if you have questions about commingling situations, specific situations where you want to know is this allowed or is not allowed, that you contact your MAC, your FI, your carrier or your regional office to determine the permissible resource sharing situations and determine the proper cost reporting method.

Okay. The last item in this section is high cost drugs. Rural health clinic reimbursement includes the cost of drugs provided incident to a patient visit and we are aware that high cost drugs such as cancer treatment drugs may pose a financial risk to the clinic.

So we are soliciting comments about possible solutions to this situation because we know that particularly rural areas where you may be the only provider around you'd like to offer these treatments, but you'd also like to stay in business, so please, if you have any ideas about this, please send us your comments.

Keep in mind there are legislative requirements, there's commingling policies and there's the issue of administrative accountability. But we are interested in hearing any ideas that you might have regarding how to make high cost drugs more available in rural areas in rural health clinics.

I'm going to stop here and take questions on this section.

Natalie Highsmith: Okay, (Laurie) just please remind everyone.

Operator: Again, if you have a question, please press star 1. We'll go to Roger Schwartz in Washington DC.

Roger Schwartz: Hi, I actually have a two part question. The reasonable cost, reasonable charge distinction that you mentioned just now. I thought I had understood it, than when you explained it just a little while ago, I'm not sure that I did. If I have a health center, a community health center, Federally qualified health center defines that its per visit rate is in access of the so called Medicare cap it can only receive the Medicare cap, say that's $119 or $117, it changed this year.

If my reasonable charge and my actual cost of the health center is in excess of that amount then the reasonable charge, the 20% I can collect, assuming I collect it, when I add that to the 80% that you would pay me it could put me over the Medicare cap, the Medicare FQHC cap. I'm trying to figure out if that's what your proposed rule would be prohibiting, that's number one.

And the other question I have is, in your discussion, in the preamble to the rule when you talk about the 20% reasonable charge that the health is collecting, you talk about not whether its actually collected, but whether its billed and whether you understand or whether you'd be responsive to a distinction between whether the health center actually collects the reasonable charge versus whether they just bill for it.

Corinne Axelrod: Okay, great those are good questions. I will just say again that Medicare payment cannot exceed 80% of reasonable costs, so in answer to your first question, the answer is yes, what you describe I think is correct. I do also want

to invite my colleagues who are sitting here with me, Randy Ricktor our expert on payment methodology, cost reimbursement if he wants to add anything to that.

Randy Ricktor: Yes, thanks Corinne. What we're essentially doing here is we're trying to conform the regulations to what the statute says and just basically that we 're supposed to pay Medicare reasonable cost less amounts charged for services in accordance to 1866 of the Act. So, I guess, let me just answer your second question quickly.

It is the amount charged, it's not the amount actually collected. Now if there's a question with amounts not collected and you qualified, for example to claim bad debt on the cost report and you met all qualifying conditions for that, that's part of the cost report as well.

I think you had phrased your first question in terms of the cap amount of $119 for a clinic whether or not we were prohibiting collecting amounts more then that and basically what we're doing is trying to comply with the statute. I guess in essence it was possible with your charges being higher that you were collecting more then $119 previously if your charges were higher then your cap amount.

The end result of this provision would be that we would take the reasonable cost amount, $119 in your case and subtract the charges from that and pay the difference. If that is less than what we had been paying you previously where by cost before we were just paying 80% of reasonable cost than you probably would see a reduction in revenue, but it would only be where charges exceed your cap amount or if you weren't subject to a cap in the case of RHC the reasonable cost. Does that help?

Roger Schwartz: It does help, you were clear on that. I want to just make clear on that second question, those charges versus what we charge as a - what we bill as oppose to what we actually collect.

You know, actually (unintelligible) by (unintelligible) grantee have a slightly sliding scale obligation so, if someone's income is under 200% of the poverty line they would have to charge a sliding scale, they wouldn't be collecting the full amount even though they're - how would you allow for that? Otherwise you'd be basically penalizing health center based on what they're charge is, their billing versus what they actually collect.

Randy Ricktor: Yes, I don't think we would be.

Roger Schwartz: I don't believe we're allowed to collect under the bad debt policy.

Randy Ricktor: Yes, I don't think we would be in the sense - well first of all we do have to follow the statute, which says basically its 20% of the reasonable charges, that's what 1866(a) says. So, it's clear, it is the amount that's charged that is the reduction from reasonable costs.

However, there are also provisions in Medicare reasonable costs principles for allowance for bad debt amount. So, if you have a patient that's at 200% of the poverty rate or whatever and you make a charge but they're only paying a fraction than that would be, you know that's - they're a candidate for a bad debt payment under Medicare principles of reimbursement, which are also part of the Medicare cost report and part of the methodology. So...

Roger Schwartz: But that usually requires that you take certain steps to collect and the whole point of the bad debt policy is that we don't do that. We have to take the charge on a sliding scale.

Randy Ricktor: Okay, well I think - actually I mean I'm not passing the buck, but I think that's a good comment to write in on and it might be something where our bad debt policy for FQHC might need to be modified a bit to say you don't necessarily have to go through these steps that an ordinary provider might otherwise need to do so to claim a bad debt simply because these are a special class of providers that get their certification through HRSA and HRSA prohibits certain of these requirements for collection of their debt.

And if you could - the more specific you can be about what requirements that might be, I think the better it might be for us to consider that, because I follow what your saying, it seems reasonable. If you're not really allowed to follow these steps to collect the full amount of charge because of other provisions it would seem that should be something we should take a look at Roger.

Roger Schwartz: Thank you very much.

Randy Ricktor: Okay, thank you.

Operator: We'll take our next question from Mary Peterson in Wisconsin.

(Nancy Ness): Yes, this is Doctor Nancy Ness from Mile Bluff Clinic in Wisconsin. We are an independent rural health clinic. Accordingly our reasonable charge is our usual and customary charge. We receive payment which is equal to the payment limit, the encounter rate.

You are proposing that for example if there are two different patients that come in, one has let's say a small skin cancer taken off for which the charge might be in the range of $350 to $400. Another patient comes in to have stitches removed for which the charge might be only $50 or $60.

Those two patients, we obviously are charging a different amount to each person and the patient obligation is the 20% of our reasonable charge which is the charges that I mentioned, not 20% of the encounter rate. Yes, we are going to receive the encounter rate as a payment from Medicare for each patient, which we're then going to average out over the course of time.

Because over time we will have more of the low level visits of the high expensive level visits, that was the whole idea that you're averaging out. Its kind of a per encounter capitation. It seems like your confusing the reasonable charge with the set by CMS cost upper payment limits.

And the impact of this is going to be massive if what your going to say is that your going to now take away the additional money that a patient who has a very expensive procedure done would be paying, which is appropriate and fair.

If you're going to say the patients can only pay 20% of the encounter rate then you're going to be decreasing our revenue by at least 25%, which I don't think was the intent of anybody in CMS or Congress. It seems like somebody is interpreting this in a completely different way then it has been interpreted over many years.

(Randy Ricktor): Well, the law is clear as far as what the law says. It does say take reasonable costs and it does say less the amounts that a provider may charge in 1866, which is clearly 20% of the reasonable charges.

Now, you had said earlier you may have a lump procedure that's $350 and you may have many more procedures that are at $50. This is aggregated at the

year end and averaged out. So, those charges that are based on the $50 service are offsetting the $350 charge. Its aggregated and averaged out.

(Nancy Ness): Yes, but you don't understand. Our average cost, our actual cost per encounter are well over $110.

(Randy Ricktor): Uh-huh.

(Nancy Ness): So the - this is not a matter of looking at what our reasonable cost are, what your doing is your saying okay this is not the reasonable costs, this is the artificial cost that have been imposed upon us by the encounter rate. And if it was so crystal clear now, why was it so not so crystal clear in previous years as Bill Finnerfrock testified at the Senate Aging Committee just last week?

Something has changed drastically from previous years to this year. And nobody would ever become a rural health clinic with this particular interpretation if the patient's payment amount is limited to 20% of the encounter rate.

(Randy Ricktor): The law doesn't say that is the only thing I can say. I mean, you know, yes what is probably occurred...

(Nancy Ness): Well that's what you're interpreting it as to...

(Randy Ricktor): Okay, let me finish. The law, you know, over the years, I'm sure your charges have edged up and I'm not disputing the fact that your saying your costs have edged up and its really - if I'm hearing between the lines maybe what your trying to say is the upper payment limit and your costs are varying quite a bit and your costs in relation to your charges really are close to what your costs are and that's really another issue that - obviously the payment limits is

another issue, but the amount that's in the - with the language in the law is, is another issue.

If the law was amended to say that in 1866 the provider agreement section that the rural health clinic was to charge 20% of Medicare's payment amount, for example, then that would fix the problem, but it doesn't say that.

It says 20% of the charges and as far as historically speaking, I think what the thought process was, and I wasn't here in 1977 obviously, but the - I think the thought process there was that on the average charges would roughly equate to 20% of the costs. Therefore I think the cost - the process...

(Nancy Ness): What? The charges would equate to 20% of the cost to deliver that service?

(Corinne Axelrod): Excuse me, but we're going to have to move on.

(Nancy Ness): This is not making sense.

(Corinne Axelrod): Excuse me, but we're going to have to move and I suggest you send a comment on that.

(Nancy Ness): I certainly will.

(Corinne Axelrod): I do want to point out that the language that's in the proposed rule on the revised payment methodology is identical to what was in the 2003 final rule, which was, I believe also in the 2000 proposed rule. So, it has been out there for a long time.

This is not something that we just pulled out of a hat recently. But, I do want to move on. I think we can maybe just take one more question regarding

payment and then we're going to move on to a health, safety and quality section.

Operator: Up next is (Michelle Copenhagen), Florida.

(Michelle Copenhagen): Hi, thank you. Earlier it was mentioned that this 80/20 methodology excluded pneumococcal and influenza vaccines, does it also exclude mental health and diagnostic mental health and laboratory services?

(Randy Ricktor): The statutory provision that applies to RHCs and not FQHCs with respect to mental health services that permits only 62.5% of such expenses to be considered as allowable costs and that's unchanged. So, that is - it is something different just like pneumococcal and influenza which are paid at 100%.

So, I'm not sure what your question was. Those limits still apply until they're changed. I think there was some talk or - there may be even something in the most recent legislation that I think phases in some differences in co-payments for mental health as they're phased in, I think we would probably - whether they would be phased in (unintelligible) as well, but as the statute is right now, 62.5% are considered covered expenses for certain mental health, I should say, because its not even all.

Corinne Axelrod: And that's a really good question that you may want to also send in a comment so that we can clarify it in the final rule. I'm going to turn this over now to - oh, I'm sorry, did you have a follow up? Okay, I'm sorry I thought I heard talking.

We're going to turn this over now to Mary Collins and Scott Cooper from our office of Clinical Standards and Quality to talk about the health safety and

quality section. And we're still - I think we're on our timeframe, so we're doing well and we should have time at the end for any additional general questions on any parts of the proposed rule. So, there you go.

(Mary Collins): Thanks Corinne. Again, my name is Mary Collins. Scott Cooper and I will discuss the proposed health and safety standards. I will discuss the proposed quality assessment and performance improvement requirement.

So, we'll have clinics infection control requirement and the requirement for rural health clinics and FQHC to post their hours of operation. And Scott will summarize the emergency services and patient health records.

The proposed rule would implement the statutory requirements for rural clinics to establish a QAPI program. The QAPI program would replace the long standing annual program evaluation requirement. We have proposed that we will have clinics develop, implement, evaluate and maintain an effective QAPI program.

The self assessment and performance improvement program should be appropriate of a complexity of the rural health clinic, organization and the services and focus on maximizing outcomes of by improving patient safety, quality of care and patient satisfaction.

We purpose that the rural health clinics would use objective measures to evaluate the organizational processes, the functions and services and utilization of clinic services.

The rural health clinic would adopt or develop performance measures that reflect processes of care and rural health clinic operations and are shown to be

predictive of desired patient outcomes or be the outcomes themselves. They would use measures to analyze and RHC its performance.

We propose that the clinic would set priorities for certain areas for performance improvement considering either high volume, high risk services, care of acute and chronic conditions, patient safety, coordination of care, availability of service, grievances and complaints.

The clinic would conduct distingue improvement projects. We have not proposed that they conduct a certain number or a frequency of distinct improvement projects. But we have proposed that the projects conducted must reflect the scope and complexity of the clinics services and available resources.

A clinic that develops and implements an information technology system explicitly design to improve patient safety and quality of care would meet the requirement for a performance improvement project. And the clinic would maintain (record) specific programs and their quality improvement projects.

We also purpose that the responsibility of the RHC professional staff, administrative official or the govern body; they would be responsible for identifying or approving (QAPI) priorities.

So, moving onto the next topic - infection control. We took the opportunity in this proposed rule to update the regulations to add an infection control requirement. The purpose rule would require rural health clinics and (FQHC) to maintain and document an infection control process that follows accepted standards of practice.

The next area is just to - we purpose to add a requirement for rural health clinics and FQHC to pose their hours of operation. And that would advise the public of the days of weeks and hours when RHC or FQHC services were provided.

So, with that I will stop and see if there are any questions on these sections before we move onto the other two areas.

Operator: Again, if you have a question please signal by pressing star 1. We're going to (Carrie Mitchell) in Massachusetts.

(Carrie Mitchell): Can you hear me?

(Mary Collins): Yes.

(Carrie Mitchelle): I just wanted to confirm that the quality requirements are applicable only to RHC while the infection control and the posting of the hours of the operation are applicable to RHC and FQHC?

(Mary Collins): That's correct.

(Carrie Mitchelle): Okay, so FQHC do not have to compile with the (quality) language in this purpose rule if it becomes final?

(Mary Collins): Correct. Currently the FQHC have an effective (QAPI) program and we sort of went through this back in 2000 when it was proposed and finalized in 2003. But, if you have any comments or questions to the contrary, by all means submit those. But, you are correct in your understanding.

(Carrie Mitchelle): Okay, thank you.

(Mary Collins): Sure.

Operator: Again, if you have a question, please press star 1. No further questions on this section. I'm sorry we do have a question from (Shelton Evans) in Louisiana.

(Shelton Evans): Hi. For mobile clinics the hours of operation posted, would that need to be located in, I guess their stationary clinic?

(Mary Collins): I would think so.

(Shelton Evans): Okay.

(Mary Collins): Yes. But again, you can certainly think about that as we work through comments on this.

If there are no more questions at this time, I will turn it over now to (Scott Cooper) who will talk about emergency services and patient health records. And at the end of his discussion, as Corinne stated we can also, if you have question on any of the sections we can revisit them.

(Scott Cooper): Thank you Mary. I'm going to be going over just two small proposed requirements, its small in the over scheme of the rule itself. I'm going to start with proposed section 491.9c3, which is found under the provision services CSC and it's also under the direct services standard emergencies.

This requirement would be requirement for both RHC and FQHC and would still require the clinic or center to provide medical emergency procedures as a first response to a common life threatening injuries and acute illnesses. However, it would divide the current requirements into three revisions and

would differ from the current requirement by eliminating the prescriptive list of drugs and biologicals.

Would also specify that equipment and supplies must also be available and would now - would purpose to require training for staff in emergency procedures as appropriate to their role. Overall the proposed requirements here would clarify the roles of the clinic or center and their staff when providing a first response to medical emergencies and that is to assess treatment, stabilize the patient until transferred to an advanced level of care.

These proposed requirements are consistent with current standards of practice for example, the requirement now for staff training and whether that be BOS or ACLS depending on the staff person involved. We believe that most, if not all RHC and FQHC would have the items and supplies necessary as required under the current regulations.

Moving on, the next purpose requirement is found under the patient health records CSC and under the record systems standard at section 491.10A3v. This would add a new provision that would require all entries in the patient's health records to be legible, complete, dated, time and authenticated by the person responsible for ordering, providing or evaluating service. Again, this would be required for both RHC and FQHC.

Again, it also reflects current standards of practice and also current CMS requirement for other participating providers particularly with regards to the completeness of the medical records and the authentication of entries in the record.

The proposed requirement would allow for either written or electronic authentication and also unless there's a State law specifying another time

frame for authentication, all entries would need to be authenticated within 48 hours.

This would be a significant factor in those settings where verbal orders are used frequently and the practitioner is not present on site, therefore we believe this would not significantly impact RHC and FQHC where authentication would most likely always be prompt as required here.

And finally, we believe this requirement with help for those patients' safety and quality of care by requiring that all entries are complete and are verified by the health care professional or staff member responsible for the entry. And with that, as Mary said, any questions on the two - the sections that we covered as well as any general questions, we'd be glad to takes those at this time.

Operator: Again, ladies and gentlemen, if you have a question, please signal us at this time by pressing star 1 on your telephone keypad. Our first question comes from Mary Peterson in Wisconsin.

(Nancy Ness): This is Doctor Nancy Ness from the Mile Bluff Clinic. I disagree with your assessment that the authentications of standards that are required are the standard of care for clinics, they are not. Those are standards that apply in the hospital facility, not in the clinic environment.

That is not the standard care to date and time every single entry in the chart; a lot of times physicians and other providers merely initial lab work (unintelligible) things like that. The amount of effort in the additional time that it will take people to do that is very, very considerable.

Most small rural health clinics do not have electronic records that would automatically (enter) these things, a recent study publish in the New England Journal demonstrated that only 5% of physicians nation wide have fully functional medical records of the kind that you envision.

Rural health clinics are even less likely to have that kind of functional authentication ability as part of their records. The key important thing here is providing the flexibility for the rural health clinics to determine what is appropriate way of maintaining its medical records that is consistent with good clinical practices, not standards that necessarily apply in hospitals.

There is a major difference in the urgency of most of the actions that are taken, patients that are being seen in a clinic are generally not critically ill. And it's a question of whether or not a notation on a lab order that it was seen by the physician was done at 10:00 or at 11:00 is of absolutely zero consequence in the scheme of things. Thank you.

(Scott Cooper): Well, thank you for your comment and as we've stated before this is a proposed requirement, so we welcome your comments on it, thank you.

Operator: We'll go next to (Patrick Litford) in Tennessee.

(Patrick Litford): Thank you Corinne for the update. I have two very short but separate questions on location requirements and exceptions. Number one, would you please confirm that if a facility is in a CMS designated non-urbanized area, if the new rule goes into effect, that it's still qualified regardless of its RUCA identification.

And my second question is, is there an exception to a facility being physically located in a HPSA if it is serving the HPSA if it is only separated by the width of a two lane paved road? Thank you.

(Corinne Axelrod): Hi, Patrick how are you?

(Patrick Litford): Doing great, thanks Corinne.

(Corinne Axelrod): Good, so your first question, I want to make sure I understand it right, that if a facility is in a non-urbanized area, do they still have to be in a RUCA four or above. Is that what you were asking?

(Patrick Litford): No, basically if it is in a non-urbanized area that it automatically re-qualifies under that provision or does the new rule require the RUCA designation?

(Corinne Axelrod): The only time that the RUCA is required is if the rural health clinic is not in a non-urbanized area.

(Patrick Litford): Okay, that clarifies it, thank you.

(Corinne Axelrod): I know it’s confusing when I say not in a non-urbanized area, but yes that’s the only time that the RUCA is required.

(Patrick Litford): Okay.

(Corinne Axelrod): And your second question. I already forgot.

(Patrick Litford): A facility that is serving a designated geographic HPSA, but due to the nature of the location is not physically located within the boundaries of that specific HPSA it is across the width of like two lane paved road. Is there an exception?

(Corinne Axelrod): Yes, actually, if you look at the exceptions criteria there are four of them and as I mentioned earlier and so, I think if you look at those, see if that would fit into any of these and if it doesn't and you think that it's a situation that should get an exception, then send us a comment and suggest that.

You know, we really do look at your comments and in fact the fourth type of location exception, the extremely rural provider is a direct result of a comment that we got to the 2000 proposal. So, Patrick if you can look at that situation that your describing and see if it fits into any of the proposed categories that we have and if it doesn't, then you might want to send that in as a suggestion for another category.

(Patrick Litford): All right, thanks Corinne.

(Corinne Axelrod): Thank you.

Operator: Our next question comes from (James McGee) in Arkansas.

(Tonny Demitt): My name is (Tonny Demitt) and I'm with the (unintelligible) hospital, I work at a rural health clinic as a nurse practitioner in (Rector) Arkansas. And my comment is that I agree with the physician on the restrictions on the medical record for the rural health clinics that would be very difficult to maintain in a rural setting with the frequency of the providers. And I do not agree with that proposal. So, I just wanted to make my comment.

(Randy Ricktor): Okay, thank you.

Operator: Okay, our next question is from Roger Schwartz in Washington DC.

(Roger Schwartz): Hi, actually I just wanted to make one comment and, actually two comments if I may. One with regard to the reimbursement methodology change. And I'm making this so that you'll appreciate why we will be commenting on this with some great detail when the time comes to comment.

From what I can see in the 2003 final rules that you propagated in December 2003, in the rule itself 455.2410 and 2462 and in the preamble there is no suggestion that could not - a health center could not collect 20% of its reasonable charge from a patient and get 80% of its reasonable costs even when those together exceeded what would be the overall reasonable or whatever the case may be.

There's a statement of the rule that says you can't collect any more then 20% of the clinics reasonable or customary charge, there's another statement that says that FQHC and RHC are to be paid on the basis of 80% of the all inclusive rate, but it doesn't say the two things together.

And actually I think even your rule does not say it, until we look at the preamble and we see the - we see how your reading rule. So, I think it's important to understand that from like what I can tell, there really is a change in what you said in 2003 and what you're proposing here, number one.

Number two, on this issue of the patient's records and the doctor having to do it within a 48 hours, one of the comments we've heard from community health centers is that there are significant number of health centers that as a practical matter do it by - they have a contractual obligation that may transmit all the dictation via the transcription services. And the transcription service has a contractual obligation to transmit all dictation back to the health center within 48 hours.

And so it's a practical matter that really means in its business day if the transcription is recorded and sent to the service on a Friday, the health center probably won't get it back until Monday morning.

So, you might want to, number one, make it clear we're talking about 48, maybe business hours. But, also in health centers, I assume this makes true with rural health clinics as well, often a doctor may be working at that health center only one day a week and may not be there then to sign off the chart when the transcript is ready.

So, practically speaking again, the 48 hour period may be problematic. And if you could recognize it or allow for that in your final ruling, plus we'll comment on it.

(Randy Ricktor): Thank you.

(Corinne Axelrod): Thank you.

(Roger Schwartz): Thank you.

Operator: Okay, our next question or comment is from (Lisa Horaria) in Idaho.

(Lisa Horaria): Hi, thank you. I just needed some clarification in the location requirements there was three points, I believe for the essential provider. And Corinne could you please repeat those please?

(Corinne Axelrod): I think what you are referring to are the three points that only apply to rural health clinics that don't meet the first location requirement which is up there in a non-urbanized area. That's the one that has the 51% RUCA four. Is that what you're referring to?

(Lisa Horaria): Yes.

(Corinne Axelrod): Yes. So, this only applies to rural health clinics that are in areas that have been determined by the Census Bureau to be non-urbanized.

(Lisa Horaria): So that they are urban areas?

(Corinne Axelrod): That they're in a UA, not a UC ,and that, yes for those clinics before they can apply for the exception they have to meet the other two criteria, which is that 51% of their patients are in an adjacent designated area and that they're in a RUCA four or higher.

(Lisa Horaria): Okay. Okay, thank you.

(Corinne Axelrod): You're welcome.

Operator: We'll take our next question from (Mike LaFever) in Wisconsin.

(Mike LaFever): Hi, this is (Mike LaFever) with (Denderson Luthen). I just had a question on the three year requirement on the (HPSA).

(Corinne Axelrod): Yes.

(Mike LaFever): Does HRSA automatically review those when they're three or four years and their case is expiring or does a request have to be made?

(Corinne Axelrod): At this time HRSA, the Health Resources and Service Administration does not automatically review any designations.

(Mike LaFever): Okay.

(Corinne Axelrod): It has to be - the States have to send in an application for that. I think their intention is to get to a more automated system where some designations would be automatically updated, but I don't think they're there yet.

(Mike LaFever): Okay and you said something about, you know if an application is filed, how can we tell if the State has filed one? Is there a way on their website?

(Corinne Axelrod): Unfortunately no. I've talked with HRSA about this and at this time you would have to - I would suggest first contacting your State. Your State can tell you if they have sent in an application, when they have submitted it. You could also contact HRSA's office of Shortage Designation and ask them if they have received it. I know they're not thrilled about the idea of getting hundreds of phone calls on this, but we're really trying to set up some sort of system where that could be on the website. But, it's not at this time.

(Mike LaFever): Okay, thank you very much.

Operator: Our next question comes from (Covey LaBlue) in California.

(Covey LaBlue): Hi, I just wanted to clarify, in the proposed rule it was not clear that there was a distinction between an urban are and an urban cluster. And I just want to confirm for RHC location requirements, an urban cluster is considered non-urbanized?

(Corinne Axelrod): If you are in an urban cluster that is acceptable, you fine. It's only if you're in an urbanized area. The Census Bureau uses the term urban and they include UAs and UCs, so that why it's a little bit confusing. If you are in a UA

then you would need to apply for an exception. But, if you're in an urban cluster, your fine, you don't need to apply for an exception.

(Covey LaBlue): Okay, thank you.

(Corinne Axelrod): Uh-huh, sure.

Operator: Our next question comes from (Ilene Carlson) in DC.

(Ilene Carlson): Hi, my name is (Ilene Carlson) I'm with the American Nurses Association. And we have been hearing from some of our clinical nurse specialist who are interested in working in rural health care centers, particularly in mental health. And they're running up against the problem with the requirement for nurse practitioners and Pas. And I'm wondering if you all have considered if it might be possible to open up that requirement or to consider at least some clinical specialists as the equivalent of NP or Platform A realizing that CNS are treated very differently in different States. But in some States they are the equivalent.

(Corinne Axelrod): Okay, I appreciate that comment and that would require a statutory change, so that's not something that we can do.

(Randy Ricktor): I've got a comment to add to that, this is Randy Ricktor at CMS. A clinical nurse specialist can be covered under incident two provisions in a rural health clinic or FQHC as long as they meet those conditions. If your talking about filling separately as an encounter visit then Corinne is definitely right, it would need a - you would need a statutory change.

The law as it states right now, physician and physician services (incident to) NP and PA and then they also have tagged clinical psychologist and clinical

social workers as a type of practitioner that in the RHC or FQHC setting can bill directly. So, anyway, the services could be covered as part of the encounter rate, but to get separate unique (unintelligible), I guess if you will, that would require something in the statute I think.

(Ilene Carlson): Okay, thank you.

(Randy Ricktor): Your welcome, thanks for your comment.

Operator: Our next question comes from (Angie Chaplin) Florida.

(Angie Chaplin): Hi, I got disconnected, so you may have already answered this question, but I'm calling in reference to the 20%, the payment. Does this only apply to the fee for service providers? Or does it also apply to the FQHC family practice office?

(Randy Ricktor): I'm not sure I understand the question. I think - you mean fee for service providers, you mean like somebody paid under the physician fee schedule and not part of the FQHC or RHC?

(Angie Chaplin): Right.

(Randy Ricktor): Yes, that's completely, none of this applies to them at all, whatever requirements under the regular Medicare Part B Physician Fee Schedule Program that would apply for billing beneficiaries those separate rules would apply to that.

(Angie Chaplin): Okay, that's what I was concern about. Thank you for answering the question.

(Randy Ricktor): Sure, you're welcome. Thanks for your comment.

Operator: Our next question comes from (Roger Schwartz) in DC.

(Roger Schwartz): Hi, I'm sorry I meant to ask this before. I just need to get a clarification. In your discussion about billable visits at skilled nursing facilities in the preamble I think is where you mentioned what would be a billable visit, there is no mention a clinical social worker or diabetes health management training or medical - nutritional therapist.

And I assume that there is an understanding that those would be billable visits if provided at a skilled nursing facility by an employee or a contractor of a federally qualified health to a patient, (unintelligible) in the nursing home, specifically the clinical social worker that I'm particularly concerned about.

(Randy Ricktor): Good comment (Roger). I just have to _ I have to reread it, I'm sorry. It could well be an oversight. It sounds like your trying, if I'm not incorrect, it sounds like you might be trying to point out something that might have been an oversight, I'm not sure. Let me, (unintelligible) another look at that and...

(Corinne Axelrod): I think that would be something just for you to send in.

(Roger Schwartz): Yes, no will - surely will. I think it probably was at least on a clinical social worker. (unintelligible) in that same list of (unintelligible) as you would have had the others.

(Randy Ricktor): Yes, yes, I just - it's been a while since I looked at the law.

(Cindy Murphy): This is Cindy Murphy in Claims Processing. I do not believe those services can be paid separately when the beneficiary is an in patient of a clinic. I

believe those things are included in consolidated billing. At least the medical nutritional therapy and the (DSMT).

(Randy Ricktor): Please do, we'll take another look at it, please do if you will.

(Roger Schwartz): Sure.

(Randy Ricktor): I'll take a look at it. Thanks for your comment, as always appreciate it.

(Roger Schwartz): Thank you.

(Corinne Axelrod): We try to think of everything, but, you know, it's not possible.

Operator: With that, we'll go next to (Mary Peterson) in Wisconsin.

(Mary Peterson): (unintelligible) (Ness) from (unintelligible) clinic along with (Mary Peterson). Three - four questions. First one, with the location criteria major community provider, you referred to the utilization rate. What is meant by that?

(Corinne Axelrod): We have not defined that, so this is one of the areas that you can give us some comments if you do want it further defined. It may actually something we can define better in a subsequent guidance, not in the regulations. So, if you have suggestions on how that should be defined, please let us know.

(Mary Peterson): Okay, second question, in the same provisions, what is the definition of low income?

(Corinne Axelrod):

(Mary Peterson): Normally, FQHC have a sliding scale. If you have a sliding scale your then set up to ask income questions. But, most medical clinics don't quiz people about their income. So, we have no of knowing exactly what people's income is.

(Corinne Axelrod): Okay, so that's sort of the same thing that we don't - we didn't want to make this too restrictive and say, you know, give exact numbers. So, again I give the same answer as for your other question about utilization. That its something that you can let us know if you think that - if you want this defined in a very concrete way or if there's a range that you would suggest.

(Mary Peterson): Well, the concern here is that you're asking a rural health clinic to prove that it still is eligible to remain a rural health clinic based on criteria that we really can get that, but we'll be subject to somebody who is going to be reviewing this request for an exception, what their opinion would be of it. So, it becomes a very subjective call.

(Corinne Axelrod): Yes, and it's always a balance between giving flexibility and being too vague. So, again if you have specific suggestions on that let us know and we will consider that either for the regulation or for subsequent guidance afterwards.

(Mary Peterson): (unintelligible) question that's seen provision. Where did the 51%/31% numbers come from?

(Corinne Axelrod): That came actually - that was in the 2003 final rule and I wasn't around then, but I know that they - I don't know (Randy) do you recall that? None of us were working on it at the time, but I think it was based on - I know it was based on something, it wasn't just pulled out of the air. So, but I can't tell you for certain exactly where that came from at this time. I'd have to go back and look it up.

(Mary Peterson): Because it would seem that any standards that any standards that (unintelligible) should be based on data from existing rural health clinics like the 5th percentile or the 95th percentile or something of existing rural health clinics.

The last question is on the whole community exception and this is a recurrent issue every since the 2000 rule come out. Is it is inappropriate to use the hospital standards for clinics. Clinics are located in many more small communities than we can support hospitals.

The sole community, the community definition should be zip code. Its simply, everybody knows what it is. If you're the only provider in your zip code, you're the sole community provider.

And then it doesn't really make any difference how distant other communities are, communities in rural areas self identify generally with the name of the small town, village, unincorporated, whatever it is that has a post office and that generally how they define their sense of community and that's the standard that you should be using.

(Corinne Axelrod): Okay, thanks you for your comments.

Operator: We'll go next to (Steve Rader) in Minnesota.

(Steve Rader): Yes, I had a question on the requirements fro a critical access hospital with a provider based rural health clinic. There's no legislation out there effective January 1st that prohibits a critical access hospital from acquiring or creating a provider based entity that's within 35 miles of another hospital or critical access hospital without jeopardizing their critical access status.

If you have a rural health clinic that is within 35 miles of another hospital and it gets decertified as a rural health clinic, can they still be a provider based clinic without jeopardizing their critical access status?

(Corinne Axelrod): I think that's something that we would have to talk with the people from the critical access hospital group on. ..

(Mary Collins): Actually, why don't you go ahead and send an email that question to me Mary Collins at mary.collins@cms.hhs.gov. Thank you.

Operator: We'll take our next question from (Chris Coffon) in Virginia. I'd also like to remind participants, if you have a question please signal by pressing star 1.

(Chris Coffon) Hi Corinne, sorry I kind of blew you out of the water with my second question on the location requirements for FQHC. But, my first question was does CMS view the FQHC provisions in this proposed rule as also applying to FQHC look a likes?

(Corinne Axelrod): No

(Randy Ricktor): Which provisions are you speaking of (Chris)? Just in general, I mean we would consider, I mean, if you qualify as an FQHC even under the look a like provision and your certified in your Medicare, we don't make a distinction, you're an FQHC under Medicare, but I think as Corinne had said earlier, lots of these provision only apply to rural health clinic and they don't apply to FQHC.

(Chris Coffon): Correct, no that, yes, no I just wanted to make sure because I knew - I just wanted to clarify that you guys were looking at an FQHC regardless of

whether it's a grantee or not. (unintelligible) FQHC for the purposes of the (Track).

(Corinne Axelrod): Yes. I think your question is whether the location requirements apply to look-a-likes and the location requirements in this proposed rule are specifically for rural health clinics.

(Chris Coffon): Yes, I'm going to give you guys a call a little later because I think it's a little (unintelligible), I just want to make sure I'm expressing myself clearly.

(Corinne Axelrod): I'm sorry if we're not getting it.

(Chris Coffon): Thanks a lot.

(Randy Ricktor): Thank you.

(Corinne Axelrod): Thank you.

Operator: Again, I'd like to remind participants, if you have a question please signal us at this time by pressing star 1 on your telephone keypad. We'll pause for just a moment to see if there are any additional questions.

I have a question from (Kate Simmons) in Vermont.

(Kate Simmons): Hi, I have a question about the major community provider exceptions. We have particularly one area of the State that I'm thinking that has in a single service area four family practice rural health clinics.

And, well I would consider each of them to meet the requirements of major community providers; I also find it hard to believe that CMS regulators would

say that there are four major community providers in a single service area. And I'm just - is there any way of being able to predict how these rules would play out for that service area?

(Corinne Axelrod): Yes and I think one thing that I would like to clarify is that major does not mean majority. So, you can be a major community provider but that doesn't mean more then 50%, it means a significant community provider and has all this other explanation here. So, if you're in an area where there are four RHCs and let's say your designation has not been updated and you need to apply for an exception, it is possible that all four could be considered major community providers.

(Kate Simmons): Thank you.

(Corinne Axelrod): Uh-huh, thank you.

Operator: Again, if anyone has a question pleas press star 1.

(Corinne Axelrod): Well it sounds like there are no more questions, so I would just like to, first of all again thank everybody, especially those that are still on the phone, for your interest in this. We have tried our best to put out a proposed rule that is fair and addresses the requirements of the statute and provides you with flexibility, but obviously there are things that we may have missed or are not as clear as they should have been.

So, if you have suggestions on how to make it better, we're looking forward to getting your comments. Your comments are due August 26th, you don't need to wait until August 26th to send them. You can send them in now. If you think of something else after you send it in, you can send in another comment and say in addition to the comment I just sent, I also want to say whatever. As

we said we look at all the comments and we look forward to hearing from you on that.

I also want to thank my colleagues, Mary Collins and Scott Cooper and especially Randy Ricktor who, as I said, is our expert on Cost Reimbursement, it can be pretty tricky, so I'm real glad he's here. And I guess that's it. Thank you all very much and we'll look forward to your comments.

Natalie Highsmith: Thank you all again for joining us.

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