Centers for Medicare & Medicaid Services
Special Open Door Forum:
End-Stage Renal Disease Quality Incentive Program
Notice of Proposed Rulemaking: Payment Year 2015
July 19, 2012
2:00 – 3:30 PM EDT
Conference Call Only

On July 19, 2012, the Centers for Medicare & Medicaid Services (CMS), Office of Clinical Standards and Quality (OCSQ), will host a special Open Door Forum (ODF) on the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP). The ESRD QIP is a pay-for-performance quality initiative that ties a facility's performance to a payment reduction over the course of a payment year (PY).

This ODF will focus on the proposed rule for operationalizing the ESRD QIP in PY 2015. This proposed rule was published in the *Federal Register* on July 11, 2012; see http://www.gpo.gov/fdsys/pkg/FR-2012-07-11/pdf/2012-16566.pdf.

The public will have 60 days from the publication date to submit their comments about the content of the rule. CMS encourages every dialysis facility and ESRD stakeholder to carefully review the proposed rule and participate in the comment period.

After this ODF, participants should know and understand:

- The ESRD QIP legislative framework;
- The proposed measures, standards, scoring methodology, and payment reduction scale for
  PY 2015; and
- The methods for reviewing and commenting on the proposed rule.

After CMS' presentation, participants will have an opportunity to ask questions.

Discussion materials for this Special ODF will be available to download at http://www.cms.gov/ESRDQualityImproveInit/ .

We look forward to your participation and comments.

Special Open Door Forum Participation Instructions:

Dial: 1-800-837-1935 (toll free)
Reference Conference ID#: 11365339

Note: TTY Communications Relay Services are available for the Hearing Impaired.

For TTY services dial 7-1-1 or 1-800-855-2880. A Relay Communications Assistant will help.

An audio recording and transcript of this Special Open Door Forum will be posted to the Special Open Door Forum website: http://www.cms.gov/OpenDoorForums/05_ODF_SpecialODF.asp and will be accessible for downloading beginning on or around July 26, 2012 and will be available for 30 days.

Audio File for Transcript:
http://downloads.cms.gov/media/audio/071912ESRDQIPPY2015ID11365339.mp3

Centers for Medicare & Medicaid Services

Moderator: Lindsay Bianco-Ringley
July 19, 2012
2:00 p.m. ET

Male: Good afternoon. My name is Jay and I will be your conference facilitator today. At this time, I would like to welcome everyone to the Centers for Medicare & Medicaid Services ESRD QIP QY 2015 Special Open Door Forum. All lines have been placed on mute to prevent any background noise.

After the speakers' remarks, there will be a question and answer session. If you would like to ask a question during that time, simply press star, then the number one, on your telephone keypad. If you would like to withdraw your question, please press the pound key. Thank you.

Mr. Matthew Brown, you may begin.

Matthew Brown: Thank you, Jay.

Good afternoon and good morning to those joining us on the West Coast. As Jay said, welcome to the End-Stage Renal Disease Quality Incentive Program Notice of Proposed Rulemaking Payment Year 2015.

This open door forum will focus on a proposed rule for operationalizing the ESRD QIP in Payment Year 2015. This proposed rule was published in the Federal Register on July 11 of this year.

At this time, I would like to turn the call over to Jean Moody-Williams with the Office of Clinical Standards and Quality.

Jean?

Jean Moody-Williams: Hello, everyone. And I would like to add my thanks to those that have already been offered – we really appreciate you dialing in, and we recognize that this is time away from your daily routine, and we do appreciate this and don't take this for granted. Your time is valuable and we hope that you will find that this information that we'll present today will be quite valuable as we all work to improve the quality of care for Medicare beneficiaries and support the families and caregivers that are working with them.

During this open door forum we hope to discover a number of items. We want to talk a little bit about the ESRD QIP legislative framework, then we'll go into the proposed measures, the standards, the scoring, and the payment scale for Payment Year 2015.

As mentioned, this is a proposed rule. We are really counting on receiving your comments. And you have probably seen in prior years that your comments have made a difference in the final program that's rolled out. And we assure that this year will be no exception. So we do encourage you to send in your comments, and we will give you information about how that can be done a little bit later on. And note that anything you say today should be followed with a written comment.

We'll do a summary comparison on the 2015 Payment Year rule to the Payment Year 2014. As we know, this is an evolving program and we're continuing to build upon it. And we do have some additional resources that we'll describe as well.

On the next slide, we look, as I mentioned, it's an evolving program and it's always good to know what is it that we're trying to achieve, where is it that we're trying to go. And that really is the purpose of this slide. It begins to outline those objectives that CMS has identified for value-based purchasing in general. So that means for many of the value-based purchasing programs that have either started or are coming on board. And we have some that are in proposed rulemaking as we speak.

But regardless of the program, we know that we look to say that paying for quality healthcare is no longer the payment system of the future. It is the payment system of today. That's evidenced by the fact that the ESRD QIP is at the leading edge and already operational. For our hospital value-based purchasing program, the hospitals will soon be receiving their data on their Total Performance Scores in the upcoming weeks. So this is no longer something that we're planning for; it is a reality.

As we look at our objectives, if you notice they are now – we'll go through all of them, I'm hopeful that you've seen them before – but they really do center around making sure that we have the evidence base to really promote the adoption of the clinical care that should be given to our beneficiaries. If there's transparency across all sites, we want to make sure that we have alignment in the various programs and that we can help to support because the beneficiary, of course, [gets care] from one site to the next and would appreciate it being as seamless as possible.

We are going to continually work with finer models. I think we have evolved even from our very first payment year, but again much of that comes from the comments that we receive from you. We really want to stimulate meaningful use of information with technology, and there's some exciting things going on in that arena, and we'll continue to look to see how we can stimulate that.

As a matter of fact, I think we asked for your comments in our proposed rule along those lines. And we'll continue to be cognizant of the healthcare disparity that exists in our system, and we're looking to see how we can utilize this tool as one of many to help to decrease those disparities. This program,

as others, has a foundation and a framework that we have structured around the National Quality Strategy.

At this point, I'm going to turn it over to Jordan Vanlare, who is working with us as we look at these domains of quality and see how they affect our program.

Jordan Vanlare: Great. Thank you so much, Jean, and thanks to everyone on the line for joining, and for all of your efforts to provide care to beneficiaries with ESRD.

Jean mentioned the National Quality Strategy, which is an effort that was undertaken by the Department of Health and Human Services for the first time last year. And that strategy articulates a set of three aims – not just for the federal government but for the patient community, for the provider community, for the public sector, the private sector, for everyone who's involved in delivering care to Americans – a common set of objectives for improving quality.

And the three aims that were set out in that strategy were improving health, improving healthcare, and reducing cost. And in order to help achieve those three aims, the strategy outlined six different priorities. And in order for us to be able to successfully move forward against those priorities, we need to be able to measure them. And as you know, the measurement of quality in the area of dialysis and quality measurement for care delivered to patients with ESRD is an effort that's been undergoing for a number of years.

And what the National Quality Strategy does is create an opportunity to be able to align our quality improvement effort not just within the ESRD community, but across all patients and across the continuum of care. So ESRD facilities are no longer to be accountable alone for clinical care or alone for care coordination of patients with ESRD, but are going to have quality improvement objectives and incentives aligned across in-patient care facilities, care delivered by individual physicians, post-acute care facilities, and all other parts of the healthcare continuum.

And as you look across all of the ongoing rulemaking efforts of CMS, as well as all of the support that we provide through our ESRD Networks and our

Quality Improvement Organizations, this is the framework that is guiding our quality improvement efforts across the nation. And as we go through the discussion today and talk about some of the quality measures, we'll be reflecting back on how the measures that are included in this year's proposed ESRD QIP rule [as they pertain to] the National Quality Strategy.

Moving forward to the fourth page, the ESRD QIP legislative drivers, MIPPA gives CMS the authority to establish standards by which the ESRD facilities will be evaluated, and that is the authority that we use to be able to identify the measures that we use to create the score for dialysis facilities. And it's also the authority that we use to be able to identify, within the context of that National Quality Strategy, how is it that we can best measure the quality of care that's being delivered to patients of ESRD facilities.

And to align on the intensive program – everyone is in this, as we all know, for being able to not only deliver high quality patient care, but to always be improving. And so we'll always be working towards higher standards of care delivered. And the other thing that I want to call out, which Jean mentioned briefly in her remarks, is that that standard is changing. And in collaboration with all of you, this program, over the course of the past several years, has been quite responsive to changes in evidence and changes in the needs of patients through our monitoring and evaluation efforts. And those changes, I think, have been reflected in previous program years and, as you'll see, will be reflected in the proposals for this year as well.

All right, moving on to page 5, this is an overview of section 153(c) in MIPPA, which allows us to create the Quality Incentive Program, and it outlines the process that we go through in order to be able to implement the program, beginning with selecting measures and establishing performance standards for those measures. And then outlining how those measures are going to play a role in any given year's program for the QIP.

We also have a few changes related to methodology this year that we'll be discussing later on the call. But we specify the method by which we're going to calculate the score for our facilities based on their performance in those

measures. And then also we have a mechanism for reporting the results of the performance in the quality incentive program publicly.

On page 6, the ESRD QIP rulemaking process is as follows. What happened on July 11, 2012, is that CMS released the proposed rule. These are our proposed rules for how we plan to implement the ESRD QIP for program year 2015. And we are right now in the midst of the 60-day comment period. That period will end on August 31, 2012. And this is a very exciting opportunity. For those of you who get more excited about patient care – in both patient care as well as policy making like I do – this is really, truly, an exciting opportunity to be able to shape this program and to make sure that it responds to the needs of your patients and of your institution.

We read every comment that comes into CMS, and we respond to every comment in the final rule. So this is really government at work, and we appreciate all of your efforts in being involved in that process. You'll learn a little bit more about how you can do that specifically later on the call. And then, in November of 2012, we will be finalizing the proposals based on comments from all of you.

And now I'm going to hand if off – but before I do, we're very fortunate to have a number of new colleagues on the team helping to make the ESRD QIP program better and more successful even than it has been in the past. And I'd like to just briefly introduce them.

So we have Anita Segar, who is joining us from the Division of Value Incentives Quality Reporting here at CMS; Brenda Gentles is from the Division of ESRD Population and Community Health at CMS; and Joel Andress is joining us from our Quality Measurement group here at CMS as well. So I'd like to welcome all of them and hand it off to Joel.

Joel Andress: Thank you, Jordan. As Jordan mentioned, we're going begin the discussion today talking about the clinical measures that have been proposed as part of our rule. At the risk of belaboring the point, I want to encourage you both to ask questions during the Q&A session today, and also encourage you to

follow those up with comments during our comment period for the proposed rule.

So on slide 8, you'll see a summary of the clinical measures that we have proposed for Payment Year 2015. You'll see that many of the measures, their structure, and methodology will sound familiar to those that you provided for Payment Year 2014, and we are retaining a significant portion of those clinical measures.

The Payment Year 2015 proposed rule has proposed four clinical measure topics in which we have proposed seven overall measures. These topics are Anemia Management and Vascular Access Type – both of which include measures that you saw in Payment Year 2014 – [and] Kt/V Dialysis Adequacy and hypercalcemia are new measures that have been included for Payment Year 2015.

We'll identify directionality for each measure, whether a high or low number indicates better care. And it's worth noting that these slides are summaries only. Details can be found in the technical measures specifications in URLs at the end of this presentation. And again we encourage you to provide us some comments on these proposals.

Moving on to slide 9, the important thing to note about the hemoglobin measure is that it has not changed from Payment Year 2014. Anemia management is really important, and patients face health hazards if they have elevated hemoglobin levels. The exclusions are summarized here, but more information can be found in the links provided at the end of this presentation.

For slide 10, moving on to the Kt/V Dialysis Adequacy measure topic. These measures are new and have been broadly accepted in the renal community as a replacement for the URR, which was used in previous payment years. These measures are intended to serve the same purpose as the URR measure, and we'll be replacing that in the rule. You may recall that using Kt/V was proposed originally as part of Payment Year 2014 but was not included in the final rule due to potential discrepancies when the facilities calculated Kt/V.

Change Request 7460 became effective January 1 of this year, and specified the applicable method to measure Kt/V, and we feel that this has addressed those reservations regarding the measures.

Each of the three measures in the measure topic addresses a different patient population in order to better address this needs and quality of care specific to those populations. It also expands the ESRD QIP to include more patient populations than before when simply using the URR measure. And again, we seek your comments on the proposal to replace the URR measure with the Kt/V measures.

Moving on, these slides provide the definitions and exclusion for adult hemodialysis, adult peritoneal dialysis, and pediatric hemodialysis measures from the Kt/V measure topic. Again, additional information is available in the links provided to you at the end of this presentation.

As previously mentioned, the clinical measures for the vascular access type measure topic are unchanged from the prior year. This is in slides 13 – 14 (I'm sorry, slides 14 and 15) provide you with the definitions and exclusions for the arteriovenous fistula and catheter measures within the vascular access type topic.

For the hypercalcemia measures, we have provided the definitions and exclusions for a new measure of hypercalcemia that was not seen in Payment Year 2014. As mentioned earlier, this clinical measure expands a reporting measure established the year before – part of the effort to diversify that, as well as expanding ESRD QIP's ability to quantify the quality of care provided to the patient. Unlike other measures, hypercalcemia applies to every patient treated by the facility, and is not allotted simply to Medicare patients.

And with that, I'll turn it over to Jordan for slide – I'm sorry, for discussion of the "Low-Volume" Facility Adjustments.

Jordan Vanlare: Great. Thank you so much, Joel.

This proposal was an innovation for this year's program. CMS is constantly thinking about how we connect the lines of reliability in how we measure

quality across facilities, and balance that with the need to include as many facilities as we can in each of our program, and have reliable data for those facilities that are included.

What we've done in the past is have a minimum standard of 11 cases to be able to score a facility on a given quality measure. What we propose this year is a new methodology by which we'll increase the cases according to the previous methodology up to 25. And what that's going to do is allow us to have a more reliable measure score, because we have more cases that better reflect the quality of care that's actually being delivered, as opposed to changes in the measurement that might be due to some other factors.

So we'll actually have a more reliable score for those facilities. However, we don't want to exclude facilities to have between 11 and 25 eligible cases. So what we've done is define a calculation that we can apply to the measure rate of those facilities that will give those facilities the “benefit of the doubt” and increase their measure rate for the measures where they have fewer than 25 cases or between 11 and 25 cases, so that any kind of variation that might have caused them to have a lower measure rate than if they had many, many more patients will be eliminated.

So this is a way for us to be able to improve the reliability of measurement and help out facilities [that] are serving between 11 and 25 beneficiaries on a given measure, and make sure that the measure rate fairly reflects the kind of care that is being delivered.

And I just want to emphasize again, this proposal is not in any way going to penalize facilities. The adjustment that we're making to facilities to have between 11 and 25 patients who are included in the measure is only an upward adjustment. So we think that this is a proposal that really strengthens the program – both because we can be confident that facilities that are getting their actual measure rate with 26 or more patients are having more reliable measure rate, and we're giving the benefit of the doubt to the facilities that have between 11 and 25 patients.

And now I'm going to hand it over to Teresa Casey, whom all of you know. She's the division director of ESRD Population and Community Health at the Office of Clinical Standards and Quality here at CMS.

And Teresa, I'll hand it to you.

Teresa Casey: Thank you very much, Jordan.

The proposed scoring for Payment Year 2015, year 4 of the quality incentive program, is similar to the scoring method finalized for Payment Year 2014, year 3 of the Quality Incentive Program. And that we propose again a 100 point scale for the Total Performance Score and two opportunities for facilities to earn points, first through achievement and secondly through improvement. We propose this for each individual measure and then combine the scores to reach the Total Performance Score. And we'll talk about weighting in just a minute. In this next section, we'll describe how we propose to compute the measures for them.

Slide 19 – let's start with our proposal for how to score measure topics that are made up of more than one measure. And certainly this year we have a new measure topic that we're proposing – Kt/V Dialysis Adequacy – which would include three different measures. And then, of course, again we have the vascular access type measure topic composed of the AV fistula and catheter measures.

First, a score would be calculated for each individual measure. Next a single measure topic score would be calculated by weighting the individual measures based on the number of patients in each individual measure denominator. And we provided an example here on slide 19, as well as the next slide.

For example, if the number of patients included in the denominator for the vascular access type AV fistula and catheter measures are X and Y, respectively, the weight applied to the fistula measure would be X/X+Y. If a facility is not eligible for a score on one of the individual measures in the measure topic, then the other scores would be assigned proportional weight that would then add up to 100 percent for that measure topic. We propose that

as long as the facility has one individual measure that can be included in the measure topic, that measure topic then would get a score.

Now let's look at the example on slide 20 using the Kt/V dialysis adequacy measure topic. Let's assume Facility A serves all three adequacy measure patient populations and has a total measure exclusion patient population of 100. So if we use the example here, for the hemodialysis adequacy measure we would have 50 patients hitting that measure target out of 60 that were eligible for inclusion in the measure. And likewise for peritoneal dialysis, we have 15 of 20 patients, and for pediatric dialysis adequacy in our example, we have 10 out of 20 patients.

And then we give example measure scores here as well. So if you drop in to the next bullet on this slide, you can see the mathematical formula used such that we weight that measure topic according to the number of patients on each of those individual measures. And then we would round that measure. In this particular instance, we would come up with a score of 6.8, and, applying conventional rounding, which we again proposed in this rule, we would have a measure topic score of 7.

I'm going to skip slide 21 for now and come back to that momentarily. I'll ask you to please go to slide 22. We propose to establish Calendar Year 2013 as the performance period for this Payment Year 2015. Second, we propose to use Calendar Year 2011 as the time period that provides the basis for our national standard, achievement threshold, and benchmark. Third, we propose to use Calendar Year 2012 as the basis for the improvement threshold when calculating the improvement score.

And our goal is to move the time period and threshold closer in time to the Payment Year 2015 year, but also ensure that we publish performance standard prior to the start of the performance period. And this may be a familiar topic to you if you've listened in on our previous ODF for the previous rule. And we'll talk a little bit more about that in just a moment.

So using these time frames that I've just mentioned, we're proposing two opportunities for our facility to earn points – again, very similar to Payment

Year 2014. An achievement score will be derived when the facility's performance is compared to the national performance standard. An improvement score would be calculated based on the facility rate during 2012. The higher of these two scores would be applied.

Slide 23 – to determine the achievement score, the facilities would receive points along an achievement range. The achievement threshold, or the lower end of the scale, is proposed as the 15th percentile during Calendar Year 2011 using the national performance standard.

The benchmark, or the high end of this scale, is proposed as the 90th percentile during the Calendar Year 2011, such that the achievement range is the scale that runs between the achievement threshold or between the 15th percentile and the benchmark or the 90th percentile. And again, the proposed time period for the national performance standard and calculating the achievement threshold, benchmark, and performance scores is Calendar Year 2011.

Now, we do include an alternate proposal in terms of this one-year period that we're using for these standards, in that we are also potentially considering based in large part on your comments, using the time period from July 1, 2011, to June 30, 2012. And if we did use this period, the positive side of that is we would have more current data on making these comparison. However, on perhaps the negative side, we would have difficulty publishing in our final rule those thresholds, benchmarks and standards, which you would definitely want to have before the performance period begins.

Now we did, in fact, do this using the July 1 to June 30th time frame for Payment Year 2014, and we did manage to publish these standards prior to the beginning of the performance period – that was the last week of December. However, we don't have the certainty that we would able to do it as soon as that. We might have to publish those standards in January. And so that's something that we ask you to consider as you submit your comments on these timeframes.

Now let's go back to slide 21. In the proposed rule we acknowledge some data challenges associated with establishing achievement standards in two areas. And these two areas are the hemodialysis adequacy measure as well as the hypercalcemia measure. In terms of the hemodialysis adequacy measure, we began collecting uniform Kt/V data as of January 1, 2012, and that was per Change Request number 7460.

Prior to that time, a formula not specified in the NQS measure was used by some facilities to calculate the Kt/V. In looking at the data that we had available to us, we estimate that in Calendar Year 2011, about 88 percent of the reported Kt/V value on claims were computed using an NQS-accepted formula.

Given this high percentage, we propose to still use Calendar Year 2011 claims data to establish the performance standard, and even [the] thresholds and benchmark for the hemodialysis adequacy measure.

And then when we look at the hypercalcemia data – again, a challenge. The serum calcium values needed to calculate the national standard are limited to those submitted via the CROWNWeb pilot. This CROWNWeb data that we do have represents 63 percent of the facilities and 80 percent of the patients. And this is the best data that we have currently. So we propose to use this Calendar Year 2011 CROWNWeb pilot data as our basis for establishing the performance standard, achievement threshold, and benchmark for the hemodialysis – for the hypercalcemia measure. Again, this is the data we have available to us at this time, and in order to move forward with these measures, we would ask you to provide comments on these proposals.

Now let's go to slide 24. Now that we understand the basis for the performance standard, the achievement threshold, and the benchmark, let's look at an illustration of the achievement scoring. And that's what you can see for yourself on the slide. We talked about an achievement threshold to be the 15th percentile, in this case 46 percent in this example of an AV fistula, and that marks the bottom end of the achievement range.

We also see the 90th percentile benchmark as shown as 74 percent, and that marks the high end of the achievement range. And so you see a scale running from zero to 10 of the kinds of points a facility might be awarded for achievement. So in this illustration, Facility A performed at a rate of 54 percent and, if you drop your eyes down to where that falls on the scale, that would correspond to a score of 3.

Now moving to slide 25, we have the mathematical equation that is used to compute the measures number exactly. Now, this formula will only be used if the facility's performance rate falls within the achievement range. If the performance rate is below the achievement range, the facility would receive zero points for achievement. And if the rate is above the achievement range, it would receive 10 points. And this is very much the same as what you used for the year 2014.

Slide 26 shows those visual graphics to help you think through the scoring, as well as the mathematical formula. And here we see that the exact number for the score would've been a 3.07, rounded to 3.

Slide 27 – now let's look at improvements for the proposal. Again, this is very much like what we saw for 2014. To determine the improvement score, facilities will receive points along an improvement range. The improvement threshold, or the low end of the improvement scale, is the individual facility's performance during Calendar Year 2012. The high end of the scale would be the benchmark, or the 90th percentile of the national performance curve.

Performance range then is the scale going from zero to 9 points running between the improvement threshold and the benchmark. And we can see this on slide 28. If we look all the way to the left of this visual, you'll see the improvement threshold for Facility A of their performance rate in Calendar Year 2012 was 26 percent. Again, if you look towards the right side of the slide, you'll see the benchmark – the 90th percentile mark, at 74 percent. And, again, that marks this high end of the improvement scale.

So here we look again, the facility's performance rate during the performance period is 64 percent. So again, if you drop your eyes down to the corresponding space on the scale, that would produce a 5.

And, if we look at slide 29, we can see the mathematical equation and we can see the consequences of a performance rate that is either below the improvement range or above it. And that again is very much the same as what we had finalized for Payment Year 2014.

Slide 30 – it shows those together. You see the illustration – the visual as well as the mathematical formula with the numbers punched in – and this would produce a score of 5.33, given this example, and we would round that to 5.

Let's just quickly look at what happens if the facility has a performance rate that is above the achievement range. In this example, the facility's performance rate is 86 percent, [which is] above the achievement range. In this case, they would be awarded 10 points. We do not use the mathematical formula in cases where the performance rate falls outside the scale. So again, if the facility performance is at or above the benchmark, they would earn 10 points, according to what we proposed for Payment Year 2015. And likewise, if we look at slide 32, if the facility's performance rate is below the scale, we can see that they would be awarded zero points.

Now we just talked through some examples of all the scoring work and we showed the achievement threshold, the performance standard, and the benchmark. Now here on slide 33 and 34, we have those data points listed for you for each of the proposed measures for Payment Year 2015. Now I want to just kind of notate that these are estimated values that you're seeing on this table, and at this point in time or when we publish the final rule, we'll use the most current data that we have available. And so we'll use data for October 2010 through September 2011 in order to compute these particular points and threshold. In the rule, we propose to use Calendar Year 2011 data such that the actual data that would be used for the final rule would be moved forward by three months.

The performance standard is the 50th percentile of the national performance, and this number is used to establish minimum performance scores, and we'll get to the scoring in just a little bit. I do want to just notate that on slide 34, the achievement threshold, benchmark, and performance standards shown for the hypercalcemia measure topic utilized the CROWNWeb pilot data that I just recently talked about. And that data is based on the time frame of April 2011 through October 2011.

Now we're going to move to the reporting measures, and I'd like to turn you over to Anita Segar.

Anita Segar: Thank you, Teresa.

In this next session we will examine the four proposed reporting measures for Payment Year 2015. We will also discuss the reporting provision for new facilities that will receive their CCN in 2013.

Slide 36 – we have a total of four reporting measures in Payment Year 2015. We have one measure from Payment Year 2014 that will continue into Payment Year 2015, namely ICH CAHPS, which is the patient's experience of care survey administration via the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems survey. Two reporting measures, namely the NHSN and the mineral metabolism reporting measure from Payment Year 2014, have been expanded from attestation to actual provision of data. We have one new reporting measure, namely, the anemia management reporting measure.

Scores for applicable reporting measures will be weighted equally to comprise 20 percent of the Total Performance Score. Please note that the performance period is Calendar Year 2013 for all reporting measure, and facilities are to report events that occurred during this year only.

Moving on to slide 37, the anemia management reporting measure. This measure applies to hemodialysis, peritoneal dialysis, and pediatric patients alike. Claims for peritoneal dialysis patients must include ESA dosage and hemoglobin or hematocrit value. The inclusion of other facility lab work is

encouraged if you do not otherwise have the data available. This is an important example of coordination of care.

And, as in the case of the clinical measure, certain patients are excluded when determining if the reporting requirements are met. For example, claims for hemodialysis patients treated only once during the claim month will be excluded. Further information can be found in the link provided at the end of this presentation.

To earn the maximum 10 points on the measure, facilities will need to report 12 months of data for every Medicare patient. And to earn 5 points, report at least six consecutive months of data for every Medicare patient.

Moving on to slide 38 – the NHSN Dialysis Event reporting measure. Facilities that treat in-center hemodialysis patients must report information about dialysis events to NHSN on a monthly basis. A one-month grace period applies, so data for a particular month must be reported at the end of the following month. Facilities can earn 5 points for reporting data for half of its eligible months, so that would be six consecutive months the facilities with a CCN for the entire performance period, and 10 points for reporting data for the full performance period.

Eligibility for some of these measures is based on how your facility is categorized. So you should make sure the record of modalities you treat are up-to-date. Please contact your Network for more information. Your facility is only required to report for the NHSN dialysis event measure if it treats in-center hemodialysis patients.

Moving on to slide 39 – Calculating the mineral metabolism reporting measure. A form of this reporting measure was in place for Payment Year 2014. Now instead of the simple attestation, facilities must deliver actual information via CROWNWeb for Payment Year 2015. Again, as with the clinical measures, certain patients are not counted when we see if the reporting requirements are met.

Further information could be found in the link provided at the end of this presentation. The one-month grace period applies here as well. The inclusion

of out-of-facility lab [results] is encouraged if you do not have the data available. It is an important example, again, of coordination of care. CMS seeks comments about the expansion of and exclusions for this measure.

Slide 40 – For Payment Year 2015, the ICH CAHPS reporting measures are unchanged from Payment Year 2014. It is still a required attestation through CROWNWeb. The ICH CAHPS survey specifications are established by AHRQ. So be sure to follow their guidelines because you can only attest to administrating the survey if you follow those specifications. You will be able to find more information on AHRQ's website.

By attesting to successfully administering the survey, facilities would earn the maximum 10 points on this measure. This measure only applies to facilities [that] treat adult in-center patients.

CMS has made a specific request for comments about whether requiring six consecutive months of reporting will improve quality more than awarding points for non-consecutive months of reporting. We greatly appreciate your comments.

Moving on to slide 41, we will examine how the reporting measures will be applied to new facilities. For clinical measures, new facilities are scored just as every other facility is scored – based on the number of cases for each measure.

Data requirements for reporting measures have to be evaluated differently, because there are no cases or case minimums on the reporting measures. CMS's approach to scoring new facilities on reporting measures is determined by when the facility got its CCN.

CMS proposes that any facility that receives its CCN after June 30, 2013, would not be scored under reporting measures, and thus will not receive a Total Performance Score for the payment year. We will talk about this a little more later on in this presentation.

Now, for facilities receiving their CCN in the first half of 2013, to earn 5 points, the facility has to report for at least half of the months for which it has

the CCN. And to earn 10 points, it must report for all of the months for which it has the CCN. The eligible months begin on the first day of the month following the certification of the facility. And CMS will run down to determine half the eligible months.

For example, if reporting requirements begin on April 1, then the facility is eligible to report nine months of data. So, to earn 5 points, the facility must report for 4 months, rounded down from 4.5, which is half of nine.

That brings me to the end of slide 41. Now that we've discussed how clinical and reporting measures will be scored, we will talk about the proposed methods used to calculate the Total Performance Score and the structure by which any payment reduction will be applied.

Moving on to slide 43, the process of calculating the Total Performance Score in Payment Year 2015 is similar to the process in place for Payment Year 2014. In Payment Year 2015, clinical measures will account for 80 percent, and reporting measures will account for 20 percent. The Total Performance Score will range from 0 to 100 points.

For Payment Year 2015, we require that a facility have a score on at least one clinical measure and at least one reporting measure. So, as mentioned earlier, a facility that receives a CCN after June 30, 2013, will not receive a Total Performance Score and will not receive a payment reduction.

Again, CMS seeks comments on these proposals.

Moving on to slide 44, the payment reduction structure for Payment Year 2015 is also the same as in Payment Year 2014; that is, for every 10 points below the minimum Total Performance Score, there is an additional 0.5 percent payment reduction, with a maximum of 2 percent.

We calculate the minimum Total Performance Score by scoring a hypothetical facility as if it reached the performance standard – the 50th percentile nationally – for each clinical measure, and scores zero on each reporting measure. The minimum Total Performance Score will be calculated, and it is estimated that, at this time, it would be 52.

Slide 45, in accordance with the statute, the maximum payment reduction for any facility would be 2 percent. On slide 45, you will see a chart demonstrating the ranges for payment reduction based on a facility's Total Performance Score. Again, it is based on the current estimates for the minimum Total Performance Score, which is 52.

Moving on to slide 46, this slide provides a summarized graphical interpretation of how facilities will be scored, and how those scores will translate into a TPS or Total Performance Score. On this chart, you will be able to see how several different elements of the program are pieced together. For example, the data sources are identified, if we're receiving the data from a Medicare claim or CROWNWeb. The measures are listed, and the form those outputs will take is listed for reporting measures; then you have the category weights and the scales for the payment reduction that applies, if any.

This concludes the slide presentation on the Total Performance Score calculation and payment reduction. I'm happy to turn over the presentation of the next section to Teresa Casey.

Teresa Casey: Thank you, very much, Anita. Well, a number of additional proposals are included in this rule, and I'm going to just very, very quickly touch on them. I really want to simply bring at least additional proposals to your attention so that you might be sure to look for them and provide us your comments.

Starting on slide 48, there are three proposals included in this rule that would be applicable to Payment Year 2014. The first one is related to the mineral metabolism reporting measure, and we are proposing for Payment Year 2014 that we include those additional factors that Anita really just described for Payment Year 2015, such that for Payment Year 2014 if the patient is treated elsewhere during a given month (in a hospital, for example) and a dialysis the facility obtained the calcium and phosphorus levels and included that in their monitoring, they can attest that they have in fact done the monitoring required for this measure.

In addition, patients who are treated only once during the claim month will be excluded from this reporting measure. Additionally, we have a proposal

related to the Performance Score Certificate and that we are proposing that facilities post both an English version as well as a Spanish version of the certificate. We would provide the Spanish-version certificate along with the English one.

We also are proposing to increase the flexibility as to when the facility must post these Performance Score Certificates. We have a timeframe of five days from the date the certificate was made available to the facility. We are proposing to modify that to the first business day of whatever that payment year is. So, in the case of 2014, the certificate would be posted by January 2, 2014.

We also discussed in these rules public reporting on the CMS website and providing a transcript [of this presentation] and the projected measure rates and Total Performance Scores, and invite you to look at the discussion and provide any comments to us.

Additionally, we proposed to clarify starting in 2014 the rules surrounding change of facility ownership such that if a CCN remains with a new facility owner, then within our program, the QIP program, we would treat the facility as the same facility. If there were to be a new CCN, the facility would be treated as a new facility.

The data validation of pilot projects is discussed in this rule. This is a first step in moving into data validation so that we can ensure the accuracy of the data we are using for the Quality Incentive Program. We have listed on this slide, as we have in the rule, these parameters that we would like to undertake in terms of a first step in the form of a pilot.

We are proposing that there would no penalties associated with this pilot phase. However, we do want to hear your thinking in terms of the next steps following the pilot in terms of methodology; how we might develop a data validation measure; whether we might want to include an additional reduction tier if the data is, in fact, inaccurate once the validation is off and running. And we certainly intend to provide further information about methodology in future rulemaking, but we would like to hear from you on this topic.

Slide 50 – there are a number of other proposals included in this rule, and again, I'd like to quickly bring them to your attention and highlight them here just ever so quickly. We are proposing, in this rule, measures for Payment Year 2015 will carry over into subsequent years of the Quality Incentive Program.

And so, I want to alert you to that. We also have included a discussion regarding the removal of measures, and so I'd ask you to look for that in the rule. We would like to include measures that are consisted with the National Quality Strategy and the value-based purchasing objectives as described earlier in the presentation, and we would like to include measures that would address care coordination, population and community health, efficiency, and cost of care. We are also interested in moving increasingly towards outcome measures.

There are two specific measures that are under consideration towards future years of the QIP. The risk-adjusted Standardized Mortality Ratio, which is NQF number 0369[, is one]; this is an outcome measure of overall care. It's the ratio of the number of Medicare ESRD patient actual death versus expect death adjusted for the facility's case mix.

The ratio is currently shown on the DFC website and has been shown since 2001, and it categorizes this [as] "as expected," "worse than expected," or "better than expected."

There's a second measure that is under consideration for future years of the QIP, and that is the Standardized Hospitalization Ratio, NQF number 1463, which is the ratio of the actual number of hospital missions over a specified time period over the number of hospital admissions that would've been expected, specifications under the care of the facility experience hospital admissions at the national (rate) for patients with similar characteristics.

This SHR measure was proposed for the QIP Payment Year 2014. We did receive comments expressing concerns. One concern was particularly regarding accuracy as comorbidity (inaudible) calculation, and whether the

comorbidity rate was up to date to (help identify) an area on the claim where comorbidity can be added, and this is pointed in the rules.

We are encouraging providers to even now begin to provide this up-to-date comorbidity data. Additionally, we are looking at posting the SHR ratio number for this facility on the website, and posting the actual SMR value as opposed to "as expected," "worse," or "better than expected" in 2013.

So, please take this into consideration and we look forward to your comments. There are additional measures that are referenced in the rule as being under development. For example, the 30-day hospital readmission measure to commit their coordination as hospital readmission is often the outcome of [poor care] coordination. [Your comment] is invited (inaudible). Additional measure areas are pointed out in terms of population and community health.

While we're monitoring access to care and unintended consequences, we are also requesting comments regarding the development of new measures or adjustments to the measures that we're proposing or to incentivize facilities that care for the sicker patients [who can] generally contribute to lower facility measure rates.

Efficiency and cost of care topic area – we're not currently aware of these issues and measures that might be appropriate for the ESRD population that we might have to include in the Quality Incentive Program. We are requesting comments on this.

And then there are rules of other potential areas for measures development including kidney transplant to health-related quality of life, the use of health information technology for quality improvement in the provision of care. And the next one is exchange of information and care coordination as Jean mentioned earlier in this presentation, and essentially, the blood transfusion measures, and other suggestions that you might want to make.

And I want to highlight this one other proposal. We are proposing to establish a format whereby the performance standards, achievement threshold, and benchmark would not be moved in the direction of a lesser performance measure. That is, if the final performance values for Payment Year 2015

performance standard would not be worse than the [previous] Payment Year 2014 performance standard for the measures, we would then propose to substitute the better of the two, or the Payment Year 2014 performance standards, of that measure.

We believe that the Quality Incentive Program should not have lower standards than in the previous years, and certainly we intend to continue to go in the direction of improving care, as Jordan stated earlier.

We look forward to receiving the comments about any or all of these areas, or any other topics that you wish to address. We're very much looking forward to your comments. Now, I'd like to ask Brenda Gentles to walk you through the commenting process.

Brenda Gentles: Great. Thank you very much, Teresa. Now that we've shared so much information about the proposed rules, the clinical measures, the reporting measures, the scoring, and the methodology, let's switch gears and talk about the commenting process.

Beginning on slide 52, you'll see outlined for you the ESRD QIP timeline and what you'll see is that there are multiple activities occurring simultaneously throughout the payment year.

As we're looking at the slide, we're in July of 2012. You'll notice for Payment Year 2013 that we're in the Preview Period. For Payment Year 2014, we're in the performance period. And for Payment Year 2015, the proposed rule has been posted, and the comment period is open.

Moving on – this slide 53 [shows] your role in the regulation process. Slide 53 provides a high-level overview of the federal rulemaking process. And what you'll notice here is that your public comment is listed in here as well.

As Teresa said, and as many of my colleagues have said, we really want your comments on the proposed rule. But please note that your participation in the process is essential to creating the best possible program. In the past, we have changed course based upon your feedback. And again, please note that the

public commenting period will be ending August 31, 2012. Your comments matter.

On slide 54, we'd like to share with you a screenshot; perhaps the most efficient way to submit a comment is online. So, if you're looking here, you see the screenshot, you can use the search feature and type in the actual regulation that you're looking for, and you can do this in multiple different ways. It will launch many, many results for you.

On slide 55, you'll see the results that will come up for you. Over to the right hand column, you'll see that there is a comment box. Once you found the particular regulation title, you click on "Comment Now." And it will launch, on page 56, the actual comment box where you could begin your comments.

On all of your comments as well as any of the files that you upload, we ask that you place the file number, CMS-1352-P, on all correspondence.

On slide 56, you have an area to input your demographic information, another for your comments, and [the chance to] upload any additional files. Before submitting, you can certainly preview your comments. Please note that you only have 20 minutes to complete your comments.

We'll move over to slide 57. All of you, please don't worry. If you don't like to do it online, we do have an alternative method that's listed on slide 57. You can use regular U.S. Postal Service mail. Just please allow enough time for delivery. Express overnight, as well as any courier or hand-delivered mail, will be accepted.

Please review the proposed final rule for the specifics of how to go through this process.

Slide 58 – CMS welcomes comments on any portion of the proposed rules that any of my colleagues mentioned. Slide 58 reiterates that we look forward to your comments and we value your comments.

In particular, we'd like for you to consider sharing your thoughts on the sub-bullets that you see listed here: proposed rules about reporting requirements

such as the PSC; the method for creating a single score for each of the two measure topics; achievement and improvement comparison periods; use of small facility adjusters; weighing of clinical and reporting measures to create the TPS; and, of course, future measures.

This [commenting process] is one of the best ways to get your voice in the room. And now, I would turn the presentation back over to Anita.

Anita Segar: Thanks, Brenda. To recap this presentation today, the proposed rules for Payment Year 2015 shares a lot of the basic structure with Payment Year 2014, while additionally making several important distinctions.

I'm on slide 60. This slide lists the similarities between the two program years, 2014 and 2015. As you can see, the overall structure has not changed in terms of the Total Performance Score being comprised of the clinical and the reporting measures, the Total Performance Score ranging from 0 to 100 points, et cetera. We have a combination of clinical and reporting measures that are either included or expanded from previous years.

Moving on to slide 61, Payment Year 2015 does present some program evolution, including a more comprehensive measure of dialysis adequacy. The URR is replaced by the Kt/V dialysis adequacy measure, [and also includes] a hypercalcemia measure. We demonstrate for the first time the ability to use reporting measures as the basis for new clinical measures.

The proposed small facility adjuster creates a new method of scoring low-volume facilities, [so that] we can continue to apply the ESRD QIP to the widest possible spectrum of facilities. The new anemia management reporting measure allows CMS to monitor care with regard to low hemoglobin results, and presents a more comprehensive picture of anemia management in addition to the clinical measure capturing the high hemoglobin result.

Slide 62, this slide demonstrates some of the updates to the mechanism of the program – I'm sorry, the mechanics of the program including the use of more-recent data for the program year. Payment Year 2015 re-weighs the balance

between clinical and reporting measures in creating the total performance score.

Also proposed is that a facility must have scores in at least one clinical measure and one reporting measure to be eligible for participation, and that's included before CMS seeks comments on these proposals.

The last slide in this section is slide 63. For your convenience, this table details the comparison between Payment Year 2014 and 2015 in terms of the measures, the other calculations, related criteria, and specifics. And now, I'm happy to turn the presentation back to Brenda.

Brenda Gentles: Thank you, Anita. In this next section, we actually outlined some resources and the next steps with you.

On slide 65, you'll just notice we have outlined here [that] not all measures apply to all populations, but at least one measure applies to each population. So, again, it's broken up by the modalities that you can see here.

Moving on to slide 66, we have listed websites of the resources that we have for you. Of course, MIPPA is listed at the top. But what I really would like to do is to point out the Dialysis Facility Reports [site] that's listed at the bottom. You'll notice if you go to that particular website, of the options that's listed here up at the top, there is a tab that's listed FAQ.

And if you click on any of the FAQs, you will already see some of the questions that have been asked. So, there's a long list of questions that are listed there. There are questions in regard to DFR that's also listed there, as well as all of the resources, the web resources that are also listed in this presentation. But I wanted to bring your attention specifically to that particular URL.

Slide 67 has listings for the clinical measures, and again, once you click on those particular clinical measures, a PDF will come up with the measure description, the numerators, and the denominators as well.

Slide 68 has the reporting measures, which are also listed in a very similar fashion.

On slide 69 are some of the next steps that we would like for you to take. Certainly, we want you to comment on the Payment Year 2015 proposed rule. We want also want you to click on your calendars and make sure that you're inputting the rest of the next steps that are listed here.

Review the Payment Year 2013 preview Performance Score Report, which will be available July 15, 2012, and submit any clarification, questions, or a formal inquiry there.

Please read, in early November, the Payment Year 2015 final rule when it is actually posted. And then review the Payment Year 2013 final PSR when available, which will come up in mid-December. Post the Payment Year 2013 PSC are available, again, in mid-December.

To wrap up this presentation, I would like to turn it back over to Matthew Brown. Matthew?

Matthew Brown: Thank you. And we will have time for a few questions, yes?

Teresa Casey: Yes.

Matthew Brown: OK. Jay, if you would remind the callers how to enter the queue to ask their questions?

Operator: As a reminder, ladies and gentlemen, if you would like to ask a question, please press star, then one, on your telephone keypad. If you would like to withdraw your question, please press the pound key.

We'll pause for a moment to compile the Q&A roster. And the first question today will come from Andrew Barba with DaVita. Your line is open.

Andrew Barba: Hello. Thank you for taking my question. For the Kt/V measures, will there be a minimum claim requirement of four, as in [other] clinical measures?

Joel Andress: For the Kt/V measures, there is not a minimum required score, and the minimum claim is one. So, there is no minimum claim requirement for the measures themselves, no.

Andrew Barba: And could I ask, why would that be different than how we are thinking about URR?

Teresa Casey: Can I just also point out that when you look at the exclusions, though, patients on dialysis less than 90 days are excluded from the measure? So, that if that's what you're getting at, if you're getting it something else in terms of the number of claims.

Andrew Barba: Not to lengthen this too much, but [can you tell us] more about being responsible for the patient during the year, as opposed to a patient that comes in just once as a visitor and then is really cared for in another facility.

Teresa Casey: Thank you for your comment. We do have criteria that the patient has to have been at that facility at least twice during the claim month. We would look forward to your comments. Certainly, I think that this measure has gone through NQF endorsement, and I don't know if that has been discussed at that point in time, but certainly we would invite you to send your comment about that.

Andrew Barba: Thank you.

Teresa Casey: Thank you.

Operator: The next question comes from the line of Gareth Paglinawan with CSC, your line is open.

Gareth Paglinawan: Do we have plans of including the Standard Hospitalization Ratio for 2015?

Teresa Casey: I'm sorry, I could not quite understand your question.

Jordan Vanlare: No, we do not propose including Standard Hospitalization Ratio in Payment Year 2015, but we are seeking comment on how we might be able to

effectively incorporate it into the program in the future. And we welcome your thoughts on that.

Gareth Paglinawan: OK.

Teresa Casey: And we are looking forward to public listing of that information on Dialysis Facility Compare in 2013, which is separate from the QIP itself.

Operator: The next question comes from the line of John Stivelman with Northwest Kidney Center. Your line is open.

John Stivelman: Yes, thank you very much. This actually is a two-part question. I see in the rule that in the anemia management part, you're still potentially accepting both hemoglobin and hematocrit. I was wondering if a) if that is going to change anytime in the near future so that only hemoglobin is accepted without a division of the hematocrit by three; and second, the ESA reporting with the hemoglobin which I see as part of that measure, will that be measured going to an absolutely delivered dose of the ESA, or a weight-normalized dose of the ESA per kilogram body weight?

Thank you very much.

Teresa Casey: I thank you for your question. And the parameters surrounding the reporting for the claim is outlined on Change Request 7460. And so, you know, outside of those instructions, I really cannot add to that in terms of whether we're planning a change to restrict the submission to hemoglobin. I'm not aware of a plan – any immediate plan – to do that.

Although certainly, I do understand that you know, perhaps hemoglobin could be more desirable in terms of what is measured. I'm not aware of any movement on that. If you would like to submit that as a comment, we would be happy to further consider your comment.

John Stivelman: Thank you.

Teresa Casey: Thank you.

Operator: The next question comes from the line of David Blaszczak with Potomac Research Group. Your line is open.

David Blaszczak: Hi. Can everyone hear me OK?

Teresa Casey: Yes, we can hear you fine. Thank you. Go ahead.

David Blaszczak: Great. Thanks for doing the call. There's a lot of very helpful information. I just have a question on ESRD integrated care models. There's been a lot of talk since the beginning of the year, from particularly a couple of large dialysis organizations, about an integrated care model developing pretty quickly – as soon as this year possibly. And it seems to me, it's kind of odd because you have a very new payment system that we just went to everything that's happened with QIP recently.

And if that's the case, if you could address or talk about that a little bit? I think it helps people in the ESRD arena of you know, how to prepare for something like that especially if you have a lot of doubts in organizations that are going into an integrated care model.

So, how would that work with – is that even a possibility? And then, two, I guess how does that work with the current payment model?

Jordan Vanlare: Thanks so much for your question and for bringing up the topic that, you know, really is a primary focus of CMS and was the major thrust behind the Affordable Care Act. So, there's a number of programs at CMS that we think are helping to facilitate transition from volume to value, and also that we're looking at delivery system reforms. Specifically as things relate to the QIP, I think an important effort that we're looking at seeking comments on is the measures that are actually a part of the program, and to the extent that measures are outlined across the QIP and other settings of care that can lead to a more integrated care experience for our beneficiaries.

The Center for Medicare & Medicaid Innovation is actually the part of our agency that is leading the pilot programs and demonstration projects behind delivery and payment system reforms that go beyond the value-based purchasing and shared-savings type of programs that are already has been

rolled out nationally, and would encourage you to look at some of the materials that they [make] available to find out more about how we're thinking about innovating in its delivery and payment system for the ESRD community.

David Blaszczak: But is that something dialysis organizations should prepare for, I guess if something is moving that quickly toward to an integrated care model for, you know, should the assumption be you're in this payment model for a certain period of time?

Jordan Vanlare: So, to the extent that the QIP captures the sense of more accountable care and that the measures that are currently proposed in the contracts of the QIP as well as the measure concepts that we have, we are seeking comments on [them] in this year's rule. We encourage dialysis facilities to be preparing for those transitions in the program. And beyond that, we just ask that you keep abreast of what's coming out of the CMMI, and thank you for your thoughtfulness on supporting the health systems through its transformation.

David Blaszczak: Great. Thanks for your time.

Operator: The next question on the line comes from Dolph Chianchiano with the National Kidney Foundation. Your line is open.

Dolph Chianchiano: Thank you for the excellent and thorough review of the Federal Register posting on the 11th. I have a question specifically with regard to new measures or upcoming measures within [the program] that has to do with population community health measures.

From what you said, Teresa, and from what I read in the Federal Register, am I correct in assuming the agency is looking for a measure that would track whether or not there is cherry-picking among dialysis stations?

Teresa Casey: Thank you, Dolph, for your question. The answer is, yes, I agree. Joel, do you want to…

Joel Andress: Well, I just wanted to say that we're always cognizant of the risk of that, and also the consequences when we implement measures. And so we always want

to be – always want to be on the lookout when we make rules. We may find unintended consequences to care within the current system of care.

And so, I think the simple answer to your question is yes. We're certainly interested in measures that accomplish that. We're interested in minimizing any potential risk resulting from our VBP programs.

Dolph Chianchiano: Thank you.

Teresa Casey: Thank you, Dolph.

Operator: The next question comes from the line of Vladimir Ladik from DCI. Your line is open.

Vladimir Ladik: Hello. I have a question about reporting measure [for] mineral metabolism, and my understanding is that this measure will be derived from data submitted through CROWNWeb. I do have several comments about that and one is CROWNWeb is just released and still has a lot of defects. What if I or my clinic was not able to submit calcium and phosphorus data because one of CROWNWeb's defects? Then my clinic will be penalized because I do have one or several patients without data and because they don't have data, I would not have 12 consecutive months of old patients having data.

Teresa Casey: Thank you for your question. Now, CROWNWeb, as you mentioned, went national on June 14th. Now, when we're talking about the calcium phosphorus monitoring reporting measures, we're talking about a performance period of Calendar Year 2013.

Vladimir Ladik: I can guarantee you, the defects will not be fixed.

Teresa Casey: I understand your comment and I certainly agree that we have some work to do in terms of CROWNWeb, and we are making improvements and corrections on weekly, if not daily, basis.

And so, for the purposes of the QIP, the reader should make the assumption that CROWNWeb will be up and running and certainly, if we run into issues with that, we would have to take a corrective action or mitigate that particular

issue. But we are expecting that CROWNWeb would be able to accept calcium and phosphorus levels in 2013.

Vladimir Ladik: The second question I have is the way you design this reporting measure is that the clinic has to have calcium and phosphorus for every patient, every month across the whole year. And if that particularly could not be achieved, for example, there could be a patient who came in the first of the month, and was in the clinic again in the third of the month, and the clinic's scheduled to have the monthly chemistry normally on a seventh of the month, but this patient dies.

And because of that, we would not have calcium and phosphorus with this patient. You however, would have this patient dialyzed in the clinic for two treatments, and because of that, you would require to have calcium and phosphorus for this patient.

I think the situation where the clinic is scheduled to have monthly chemistry to be done in the first week of the month, but the patient actually came in a last week of the month and was in clinic only for two days, and again, for this patient, you will miss – my estimate and based on the data is that at least you know, you have to – you probably are going to miss calcium and phosphorus for at least 5 percent of the patients every month.

Teresa Casey: Thank you for your comment. And looking at some of the data that we do have, it looks as if there will be – already was a pretty high compliance rate of something in the neighborhood of at least 95 to 96 percent.

Now, we have proposed to include some additional criteria for the measure, and that the patient would have to be alive at the end of the given month in order to be included for this measure. The patient had been in the unit for dialysis of at least two times during the month.

And you know, I have to, you know, note that really the purpose of this measure is to encourage facilities to set up the systems, procedures, and processes so that, you know, patients don't get missed. Now, I will also encourage you to take a look at the statement in the rule regarding these changes, and we also ask for a comment on whether that 100-percent

threshold should be reconsidered or changed to something more like 98 percent.

And so, we have asked for comments on that very point and I would encourage you to send a comment to us.

Vladimir Ladik: Yes, we are preparing comments. Another question I have is about hemoglobin measure. And in hemoglobin if, you know, the hemoglobin that we report on the claim has to be hemoglobin from a previous month. And so, to demand that every patient have a hemoglobin from a previous month [is] unreasonable because the patient may not be even in my clinic in the previous month.

Teresa Casey: So, again, I would ask you to look at the, you know, inclusions/exclusions that we have, you know, put out there to the public for comment and encourage you to send that comment into us. We'll look forward to it.

I think we might be – have time for only one more commenter. So, I would like to ask our facilitator if there's maybe one more comment that we might address.

Operator: The next question will come from the line of (inaudible) with CSC.

Male: Thanks to all the presenters. I have two questions. One is that you have mentioned about the measures and exclusions. I wonder if these exclusions are (inaudible) conditions, that means all the – if exclusion condition won't be satisfied, or at least one of them could be satisfied for the measure to be excluded.

Teresa Casey: If you feel one exclusion criteria applies, then that patient would be excluded from the measure, and I would encourage you to go to the specifications in the URLs that were listed in the rule, as well as in this presentation. But I would highly encourage you to read the rules.

Male: OK. And a related question in the Total Performance Score calculations, if there are any problems with respect to certain measures, can we suppress that measure and include only the (inaudible) measures for the total calculations?

Teresa Casey: I couldn't quite hear your full question. It sounded like you were asking about measures suppression?

Male: Yes. If there are any problems with certain measures, in the total calculations, can we ignore that and calculate for the rest of the measures to compute the total calculation?

Teresa Casey: OK. If you're talking about the development work for the QIP, I think we need to have offline conversation about that.

Male: OK.

Male: Can you provide your phone number, (Rama)?

Male: Yes, that's fine.

Teresa Casey: I think we don't have enough time to [continue answering] questions. I'd like to thank everyone for your participation. I regret that we didn't have time to, you know, answer all of the questions or even to have the questions asked. Our minutes are up and we, again, for the hundredth time, encourage you to send us your comments. Thank you very much.

Matthew Brown: Thank you and remember there will be an encore – excuse me, not an encore but a transcript – posted to our website, our Special Open Door Forum website, and we hope to have that up in the next few days. So, look forward to that. And we will make sure that it sends an update to your e-mail subscriptions.

So, thanks again. Jay, do you have anything else to add, or should we just end the call there?

Operator: I have nothing else to add, sir. Thank you, everyone, for joining. This concludes today's conference call. You may now disconnect.

END