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National Provider Call - Transcript

Centers for Medicare & Medicaid Services
ESRD Quality Incentive Program
Notice of Proposed Rulemaking: Payment Year 2016
MLN Connects National Provider Call
Moderator: Aryeh Langer
August 14, 2013
3:00 p.m. ET

Contents

Operator: At this time, I would like to welcome everyone to today's MLN Connects National Provider Call.

All lines will remain in a listen-only mode until the question-and-answer session. This call is being recorded and transcribed. If anyone has any objections, you may disconnect at this time.

I will now turn the call over to Aryeh Langer. Thank you. You may begin.

Announcements and Introduction

Aryeh Langer: Hello. This is Aryeh Langer from the Provider Communications Group here at CMS, and I'm your moderator for today's call.

I would like to welcome you to this MLN Connects National Provider Call on the End-Stage Renal Disease Quality Incentive Program. This call focuses on the proposed rule for operationalizing the ESRD QIP in payment year 2016. This proposed rule was displayed on July 1st and published in the *Federal Register* on July 8th. MLN Connects Calls are part of the national Medicare Learning Network.

The ESRD QIP is a pay-for-performance initiative that ties a facility's quality scores to a payment percentage reduction over the course of a payment year. The public will have until August 30th, 2013, 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. A question-and-answer session will follow today's presentation.

Before we get started, I have a couple of announcements. You should have received the link to the slide presentation for today's call in previous registration emails. If you have not already done so, please download the presentation from the following URL: www.cms.gov/npc. Again, that URL is www.cms.gov/npc. At the left side of the web page, select "National Provider Calls and Events," then select the date of today's call from the list.

Second, this call is being recorded and transcribed. An audio recording and written transcript will be posted to the MLN Connects Call website. An announcement will be placed in the MLN Connects Provider eNews when these are available.

And third, registrants were given the opportunity to submit questions in advance of today's call. We thank those of you who took the time to do so. While they may not be able to be addressed today specifically, they will be used for future presentations, frequently asked questions, or other educational materials.

At this time, I would like to turn the call over to Jim Poyer, director of the Division of Value, Incentives and Quality Reporting in the Center for Clinical Standards and Quality, or CCSQ, here at CMS. Jim?

Presentation

James Poyer: Thank you. I'd like to thank everyone for participating in today's meeting. Today we are going to discuss the proposed rule for the payment year 2016 ESRD Quality Incentive Program, or QIP, which, as you know, is very complex. We'll discuss why this proposal process is important to you and what steps you'll need to take to participate in the comment period.

We'll be presenting a great deal of information over the next 90 minutes, and I think that we'll be able to provide a good understanding of how facilities will be impacted by the proposed features of the payment year 2016 program. We'll go over our prepared presentation with you and then open up the discussion for questions.

We need to emphasize a couple of points, though. Please save your ideas and questions about the proposed rule itself, and please share your thoughts formally by participating in the formal comment period that is now ongoing.

And many of you will want additional information that we won't be able to cover today, so I invite you to review the online resources listed in our slide deck. Questions that remain can always be sent to our mailbox, esrdqip@cms.hhs.gov.

And I'm going to slide 5, if you're following on the slide deck.

Joining me today presenting information are Joel Andress, the measure development lead for the ESRD QIP program; Anita Segar, the ESRD QIP program and policy lead; and Brenda Gentles, the ESRD QIP communications and monitoring and evaluation lead.

And I'm going to turn to slide 6.

Introduction

Payment year 2016 represents the fifth payment year for the ESRD QIP. It reflects the increasing complexity of the program and the variety of strategies we want to take in improving the lives of patients with ESRD. But how does the program fit in CMS's overall goal of improving quality?

And I'm on slide 7.

The Value-Based Purchasing, or VBP, programs at CMS incentivize better care across care settings. We expect—patients should expect cost-effective, quality care. And VBP is an avenue to assist CMS in achieving that goal.

And the VBP programs—and QIP is one of them—promote CMS's three-part aim: better care for individuals, better care for populations and communities, and lower cost through improvement. And the ESRD QIP was the first Federal Value-Based Purchasing program. And rather than paying dialysis facilities based on how many patients they treat, Medicare can now pay dialysis facilities on how well those services help to keep patients safe and healthy.

And the ESRD QIP uses the Government's purchasing power through Medicare to incentivize improvement in treatments of patients with ESRD. These incentives drive care throughout the health care sector, not just to Medicare patients. And I refer to slide 8 in the slide deck.

The ESRD QIP for payment year 2016 addresses three of the six Department of Health and Human Services, or HHS, National Quality Strategy domains. And the three domains are safety, patient and family experience of care, and treatment and prevention of chronic disease.

The next few slides will provide an overview of the legislative aspects of the program. And for that, I will turn the presentation over to Anita Segar. Anita?

ESRD QIP Overview

Anita Segar: Thank you, Jim. In this section, as Jim referenced, we'll share some information about the legislative nature of the ESRD QIP before delving into the composition of the payment year 2016 program and the comment period itself.

Slide 10. MIPPA amended the Social Security Act to mandate the creation of the ESRD QIP. ESRD QIP is intended to promote patient health by providing a financial incentive for renal dialysis facilities to deliver high-quality patient care. MIPPA also provides the mechanism for establishing standards of care and authorizes payment reductions for facilities failing to meet those standards.

Slide 11. MIPPA gives CMS the authority to establish standards by which ESRD facilities will be evaluated. ESRD QIP also sets down the way individual measures are used to create an overall score. CMS will impose a payment reduction of up to 2 percent if the facility score does not meet a minimum Total Performance Score.

Information about the facility's performance in the ESRD QIP is contained in the Performance Score Report, or the PSR. As you know, public reporting of the results is a key component because it allows consumers to select facilities based on care, and it provides a mechanism by which facilities may judge their performance compared to the performance of others.

The Performance Score Certificate, the PSC, is a prime vehicle for communicating the facility's performance under the ESRD QIP to its patients. Dialysis Facility Compare, or DFC, also provides information about facility performance to the public. CMS releases detailed facility performance information in a large spreadsheet, as well, and posts it on the web.

With the structure of the program in mind, we turn now to how it evolved from year to year through the rulemaking process.

On slide 12, CMS outlines—you'll see that CMS outlines payment year programs by creating rules on an annual basis. So every year to date, CMS proposes a rule that specifies measure selection, scoring and weighting methodologies, and payment reductions. A public comment period follows, and CMS considers these comments in preparing the final rule for publication. Now, as the program evolves, CMS will continue to establish measures that reflect standards of quality in the care of patients with ESRD.

And with that background in mind, let me turn the presentation over to Joel Andress, who will open our discussion of the proposed rule with a review of the clinical measures. Joel?

PY 2016 Proposed Clinical Measures

Joel Andress: Thanks, Anita. My name is Joel Andress. I'm the Government task lead for ESRD quality measure development at CMS.

In this section, we'll be looking at the measures we propose to use in the clinical performance portion of the payment year 2016 payment determination, both old and new. Please note at the bottom of this slide, we provide a disclaimer that says these elements presented—the elements presented in this section, the quality measures and all other portions of the proposed rule, are subject to change until the rule has been finalized.

Moving on to slide 14, we have here a graphical representation of the proposed rule and its measures. The nine proposed clinical measures will make up five distinct scores that comprise 75 percent of a facility's Total Performance Score. These distinct scores are considered measure topic scores and will be referred to as such throughout the remainder of this presentation. Of these measures, six are carried over from the payment year 2015 rule while three are newly proposed in the 2016 NPRM.

The five proposed reporting measures will make up the remaining 25 percent of the Total Performance Score. Of these, one measure has been expanded, two have received minor revisions that Anita will be addressing later in the presentation, and two are newly proposed in the payment year 2016 NPRM.

Please note that the new measures are indicated by a gold star in the—in the slide you're now looking at. And that icon will appear when we talk about each measure in turn.

In slide 15, we have a brief discussion regarding the directionality of measures. Among the clinical measures, the directionality varies. And it's important to keep that in mind when you are assessing—when we are assessing the performance rates and their comparison to achievement thresholds and benchmarks.

For some of the measures, including informed consent, dialysis adequacy, and the fistula measure—fistula measure for vascular access, higher rates of performance indicate better care provided to patients. For other measures, including the hemoglobin greater than 12, vascular access measure for catheters, the NHSN bloodstream infection measure, and hypercalcemia, a lower rate indicates better care on the part of facilities.

This slide indicates the consequences that directionality has for assessing facility performance on individual measures. As you can see, depending on directionality, the benchmark will either be at the higher or lower end of the performance range. And this will become relevant as we discuss later the methodology which is used to assess measure performance scores.

Different directionalities may even exist within measure topics. As one example, the anemia management measure topic includes the informed consent measure, for which a 99-percent rate would be a favorable outcome. But a 99-percent rate on the hemoglobin greater than 12 measure would be considered quite unfavorable.

On slide 16, we begin our review of the clinical measures proposed for 2016 with the anemia management topic. Anemia management has been a part of the ESRD QIP since the beginning, but we are proposing to expand it in payment year 2016.

In addition to retaining the hemoglobin 12 measure, which is unchanged from payment year 2015, we propose adding a measure that assesses whether individual patients have received—have reviewed the risks and benefits of anemia treatment options with their physicians and have provided informed consent for that treatment.

I will also note here that for details on all of the proposed measures, including these, we have included links to the technical specifications at the end of this presentation, and they have also been provided to you through the rule.

On slide 17, we look—we are looking at the second measure topic, Kt/V dialysis adequacy. This topic is comprised of three measures, which remain unchanged from payment year 2015 and address dialysis adequacy for adult hemodialysis patients, adult peritoneal dialysis patients, and pediatric hemodialysis patients. These three measures will combine to form one unified score for the measure topic, and will be used to illustrate the relevant methodology a little later in this presentation.

On slide 18, we see the two measures that will be—form the vascular access type measure topic. These measures are also unchanged from payment year 2015. This is—this topic provides one of the examples in—one of the examples in which measures within a single topic have different directionalities, as the fistula measure indicates better performance through a higher score, and the catheter measure indicates better performance through a lower score.

On slide 19, we see one of the new measures that are being proposed in the payment year 2016 rule, the NHSN bloodstream infection in hemodialysis patients measure. In previous payment years, the ESRD QIP has monitored infections through NHSN via a reporting measure. In 2016, we propose to convert this into a clinical performance measure of bloodstream infections.

Unlike the previously discussed measure topics, this measure stands alone as its own topic. This is the first example in the ESRD QIP of using the data received in a reporting

measure to convert it to a measure of clinical quality. It should be considered an all-or-nothing measure. Whereas in previous years the reporting measure has given credit for partially reported data over the course of the year, in this case failure to properly report data for all 12 months of the performance period will result in zero points being awarded for this measure. Note also that the NHSN is a CDC program, and we have adopted their approach in order to characterize our measure as simple proposed to be implemented in the ESRD QIP.

In slide 20, we see the last clinical performance measure proposed in 2016, hypercalcemia. Hypercalcemia has been previously proposed but not finalized in the ESRD QIP due to stakeholder concerns that baseline data were not representative of small dialysis organizations because the data use—for use—that were used originated from a pilot program of the CROWNWeb data system.

We believe we have corrected for this issue using data collected through CROWNWeb since it went live in late 2012, and have—have incorporated data—by incorporating data from all dialysis facilities, not merely—and not over-representing the large dialysis organizations.

As a final reminder to all of you, technical specifications for each proposed measure, including definitions and exclusions, are available through links provided at the end of the presentation and through the proposed rule itself. Remember that you will have the opportunity to ask questions at the end of this presentation regarding the proposed measures. And we'd certainly invite you to submit comments to us prior to the end of the public comment period on August 30th.

Scoring PY 2016 Proposed Clinical Measures

In the next section, we'll be reviewing the scoring methodology used to incorporate the clinical performance measures and the Total Performance Score that will—that will assess your final payment determination. Overall, the proposal continues to use the methodology—methodologies established in earlier payment years. And this includes the application of the low-volume facility adjuster that debuted in payment year 2015.

Slide 22 presents a few terms with specific definitions in the context of the scoring – of our approach to scoring, for your reference and convenience. These terms will be recognizable to anyone familiar with the payment year 2015 rule. The data periods for establishing thresholds, benchmark, performance standard, and the performance period itself have all been updated to reflect the needs of payment year 2016.

The achievement threshold is defined as the 15th percentile of performance rates during calendar year 2012. The benchmark is defined as the 90th percentile of performance rates during the same calendar year. The improvement threshold is defined as the facility's performance rate as of calendar year 2013, and the performance period is defined as calendar year 2014. The performance standard is defined as the 50th percentile of performance rates during calendar year 2012, and the performance rate is the facility's raw score based on the particular measure's specifications.

Please note that these are general definitions. Exceptions do apply to some of the measures. And all of these exceptions are listed on slide 24 of this presentation, and we'll be reviewing them shortly. Note that the performance standard is not used in scoring any individual measure, but is used to calculate the minimum TPS.

On slide 23, you'll see a presentation of the general approach for scoring clinical measures. And this should seem—this should seem familiar to most of you from payment year 2015.

Facilities are scored on both achievement and improvement, and the highest of the two scores contributes to the measure topic score and, ultimately, to the TPS. CMS favors achievement over improvement, which is why a facility can score a maximum of 10 points using achievement while it's limited to a maximum score of 9 for improvement.

Slide 24 provides a list of scoring exceptions as they apply to three clinical measures. The first measure that—with exceptions is the patient-informed consent for anemia treatment. The facility's measure score is determined by clinical standards rather than baseline data. And these have been provided in the—in the proposed rule. Because prior performance data are not available to establish an improvement threshold, facilities will only be—will only receive an achievement score for this measure.

For the NHSN bloodstream infections measure, the comparison period for establishing the achievement threshold and benchmark is the same as the performance period, i.e., calendar year 2014. Because prior performance data are not available to establish an improvement threshold, facilities will, again, only receive an achievement score for this measure in payment year 2016.

For hypercalcemia, a slightly different comparison period—that is, May 2012 through November 2012—will be used to establish the benchmark and achievement threshold. This is owing to the fact that data are delivered in 3-month increments, and CROWNWeb went live with data collection beginning in May 2012, and so data are not available for the entire population of facilities prior to May of that year.

Now, the next six slides will demonstrate how an individual clinical measure may be scored using the example of a hypothetical facility—a hypothetical Facility A's performance on the vascular access type: fistula measure.

In slide 25, we'll look at the achievement method for scoring, which compares facility performance to national averages using the vascular access type: fistula measure as an example. The estimated achievement threshold and benchmark values are published in the proposed rule and presented again later in this presentation.

The other values used in the sequence of slides, such as the facility performance rates, are purely hypothetical to illustrate the calculations. For simplicity's sake, in this presentation, the achievement threshold and benchmark have been rounded to the nearest

whole percentage point, as you can see on the slide, and you should not take this to be representative of the actual scoring methodology.

For the purposes of this illustration, the achievement threshold, or 15th percentile of the national facility performance, is presumed to be set at 50 percent, and the benchmark, or 90th percentile of the national facility performance, is set at 77 percent. The achievement range runs from the achievement threshold of 50 percent to the benchmark, 77 percent.

On slide 26, we have the facility's performance rate for calendar year 2014 of 54 percent. And the equation we use to calculate the score—those of you familiar with payment year 2015 will note that the formula has not changed since then.

On slide 27, we incorporate values for the achievement threshold, benchmark, and facility performance rate into the equation and calculate the achievement score of 1.83. The facility's score for this measure is then rounded to the nearest whole number, resulting in an achievement score of 2.

In slide 28, we compute the improvement score for our fictitious Facility A, which compares the facility's performance rate to its own past performance with the VAT: fistula measure. In our example, the facility had a 26-percent rate in 2013, and that serves as the improvement threshold. The benchmark here remains 77 percent and provides the upper end of the improvement range.

In slide 29, we have the equation we use to calculate the score. And once again, it's the same equation we've used since payment year 2015, without any changes.

In slide 30, we plug the values into the equation for the—for the improvement threshold, benchmark, and facility performance rate and calculate the improvement score. The formula results in a score of 4.99, which we then round to a score of 5. By comparing the achievement score of 2 to the improvement score of 5, we can see that the improvement score is the higher of the two, giving Facility A a measure score of 5 for the VAT: fistula measure.

On slide 31, we observe a different hypothetical Facility B whose performance rate was higher than the benchmark. We have no need to calculate either the achievement or the improvement score in this case. Because Facility B has a rate above the benchmark, it automatically earned the full 10 points for the measure.

On slide 32, we observe the consequences of a third facility, Facility C, scoring below both the achievement threshold and the improvement threshold. Facility C had the same calendar year 2013 performance rate as Facility A at 26 percent. However, instead of increasing its rate in 2014 like Facility A, Facility C's performance rate declined to 23 percent. Because Facility C's performance rate is below both thresholds, the facility automatically receives zero points for the measure without calculating either the achievement or improvement score.

Note that it is possible to fall below the achievement threshold but not the improvement threshold. This is—the opposite is also true. In this event, it is possible to receive points for only one of the scoring methods. In such a case, the highest score is applied to the facility's measure score.

On slide 33, we demonstrate how we propose to create a score for measure topics that incorporate multiple measures by proportionally weighting the score of each component measure. It's essentially the same calculation as used in previous years.

This example uses the Kt/V dialysis adequacy topic with three component measures to illustrate the calculation. The numbers, once again, are hypothetical.

In our example, the facility treats 100 eligible patients with ESRD each month. Because 60 percent of the facility's patients are adult hemodialysis patients, the facility's score on the relevant measure weighs more heavily into the measure topic score than do the measures for adult peritoneal dialysis and pediatric hemodialysis.

If a facility reports zero patients eligible for one of the measures, then the other measures will continue to contribute for the facility's score. Each measure is independent and calculated individually. The reason they get combined into a composite score is to contribute directly to the facility's TPS.

Please note that the individual measure denominators for Kt/V use patient-month as defined by the measure specifications and made clear in the proposed rule. However, the weight—for weighting purposes and establishing the single measure topic score, the denominators used for weighting incorporate the number of patients only.

On slide 34, we see the aforementioned calculated achievement thresholds, benchmarks, and performance standards as published in the payment year 2016 proposed rule. Improvement thresholds are dependent on individual facility performance and so are not available here in this slide. These values are estimated based on the most recently available data and will be finalized at a later date.

Now that we've reviewed the makeup and calculation of the nine proposed clinical measures, I'll turn the presentation back over to Aryeh for an important announcement.

Keypad Polling

Aryeh Langer: Thank you, Joel.

At this time, we'll pause for a moment to complete keypad polling so CMS has an accurate count of the number of participants on the line with us today. Please note, there will be silence on the line while we tabulate the results.

Victoria, we are ready to start polling before we get back to Anita.

Operator: CMS appreciates that you minimize the Government's teleconference expense by listening to these calls together using one phone line. At this time, please use your telephone keypad and enter the number of participants that are currently listening in.

If you are the only person in the room, enter 1. If there are between two and eight of you listening in, enter the corresponding number. If there are nine or more of you in the room, enter 9.

Again, if you are the only person in the room, enter 1. If there are between two and eight of you listening in, enter the corresponding number. If there are nine or more of you in the room, enter 9.

Please hold while we complete the polling.

Thank you. I would now like to turn the conference back over to Mr. Langer.

Aryeh Langer: And I will now turn the presentation over to Anita.

Presentation Continued

PY 2016 Proposed Reporting Measures

Anita Segar: Thanks, Aryeh.

In this section, we'll examine the five proposed reporting measures for payment year 2016. We will consider the measure requirements as well as the way they are scored.

Slide 36. We've used the ICH CAHPS survey as a reporting measure for the last couple of payment years, but that involves only an attestation that the facility conducted the survey. We're proposing something a little different this year. We propose that the results are actually submitted to CMS.

The proposed rule requires that facilities contract with a third-party vendor to submit the data on its behalf in addition to conducting the survey itself. We intend that this new information will allow CMS to develop enhanced clinical measures in the future with regard to patient experience in receiving treatment from their dialysis facility.

Moving on to slide 37. Mineral metabolism is revised somewhat in that the proposal includes home peritoneal dialysis patients for the first time. In the event that the proposed hypercalcemia measure is finalized, we propose to remove the serum calcium component of the mineral metabolism reporting measure.

Slide 38. Similar to the mineral metabolism reporting measure, anemia management is revised also to include home peritoneal dialysis patients as well.

Slide 39. The payment year 2016 proposed rule includes two new reporting measures. The first is the measure of pediatric iron therapy. This will involve reporting treatment

data to CROWNWeb. And this measure is based on the number of quarters that the facility successfully submits this data.

Slide 40. The other new reporting measure is the comorbidity reporting measure. It also involves reporting clinical data regarding up to 24 different comorbidities to CROWNWeb. This measure is based on whether the facility satisfies the performance requirements by the deadline. As with all the other measures, detailed descriptions and exclusions can be found in the published technical specifications on dialysisreports.org. We've provided links at the end of this presentation for your reference.

Proposed Methods for Calculating the TPS and Determining Payment Reductions

Moving on to slide 41. Now that we have discussed how clinical and reporting measures will be scored, we'll talk about the methods used to create the Total Performance Score and the structure by which any payment reductions will be applied. We'll also take a moment here to identify some additional issues that are addressed in the proposed rule.

Slide 42. The process of calculating the facility's Total Performance Score is similar to what was used in previous payment years. The Total Performance Score will range from 0 to 100 points. In payment year 2016, clinical measures will account for 75 percent and reporting measures will account for 25 percent of the Total Performance Score. For payment year 2016, we require that a facility have a score on at least one clinical measure and at least one reporting measure, just like we did in payment year 2015.

Slide 43. This slide describes how the minimum TPS will be calculated. It is estimated at this time to be 46. So, we will calculate the minimum TPS by scoring a hypothetical facility as if it reached the performance standard—the 50th percentile nationally—for each clinical measure, or earned zero points for any measure for which the baseline value is not published in the final rule, and earned half of the available points on each eligible reporting measure.

Slide 44. Here's a chart demonstrating the ranges for payment reduction based on a facility's TPS. The minimum TPS is yet to be finalized. So this chart presents the ranges of potential payment reduction. And these same ranges have been used in payment year 2014, as well as in 2015.

On slide 45, you will see a graphical interpretation of how facilities will be scored, how these scores will translate into its TPS, and whether a payment reduction will be applied. This graphical interpretation shows the measures, the form those outputs will take for reporting measures, the category weights, and the scale for the payment reduction, if applicable.

Slide 46. The scope of the proposed rule also includes a handful of programmatic changes. It includes a modification of CMS's Data Validation program. We—we're proposing to reduce the number of facilities asked to participate from 700 to 300 facilities, as well as addressing possible additional efforts like the feasibility study. Also included is a modification to the requirement for posting PSCs, which is now

proposed to be extended to 15 business days after CMS has released the Performance Score Certificate, and inclusion of the Pacific Rim facilities as part of the ESRD QIP starting in payment year 2015—'14, sorry.

And with that, I'd like to turn this presentation over to Brenda Gentles for discussion about the comment period. Brenda?

Participating in the Comment Period

Brenda Gentles: Great. Thanks a lot, Anita.

Now we will share some guidance and recommendations for participating in the comment period for the proposed rule. But we begin with an overview of the program from a timeline perspective.

Slide 48. This graphic illustrates what's going on with the program as we speak. In this way, the ESRD QIP can be seen as a series of multiple-year programs. At any given time, multiple payment years are in motion.

Slide 49, Your Role in the Regulation Process. The process of creating and implementing Federal regulation includes the period in which the public may provide input on proposed rules. In past years, the comments that CMS received helped shape the final rules, and they sometimes reflected significant differences from the proposed rules as a result of those comments.

As an example, the payment year 2015 proposed rule included hypercalcemia as a clinical measure. But CMS changed course in the final rule due to the feedback it received as part of the comment process. A hypercalcemia measure is—excuse me—in this proposed rule was written in part to address the issues that commenters raised last year. Therefore, your participation in the process is essential in creating the best possible program for measuring facility performance and providing quality care to the ESRD population. Again, please note that the comment period will end at 11:59 p.m. on August the 30th, and that your comments matter to CMS.

Slide 50, Navigating the Payment Year 2016 Proposed Rule. This year, we have provided a chart to help you find your way around the proposal, and to give specific details in the proposal—to the proposal more easily. This is offered to assist you in reviewing and commenting on the rule. However, please do read the proposed rule in its entirety.

Slide 51, Commenting on the Proposed—on the Payment Year 2016 Proposed Rule. Perhaps the most convenient way to submit a comment is online through regulations.gov. Here is a screenshot of that home page. You can use the search box to navigate to the rule and the comment portion. We were able to use several search terms that successfully returned the proposed rule as a result, including the RIN, as pictured here, and "calendar year 2014 ESRD TPS," which is part of the proposed rule's formal title.

Slide 52, Submitting Comments on the Proposed Rule. Here on slide 52 we see a screenshot of our results. Use the Comment Now function to submit your comment. This slide also identifies some resources for additional help in using the system. Please note, the Help Desk phone number and hours of operation are displayed here.

Slide 53. You can upload files as part of your comment. Please note that this form has changed significantly over the last month. On this new form, your State, ZIP Code, country, and your category—whether you are submitting as an individual, a health care professional, or the like—are now required fields. You must also disclose that you are submitting the comment on behalf of a third party, if applicable.

Slide 54. You do not have to use the online interface to submit a comment. This slide identifies methods to deliver your comments in hard-copy format if you prefer. Please be sure, however, to allow time for transit and delivery to prevent any delays. More information can be found at the very beginning of the proposed rule.

Resources and Next Steps

OK. We're going to switch over to resources and next steps.

So, here on slide number 55, I'd just like to recap today's presentation. The proposed payment year 2016 rule shares a lot of structure with the payment year 2015, but includes some new measures.

New measures include patient-informed consent, HSN—NHSN bloodstream infection, hypercalcemia, pediatric iron therapy, and comorbidity. Also, the ICH CAHPS patient satisfaction survey was expanded, and the mineral metabolism and anemia management measures were revised.

Here on slide 56 we list some useful content about the program that is available online, including MIPPA, CMS ESRD QIP, the ESRD Network National Coordinating Center, Dialysis Facility Compare, Dialysis Facility Reports, and the proposed rule itself.

As promised here on slide 57 and also on 58, we have provided the URLs for the technical measure specifications for the clinical measures and reporting measures.

Moving on to slide number 59. Finally, here are a few actions that we recommend you take in the remainder of 2013. Comment on payment year 2016 proposed rule, review payment year 2014 preview Performance Score Report—and certainly, please just disregard the date that you see in there, but certainly submit any clarification questions or formal inquiries—read payment year 2016 final rule when posted in early November, review payment year 2014 final PSR when available in mid-December, post your payment year 2014 PSC in both English and Spanish when available in mid-December.

Thank you for your attention. CMS appreciates your cooperation, input, and your recommendations.

And now, at this time, I will hand the presentation over to Aryeh to proceed to our question-and-answer portion of the presentation. Aryeh?

Special Announcement

Aryeh Langer: Thank you, Brenda. Before we start the question-and-answer session, we would like to make a special announcement.

CMS will soon provide a new opportunity for Medicare-enrolled providers and suppliers to give us your feedback about your experience with your MAC, or Medicare Administrative Contractor, the contractor that processes your Medicare claims. This new assessment tool is called the Medicare Administrative Contractor Satisfaction Indicator, or MSI. Your feedback will help CMS monitor MAC performance trends, improve oversight, and increase efficiency of the Medicare program.

Each year, CMS will randomly select its MSI administration sample from a list of providers who register to become a participant. If you would like to register to become an MSI participant, or for more information about this program, please visit the website listed on slide 62.

Question-and-Answer Session

Our subject-matter experts will now take your questions. I'd like to remind everyone that this call is being recorded and transcribed, so before asking your question, please state your name and the name of your organization. In an effort to get as many of your questions as possible, we ask that you limit your question to just one. If you would like to ask a followup question or have more than one question, you may press star 1 to get back into the queue, and we'll address questions as time permits.

Victoria, we're ready to take our first question now. Thank you.

Operator: To ask a question, press star followed by the number 1 on your touchtone phone. To remove yourself from the queue, please press the pound key. Remember to pick up your handset before asking your question to assure clarity. Please note, your line will remain open during the time you are asking your question, so anything you say or any background noise will be heard in the conference.

Please hold while we compile the Q&A roster.

Your first question is from Vlad Ladik.

Vlad Ladik: Hello. I have the following question: hemoglobin greater than 12 measure, the threshold is 1.2 percent. The vast majority of clinics in the country have less than 80 Medicare patients. It means that, in those clinics, even one patient will put them below threshold. So it practically means that clinic either gets zero point or 10 point—points for this measure.

I don't believe, from statistical point, it's a good measure and a good way to score something like anemia. Is there plan to eliminate this measure in the future or at least change it to, perhaps, monthly measure similar to what we do with vascular access and kinetic modeling?

Joel Andress: Yes. This is Joel Andress, the measure lead at CMS. To answer very broadly, we're always considering the measures that we put into the rule from year to year. So we are—we are always taking—we'll take into consideration any comments about the changes that—or removal of measures that stakeholders believe is necessary.

The appropriate way to submit that—those comments is to provide it to us through the public comment period, which ends on August 30th, and we will address your concerns in writing at that time as we are finalizing the payment year 2016 rule.

Vlad Ladik: OK. Thank you. I will submit the comment.

Joel Andress: We look forward to them.

Operator: Your next question is from Joan Camarro-Simard.

Joan Camarro-Simard: Yes. I'm Joan Camarro-Simard. I'm from Intermountain Healthcare in Salt Lake. One question that I have is—regards to this—for payment year 2014, I have one of four facilities that I got zero points for the NHSN. Now, this facility only had 3 months where there were events. The rest of the months, I documented that there were no events. Could this possibly be the reason why I did not get any points for that facility?

Anita Segar: Hi, Joan. Thank you for your question. This is Anita Segar. It sounds like your question pertains to payment year 2014.

Joan Camarro-Simard: Yes.

Anita Segar: So, I would ask that you send a clarification question. We are—the preview period is under way at this time, so this is a good time for you to send your clarification question in, and we'll take a look at it there.

Joan Camarro-Simard: All right. Thank you. And I have done that already.

Anita Segar: OK, OK. Then it will be addressed. Thank you.

Operator: Your next question is from Allen Herman.

Allen Herman: Hi. My name is Allen Herman from the Rogosin Institute in New York. I wanted to know whether CMS differentiates with regard to the number of patients who have—the hemoglobin's greater than 12. Do they differentiate between patients who are receiving Epogen and those that—who are not?

Joel Andress: Yes. This is Joel. In order to qualify for the measures, the patients have to be receiving ESAs.

Allen Herman: Does that—does that mean if someone is not receiving an ESA, then . . .

Joel Andress: Then they are—then they are excluded from the measure itself.

Allen Herman: Thank you.

Joel Andress: During that claim month. Let me—let me clarify that. They have to be receiving the ESA during the claim month to qualify for the measure.

Allen Herman: OK. Thank you.

Operator: You do have a followup question from Joan Simard.

Joan Camarro-Simard: Yes. This is in regards to vascular accesses. What are they going to do in the future for those facilities that have about 20 percent of their population with functioning grafts that do not require replacement and/or the patient is unable to have an AV fistula?

Each of my four facilities were marked down because—well, three of them were—because they had at least 20 percent with functioning grafts. We passed on the catheters. But, again, are we going to continue to be penalized because the patient is functioning with an access that doesn't require being revised or changed?

Anita Segar: Hi, Joan. This is Anita Segar. Again, thank you for your question. This is an issue that has been brought to our attention, and we are aware of some of the needs over here as it relates to graft patients and where they fit in, because we have something for catheters and fistula but nothing for grafts.

So, we are aware of this. And what I would say is that, just—you know, if this is—I mean, definitely, this sounds like this is an important comment. So I would say if you would like to submit it formally through the formal comment process, this is something that we can actually address in the final rule and actually provide a response in the text of the regulation itself. But I do want to assure you that this is something that CMS is also looking at outside of the payment year 2016 rule.

Joan Camarro-Simard: Thank you.

Operator: Please hold for your next question.

You do have another followup question from Joan Simard.

Joan Camarro-Simard: Sorry. I have about four questions altogether. But this—I'm going down my list.

This past year we also got marked down on one of our facilities for the URR. The problem that, I'm thinking, might be the reason is we have a number of individual patients that (a) are noncompliant—we have very little control over that, and (b) patients that are very, very ill. We did not—we were not able to have the improvement. What type of qualifications and/or comorbidities will be—can we enter that will indicate why we're not able to increase the achievement for patients like this?

Anita Segar: Hi, Joan. This is Anita again. Thank you for your question. Again, I definitely realize—and I'm seeing that this is important to you and it's an important question. But since it pertains to the 2014 payment year and not directly in connection with the reason for our NPC today, which is payment year 2016, I would ask that you send that question to the QIP mailbox, the ESRD QIP mailbox, and we will take a look at it there, or send a clarification question.

Joan Camarro-Simard: I realize that. But this will probably be an ongoing issue that we'll probably be impacted. I'm presuming, hopefully, that with the Kt/V measure it might be easier to identify. But if this is still an issue, is this something that they might be considering in the future with looking at patient comorbidities?

Joel Andress: So this is—this is Joel. I—that's something that's difficult to respond to on the fly in terms of how measure specifications may change in the future given the processes that are—that are involved in making changes to the specifications. So, I don't think we could really do your question a good service by trying to respond to it now.

If you do submit the question in written form, however, both for the URR and the Kt/V, we will—we will do our best to get—to provide a response to your—to your question here. I just—I don't want to try to answer this on the fly, and I'm not really set up to respond to it effectively right now.

Joan Camarro-Simard: That's OK, I understand. Thank you. It was just something that I'm seeing, and I'm—you know, I'm sure other facilities have the same issue in that there are some things that we have very little control over and can have a big impact on our scores. And it's frustrating.

Joel Andress: Well, we appreciate you providing the feedback. It make—it makes it easier for us to keep track of these kinds of issues when they arise.

Joan Camarro-Simard: Thank you.

Operator: Your next question is from Lindsey Clemente.

Lindsey Clemente: Hi. I had a question about payment year 2014 QIP scores, as well. And I'm just noticing that the facilities that got kind of dinged with a reduction were the

newer facilities, and it had to do with the fact that they had such a small patient population. It was mostly the vascular access because they didn't have enough of the minimum 11 cases for hemoglobin or URR, but they apparently had enough of the minimum case requirements for vascular access type.

And I don't know what the minimum case requirements are for either of those two sub-measures. I couldn't find it in the final rule. I was wondering if you could tell me what the minimum case requirements are for patient-months for those two because I just—I can't find it in the—I don't think they should have count—have had a score for vascular access, but they did, if that makes sense.

Anita Segar: Hi, Lindsey. This is Anita. I know we've been communicating a little bit by email. So, so yes. Thank you for your question. It is important for you to be able to find the information that you require. Again, this is related to payment year 2014, but I'll—I'd be happy to respond to your question if you want to send it to my email or to the ESRD QIP mailbox.

Operator: Your next question is from Gela Mchedlishvili.

Gela Mchedlishvili: Yes. Hi. I have question about—if CMS is considering different anemia management measure in the future for patients with low hemoglobin. And the reason I am asking because there is trend of using less (inaudible) stimulating agents because of bundling and increased incidence of anemia in blood transfusions. And I wonder if CMS is considering a measure for this to be included in the future. Thank you.

Joel Andress: Good afternoon. This is Joel again. So, I would say that we are—we have received a number of letters from a number of advocacy agencies and stakeholders in the community raising this concern. We are certainly continuing to track the trends of hemoglobin and—of hemoglobin levels and ESA usage within the population.

I would say, at this time, that the reasons that we were concerned about the hemoglobin less than 10 measure—and that led us to take—to remove that measure from the QIP—are still present. And so we haven't decided at this time, obviously, to propose the measure in the NPRM. But we are keeping it close—a close eye on it and on potential—on potential unintended consequences as we are—you know, as the bundle payment is taking effect. If, at some point, we see that unintended consequences are occurring, we'll, of course, revisit the measure in a more direct fashion through the QIP.

And just to follow on that, we would, of course, encourage you to submit a—submit a formal comment prior to August 30th. And we will provide a more detailed response with the—with the rationale for why we have removed the measure from the QIP.

Gela Mchedlishvili: Thank you.

Operator: Again, if you would like to ask a question, press star 1 on your telephone keypad.

Your next question is from Shannon Walleser.

Aryeh Langer: Shannon, your line's open.

Shannon Walleser: This is Shannon from Gundersen Renal Dialysis. And I was just noticing—it seems that most of the clinical measures are on a 12-month rolling calendar now, but the hypercalcemia, I noticed, is a 3-month rolling average. Is that potentially going to change to a 12-month, or is there reasoning behind it only being a 3-month? Are we just looking at the last quarter for the year, then, for that measure? Or—if you could explain a little bit more on that one, I guess.

Aryeh Langer: Our subject-matter experts are just conferring for a moment.

Shannon Walleser: Sure.

Joel Andress: OK. So, just to answer the—I think we have a two-part question here. So, the first question is, are we planning to move to a 12-month average later on? The answer to that is no. Three-months rolling average is a part of the formal measure specifications for this measure, so any change from a 3-month rolling average would involve an alteration to the specifications. It would be reflected in the rulemaking.

In terms of the rationale for using the 3-month rolling average, I would defer to our clinical experts, and they would—they would be able to address this, I think, more effectively through writing if you submit the question formally through public comment. We will provide you with the clinical rationale for using it, the 3-month rolling average on the hypercalcemia measure.

Shannon Walleser: OK.

Operator: Your next question is from Cindy McGee.

Cindy McGee: Hi. This is Cindy and Debbie from Genesis Dialysis, and we have a question about how the data is gathered for the performance measures. Will that be through CROWNWeb? And what is the sample for patients that will be taken to get each individual unit's data?

Joel Andress: Right. So, the data sources from—I'm sorry, this is Joel again. The data sources from the clinical performance measures varies depending on the measure that you're—to which you're referring. For the hemoglobin greater than 12, the Kt/V dialysis adequacy measures, and the vascular access—the vascular access measures, the data source is claims. And so, we use data that are submitted from claims—by claims from the dialysis facilities.

For the patient-informed consent measure, it is—the source—the data source for this measure will be CROWNWeb and will be provided by the facility for each—for each

measure qualifying for the measure under the specifications, which, again, are available online and through the slide—through the link provided at the end of this presentation.

For the NHSN bloodstream infection measure, data will be submitted directly to the CDC's National Healthcare Safety Network, as have—as data have been provided previously. For hypercalcemia, again, the data source will be CROWNWeb. And it will not be a sample but will include all patients that fall within the—that fall within the—within the denominator described on the measure specifications.

Does that answer your question?

Cindy McGee: For Kt/V, is that CROWNWeb, as well?

Joel Andress: That's claims.

Cindy McGee: OK.

Joel Andress: It has been—or I should say it has—it has been finalized in payment year 2015. It's claims and will continue to be so for 2016.

Cindy McGee: OK. Thank you.

Operator: Your next question is from Wendy Lester.

Wendy Lester: Hi. I'm calling from UCSD Medical Center, San Diego, California. My question pertains to the consent for Epogen, which is one of the new clinical requirements. Is there a specific consent that you are looking for? Or is it just a facility-defined consent as long as it includes the risk, benefits, and alternatives? So is there something specific we should be using or do we develop our own?

Aryeh Langer: Just give us one moment, please.

Wendy Lester: Thank you.

Joel Andress: Hi. Yes. This is Joel. The intention of the measure is that consent is defined by the standards for informed consent. So, the attestation for the patient would require that the facility attests to the fact that informed consent was obtained from the patient or from a legally authorized representative.

Wendy Lester: So there is no specific consent, as long as it addresses the use—the typical consent requirements, which are risk, benefits, and alternatives? Is that what you're saying?

Joel Andress: Are you asking are we providing a particular . . . ?

Wendy Lester: Right. Yes.

Joel Andress: No. We are—we are not—we are not mandating a particular form to define the consent.

Wendy Lester: OK. OK. All right. Thank you.

Operator: Your next question is from Dr. Dukkipati.

Ramanath Dukkipati: It's a very simple question. Hi. I'm Dr. Dukkipati from Harbor–UCLA in Los Angeles, California. You know, in the payment reduction methodology, you said 53 patients for minimum TPS. What about these new dialysis units which have less than, let's say, 60 patients—less than 53? So, are they not going to be penalized? Do you see what I mean?

Let's say if a dialysis facility has less than 60 patients, because the minimum TPS, you said, was 53 patients—not you, I mean as part of this whole payment reduction methodology. So I was wondering what happens to dialysis centers which are fairly new and they have less than 60 patients, because, in the payment reduction methodology, 90 percent are from the clinical measures and the 10 percent are from reporting measures. And both are calculated and then—but for some reason CMS keeps saying the minimum is 50—minimum TPS, Total Performance Score, is for 53 patients. Is that—or, am I misunderstanding this?

In order words, is there a minimum number of patients beyond which—let's say a brand new dialysis center. Let's say there are only, like, 40 patients for the first 2 years. Are they still subjected to the same payment reduction methodology?

Anita Segar: Dr. Dukkipati, thank you for your question. This is Anita Segar and . . .

Ramanath Dukkipati: Hi, Anita. Yes.

Anita Segar: Hi. I think there may be a slight misunderstanding here with the Total Performance Score. So, when we say the minimum Total Performance Score, say, is 52 or, say, 46 as in payment year 2016, what we're saying is that – so, for 2016, we have 9 clinical measures and 6 reporting measures.

Ramanath Dukkipati: Right.

Anita Segar: And each of them—the clinical measures are weighted at 75 percent. The reporting measures are weighted at 25 percent.

Ramanath Dukkipati: I see.

Anita Segar: So, based on the score that's received for each individual measure topic or measure, and then they're calculated and the combined total score is what is the Total

Performance Score. So the Total Performance Score is different from the number of patients the facility may have. But, to answer your question . . .

Ramanath Dukkipati: Got you. Got you. Right, right, right.

Anita Segar: Yes. I think that what you may be asking is, is there a minimum number of patients in order to qualify for a certain measure?

Ramanath Dukkipati: Right.

Anita Segar: And yes, yes. Absolutely. You're right in that. We do have a minimum number of patients to qualify. So, for example—let me just give you an example with the—say, the mineral metabolism reporting measure.

Ramanath Dukkipati: Yes.

Anita Segar: We say that if facilities treat more than 11 patients—11 qualifying patients, then they have to report at the lesser of the 50th percentile or—there's a different standard for that. And then we say that if facilities treat less than 11 patients, we have a different standard. They have to report all but one. And if the facility has only one patient—one qualifying case—which is different from one patient—but one qualifying case, then they attest in CROWNWeb that they had one qualifying case. And then they are—in order to avoid being scored on that measure.

Ramanath Dukkipati: OK. I got you. I see where it's misleading. Because in the TPS score, the—what you guys put in as "pts." which in medical language is "patients," but it's actually "points."

Anita Segar: Right, right, right. So, they act as points.

Ramanath Dukkipati: Because it's—because it's confusing because we always use "pts." as, like, "patients." But I think when you're saying TPS score, 53 "pts." is 53 points is the minimum. Right?

Anita Segar: Yes. That's right. So, if you get less than 52 points—or 46 points, just go over 46 for payment year 2016. If you get less than 46 points, then you have that payment reduction scale that I went . . .

Ramanath Dukkipati: Right.

Anita Segar: . . . over on slide 44. That tells you what percentage reduction you get for, you know . . .

Ramanath Dukkipati: Did you guys revise this recently? Because I was always under the understanding the clinical measures were 90 percent, and the reporting measures was 10 percent . . .

Anita Segar: Yes.

Ramanath Dukkipati: . . . which, combines together, makes the TPS.

Anita Segar: So, that's right. We did have the 90/10 earlier in previous rules. That was for payment year 2014.

Ramanath Dukkipati: Right.

Anita Segar: So for 2014, we did have the 90/10. For 2015, we moved to 75/25.

Ramanath Dukkipati: Got you.

Anita Segar: And we outlined some of the reasons for that in the proposed rule. You know, the value that each of these measure bring, their clinical significance and what they actually bring to the table in terms of improving quality—so, we do take some of these factors into consideration when weighting these measures.

Ramanath Dukkipati: Got it.

Anita Segar: So—yes, we did.

Ramanath Dukkipati: Got it.

Anita Segar: But thank you. Thank you for your question.

Ramanath Dukkipati: OK. Thank you.

Operator: Your next question is from Michelle Verissimo.

Michelle Verissimo: Hi. I just had a question about the clinical measure for the NHSN bloodstream infection in hemodialysis patients. I was wondering if this measure was going to look at bloodstream infections regardless of the source, or if it's bloodstream infections related to the dialysis vascular access.

Aryeh Langer: One moment, please.

Joel Andress: So, the—in order to fall within the numerator—well, I should say the numerator is based on new positive blood culture events based on blood cultures drawn as an outpatient or within 1 calendar day of a hospital—after a hospital admission. So it's based on positive blood cultures, not—and that doesn't distinguish between the source of the infection for those blood cultures.

Michelle Verissimo: So, I mean, just a guess in terms of a comment, because I do all the infection reporting for my facilities, and we have so many positive blood cultures that

stem from a cellulitis of some sort or a wound cut—a wound on their foot that we may be treating for, and while we are reporting the minutes of dialysis event because of the antimicrobial start, it's not necessarily the care that we provided in the facility that caused the bloodstream infection.

Joel Andress: So what I would say is that—you know, this is exactly the kind of thing that we want to hear about in the public comment period because this is the kind of issue that we—and, in the case of this measure, the CDC, as well—can respond to and, you know, feasibly incorporate into later modifications of the measure. So I'd recommend that you submit this as a—as a public comment if you haven't already. And we will address it while we are finalizing the payment year rule for 2016.

Michelle Verissimo: OK. Thank you very much.

Operator: You have a followup question from Vlad Ladik.

Vlad Ladik: Hi. This is Vlad Ladik from DCI. The question I have—we are starting to use CROWNWeb data, and there is no secret that, at this point—in 2012, let's say, only 90 percent of patients had CROWN—had data entered in CROWNWeb. There are few defects in the CROWNWeb that prevent clinics from entering data or LDOs from submitting data. Those defects may be going to be fixed in the future or may not. How do you plan to address the fact that not all data is going to be in CROWNWeb at the time when you would calculate score?

Anita Segar: Hi. Thank you for that question. This is Anita Segar. And what I would suggest is for—a couple things—a couple things here. One is we would like to see that comment in the *Federal Register,* as with other comments that we want to respond to and provide information on.

But, just to assure you, we are continuing work to ensure that data is accurately captured in CROWNWeb. We put—we put in place multiple validation sets to ensure that inaccurate data is not used for the purposes of the QIP scoring in 2014 and beyond. So we appreciate your concern, definitely, and we will—going forward, are also looking to continue to improve CROWNWeb. Thank you.

Vlad Ladik: And I have another question related to previously asked question. Actually, the number of months, patient-months, I believe, is 116, because we have one patient for whom 115 was listed as not enough data, but 116 was enough to score. And, I believe, it's not—it's not—I don't know how this number came through because 116 is less than 12 months times 10 patients.

But, in relation to this, when I look at explanation for each measure, either clinical or reporting, it does not contain full detail of how data will be calculated. For example, for calcium, the website doesn't have any information how calculations will be done if patient has calcium only for 2 months out of 3.

Anita Segar: Yes. Thank you for that question.

Vlad Ladik: So, it's not really question about calcium, particularly. But, what I'm—what I'm trying to say—we need more information—we need very detailed information of exactly how calculations will be done with all possible details.

Anita Segar: So—yes. Thank you for that question. This is Anita Segar again. And a couple of things here. So, one is, I think there's—you know, I definitely realize the need for having knowledge of how the calculation is done. That is really important.

So, as it pertains to the proposed rule itself, we've outlined some of the general methodologies we've used and how these calculations are done generally for the measures and called out certain measures here. But if you would like specific information about calculations for your specific facility, that is something we'd be happy to work with you on. If you want to send us a question to the ESRD QIP mailbox, that's something—you know, throughout the course of the year, we can work with you on your specific facility calculations.

Vlad Ladik: Well, it's already too late because facility may already have penalty. What we are trying to do, we're trying to be proactive. We are trying to project what would be score for next year for our facilities, and we trying to find facilities where we need to improve. So, in that respect, I cannot really wait until the end of the year and then realize that facility has penalty and start to ask why. What I want to do is to produce calculation internally using similar—same rules as CMS going to use to project what kind of penalty we're going to have for our facilities.

Jim Poyer: Hi, sir. This is Jim Poyer. We'd be happy to entertain your question. Please send your phone number, and we'll get back to you in an expeditious manner on – at the esrdqip@cms.hss.gov.

This call pertains to the proposed requirements for payment year 2016. And if your comments are also relevant to the PY '16 proposals, please send them officially to the *Federal Register*. And we have to respond to every—your inquiry, as well as every single other inquiry in the final rule. But if they pertain to PY '14 or PY '15 requirements that are finalized, please, we encourage you to send them to the ESRD QIP mailbox.

Vlad Ladik: OK, I will do that. Thank you.

Jim Poyer: Thank you.

Operator: You have a followup question from Gela Mchedlishvili.

Gela Mchedlishvili: Yes. Hi. This is Dr. Gela Mchedlishvili, Wellspan Nephrology from York, Pennsylvania. I had question, and it might not pertain for QIP for payment year 2016. Maybe for later on. But I had question about bone health management—chronic kidney disease, mineral bone disease management. And I know that we are having now

hypercalcemia included. But in the future are we planning to include parathyroid hormone?

And also, I have question about ranges, because it's a little bit confusing according to Medicare. It's—Medicare still uses conventional KDOQI range of 150 to 300 picogram per milliliter for end-stage renal patients. And based on new KDIGO guidelines, they recommend PTH to be maintained in the range of approximately, like, 2 to 9 times upper reference limit, which, for example, for our lab, will be up to 500 to 600 from 100 to 600, which is, you know, wide range. And they disregard this conventional range due to problems of prior PTH assay and Nichols assay.

So, this is—this is very—you know, this is very unclear, and I'm not sure this is the right audience for this. But I wanted to take opportunity and ask this question if anybody knew about this—you know, PTH ranges—and if it will be included in the future QIP. Thank you.

Joel Andress: So, I don't want to get too deeply into clinical standards here for therapy. I will say that, in answer to your initial question, we are, of course, giving thought and consideration to enhancing our assessment of mineral bone disease in the ESRD population. I'll also point you to the CMS website, where we have recently posted a summary chapter report for a measure development project dealing specifically with mineral bone disease.

For—in terms of specific measures that will be implemented in future payment years, I can't really say a great deal until we've actually put forward a proposal. But certainly we are concerned with the issue. If you have specific recommendations for quality measures, as I believe you may, then my recommendation would be that you submit them via public comment. And then we can respond to your—to those specific recommendations, I think, much more effectively in writing as we are responding to all public comments.

Gela Mchedlishvili: Thank you.

Operator: Your next question is from Susan Senich.

Susan Senich: I have a question about the comorbidity measure. To gather that data into CROWNWeb, is that going to be able to be batch submitted? Or are we going to have—is every—are they going to have to submit it by hand?

Aryeh Langer: Could you give us one moment, please?

Joel Andress: So—this is Joel. I think, in this case this is—this is another one of those questions where you should submit a comment to the proposed rule, and we will get back to you in writing. And at that point, we can provide you with technical guidance regarding how this—or, well really, any other measures should be—the data for any of these measures should be provided to the CROWNWeb system.

Susan Senich: Thank you.

Operator: You have a followup question from Joan Simard.

Joan Camarro-Simard: Hi. Yes. This is my last question. In regards to the new format for the I–CAHPS survey, where can we find a list of who the CMS-approved third-party vendors are? Or do we have to have our vendor become approved? I went online to look at the statements for that, and it didn't really give me any information. What are they—how are they considering CMS-approved third-party vendors?

Anita Segar: Hi, Joan. This is Anita Segar. Thank you for your question. Yes. So, as of now, as far as the proposal goes, what we've basically proposed is that facilities will arrange by July 2014 for a CMS-approved vendor to conduct the survey according to the CMS specifications, not the AHRQ specifications. Now, that is going to be available at the ICH CAHPS website.

Joan Camarro-Simard: OK.

Anita Segar: We will make that information available on that website. And you will be able to follow on there in terms of how CMS will approve these vendors and what the process is going to be.

Joan Camarro-Simard: Yes. Because our organization already uses a third-party vendor to do our surveys, and I'm just wondering if we're going to have to possibly change to another vendor or not. But it will be posted?

Anita Segar: Right. It will be posted. I mean, I can't say for sure right now. But, you know, more information will be forthcoming on the website.

Joan Camarro-Simard: OK. Thank you very much.

Operator: Again, as a reminder, if you would like to ask a question, press star 1 on your telephone keypad.

And there are no further phone questions at this time.

Additional Information

Aryeh Langer: Well, thank you very much, everybody, for participating in today's call. If we—if you have any further questions after this call is over, you can send an email to the email address given a number of times during the call, esrdqip—that's esrdqip@cms.hhs.gov.

On slide 63 of today's presentation, you will find information and a URL to evaluate your experience with today's call. Evaluations are anonymous, confidential, and voluntary. We hope you'll take a few moments to evaluate your MLN Connects Call experience.

Again, my name is Aryeh Langer. I'd like to especially thank today's presenters for an excellent job and all the participants on today's call. And have a great day, everybody.

Operator: This concludes today's call.

-END-