



MLN ConnectsTM

National Provider Call - Transcript

Centers for Medicare & Medicaid Services
Dialysis Facility Compare: Rollout of Five Star Rating
MLN Connects National Provider Call
Moderator: Hazeline Roulac
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Operator: At this time I'd 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 Hazeline Roulac. Thank you, you may begin.

Announcements and Introduction

Hazeline Roulac: Thank you, Holley. I am Hazeline Roulac from the Provider Communications Group here at CMS and I'm your moderator for today. I would like to welcome you to this MLN Connects National Provider Call on Dialysis Facility Compare Rollout of Five Star Rating. MLN Connects Calls are part of the Medicare Learning Network.

This MLN Connects National Provider Call will provide information about the implementation of a Star Rating on Dialysis Facility Compare in October 2014—the methodology used to calculate the rating and directions on how to access and preview the rating during the July 2014 Dialysis Facility Compare Preview Period reports.

A question-and-answer session will follow the presentation. Our presenters for today are Dr. Kate Goodrich and Elena Balovlenkov from CMS, and Christopher Harvey from the University of Michigan.

Before we get started, I have a couple of announcements. A link to the slide presentation for today's call was included on the call registration site and also emailed to all registrants. If you have not already done so, you may view or download the presentation from the following URL, www.cms.gov/npc. Again, the 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 left, you will find a link to the slide presentation under the call material heading.

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.

I will now turn the call over to Elena Balovlenkov.

Presentation

Elena Balovlenkov: Thank you Hazeline. First, I'd like to thank everyone for joining us today and also to let you know that, as Hazeline said, the slides are on the website. We did make some minor editorial changes that you might see if you downloaded your slides earlier in the week. But you will see that they're really not that significant, but I did want people to know that you may see a few minor differences.

Before we get started today, I'd like to identify the people in the room. We have Dr. Kate Goodrich, who's the group director of the Quality Measurement and Health Assessment Group; myself, Elena Balovlenkov, I'm the technical lead for Dialysis Facility Compare;

Christopher Harvey is a research analyst from the University of Michigan; and we also have Joel Address, who is the lead for ESRD measurement development.

So, we will get started with slide 2. Now let's talk a little bit about the agenda that we're going to go over today. One of the first things we're going to do is talk about the introduction of the Star Rating System and the roles, talk about who is involved in the development process, give you some background on the Star Rating System, talk about what exactly Star Rating is and how it will appear on Dialysis Facility Compare. We will give you some indepth information on the Star Rating methodology that was developed and give you the rating results. We'll talk about future maintenance and any updates on the Star Rating System. And we also have a question-and-answer session because we do believe that feedback from our stakeholders is incredibly important to this process, so we look forward to your comments.

Please go to slide 3. So, as you know, the Centers for Medicare & Medicaid Services instituted the Dialysis Facility Compare website for public reporting of quality measures for the End Stage Renal Disease Program in 2001. One of the things that we've seen is, with any system, as we develop more robust systems and more robust information, we have the opportunity for improvement. And part of the improvement moving forward is instituting the Star Rating System on DFC compare, and that will premier in October 2014. But we will also talk about the preview period during this call, which will be taking place next week.

The Star Ratings will be available for preview on the web from July 15th to August 15th. This will also be during the time when we'll be getting comments from our stakeholders in response to what you're able to view on the website. We also have, as you know, University of Michigan Kidney Epidemiology and Cost Center is the ESRD quality measures development and maintenance contractor for CMS.

Next slide please, slide 4. So what I'd like to do now is turn the presentation over to Dr. Goodrich, who will provide the background information on the Star Rating System. Kate?

Background of the Star Ratings

Dr. Kate Goodrich: Hi, hi everybody, nice to have you on the call. So my job today is really to give you, number one, just a high level background about Star Ratings here at CMS, very briefly. And then I'm going to give you also another high level overview of our quality strategy that we published back in December of 2013 that has really been the framework for all of our quality measurement and improvement work.

So if you go to slide 5, we'll talk about the background on the Star Ratings within CMS. So I'm actually going to work the slide from the bottom up. In 2008, Star Ratings were introduced on Nursing Home Compare. This has been a very, very successful venture for CMS. This has really helped providers and beneficiaries and families to identify nursing homes in their area for them to choose from if they need to do so. And so we've learned a

lot from that experience. We've also used stars in the Medicare Advantage website for some time now for both the health plans and the Part D prescription drug plan services.

And in 2014, earlier this year, in about February, Star Ratings were introduced on Physician Compare for large physician group practices of 100 or more as well as for ACOs. And so expanding on this later this year, as Elena mentioned, for Dialysis Facility Compare, but also in December and January, for Home Health Compare and Hospital Compare, we will be beginning our transition to Star Ratings across all of our sites. And I might also mention that we anticipate in 2016, when we have quality measure information on all of the health plans on the marketplace, we'll also have Star Ratings for quality measures there.

And the reason we've decided to do this, as Elena said, we see this as an improvement upon a lot of the work that has already happened over the last several years. And we know from Nursing Home Compare, but also from our consumer testing that we've done extensively over the years, that consumers really feel like they can understand quality information better when it's displayed in a Star Rating or other like rating system as opposed to the way that we present information now, which I think is very useful, but maybe not as useful for consumers and other users of the site who might find a different type of display easier to understand.

CMS Quality Strategy

So if you'll move to slide 6, what we have here is the CMS vision that was articulated in our CMS Quality Strategy that was, again, published in December of 2013. And this Quality Strategy really is the guiding framework across CMS for – all the works that we do, but certainly for quality measurements, quality reporting, and public reporting.

And the next couple of slides may look familiar to those of you who are familiar with the National Quality Strategy that was originally published in April of 2011. And we used the National Quality Strategy as our framework here at CMS to build our own Quality Strategy. So the CMS vision is to optimize health outcomes by improving clinical quality and by transforming the health care system.

And moving on to slide 7, these three aims again are likely quite familiar to many of you on the phone. This really is our guiding star for everything we do here at CMS and also at HHS, which is better care for individuals, better health for the population and communities, and finally lower cost through improvement in care.

Moving on to slide 8. Underneath these three aims are the six goals of the CMS Quality Strategy. And again, these really do map to the six priorities of the National Quality Strategy. And they include:

- Making care safer by reducing harm in the delivery of care,
- Strengthening person and family engagement,
- Promoting effective communication and coordination of care,
- Promoting effective prevention and treatment of chronic disease,

- Working with communities to promote healthy living, and
- Making care affordable.

And I'm sure most of you on the phone are familiar with our quality measures, and we've really started to think about our measures within this framework of the six goals of the Quality Strategy. And many of the measures that we use on Dialysis Facility Compare fit nicely into one of these categories or may even cross some of these categories as well.

And in moving on to slide 9, I think it's critically important to emphasize some key foundational principles that we identified at CMS as we were developing strategies that don't just fit neatly into one of the six goals, but they're truly foundational and cut across all of the six goals and the three aims. These include:

- Elimination of health care disparities—something that's very important for the ESRD population in particular.
- Strengthening infrastructure and data systems—we think this applies not only to us here at CMS and our own data systems but also is applicable to frontline providers, especially with the advancement of electronic health records and data feedback.
- Enabling local innovations—you've probably heard the term all too often that all health care is local. We believe that that is true and that CMS can provide the framework and, hopefully, help create the environment for improvement, but that really in order for patient care at the population and individual level to truly improve, that it requires innovation by frontline providers. And then, finally,
- Fostering learning organization—those of you who follow our Quality Improvement Organization Program, our QIO Program, or any of the work coming out of the innovation center, know that a fundamental component of all of those programs are these learning and action networks or learning collaboratives so that those who have figured out how to improve in a particular area can teach those who may be struggling.

And so we think this is really important not only for national programs but also within local, regional, and state communities.

And now I'm going to turn it back over to Elena.

Affordable Care Act Requires Public Reporting

Elena Balovlenkov: Thank you Kate. One of the things that people ask us, so why is CMS doing this? Where did we get the directive to start reaching out even more to the consumer and making more information easily accessible and making it more transparent and open? And it all actually comes back to the Affordable Care Act public reporting.

One of the things that people may be aware of (or this may be new information for individuals) is that the Affordable Care Act goes forward stating that we need to expand quality measurement. We need to develop good measures, we need to be able to share those measures, and then we need to expand public reporting and make it easily

accessible to the individuals who access our care and also to those individuals who are our invested partners that are important to the work that CMS does. And the biggest thing is that the ACA called for easy format so that individuals from any walk of life would be able to understand what they're reading.

Slide 11 please. So as Dr. Goodrich talked about, it provided for the expansion of the compare websites looking at the Physician Compare website, talking about new reporting requirements that you will see if you use the Hospital Compare and Nursing Home Compare because we have to remember, the ESRD community doesn't live in a bubble. We have patients that are in nursing homes, we have patients that access hospital care. And the information on all of these sites is incredibly important to the population we serve.

Slide 12 please. The other thing that we have to look at is that there are new requirements for reporting on care settings, including long-term care hospitals, inpatient rehab centers, hospice care, ambulatory surgical centers, cancer hospitals, inpatient site facilities. And what's important is that, again, we have to realize that while today we're talking about DFC, one of the things that's exciting about the expansion of the Star Rating System in all of the websites is that our population who accesses many of these services will be able to use this common tread to be able to access these sites and to increase their own understanding of the information that's posted on these sites.

Part of this comes with the initiative identified on page 13—its expansion of the digital government strategy. What does that mean? That means making the computer more user-friendly to the community. This was issued by the Obama Administration in 2012 and it lays out particular milestones. It can help our public, our consumers, access high quality digital information so that if they don't have a computer, they can get it from their cellphone or they can look at it on a computer, but the idea is, is that we have a good architecture so that it's easy to read, easy to understand. And again, this increases the transparency that the government is aiming for.

Slide 14. So what does this support include? Part of it includes is good data, data contributions to the data.gov site and the medicare.data.gov site, mobile optimization of compare websites. There's research in the community that tells us that while a lot of our ESRD patients may not have a computer in their home, many of them access the Internet through their cellphones or they go to the public library to get information – that we make it easy for people to use analytical data to improve the sites because data is only as good as the ability to understand it. And then we also touch base with our consumers, the people who actually get on our site and ask them, “What do they think?” “How can we improve?” “What can we do about readability and understanding of information?” And CMS supports all of these initiatives.

Star Ratings Compare for Consumers

Next slide, slide 15. So why add Star Ratings to the compare site? Compare sites are primarily for the consumer. Consumers are the ones – they are basically the bread and butter of our business as well as the stakeholders who provide care to our patients. The

National Quality Strategy says public reporting is a key driver for improving care. The more transparent we become, the more understandable we become, the better our outcomes will be.

We know that consumers look at these sites. We've done a lot of testing out there, and what happens is when a consumer gets on the site, we want to be sure that they understand what they see so that these ratings then can be shared with their family members when they go talk to their physicians, to drive their conversations, to help them make health care decisions.

And the other thing that we look at is when providers look at the information provided on these sites. It also gives great information for their provider to go back and look at their own quality improvement efforts or to look at things that they want to do to satisfy the needs of patients they currently provide care or even to look at what they would do for newly admitted patients. So again, the biggest thing for us is public reporting and understandability by the consumers who access the site.

Star Ratings Roll Outs

Slide 16. So what are the principles for this slide – I mean for the Star Ratings? Again, consumers want information that is simple and understandable. We feel that it is important to leverage the lessons learned from the other compare websites. One of the things that's important that we want to put out on the DFC website, we're using measures that individuals are familiar with. We didn't have any new measures. We also recognize that not all measures are appropriate for Star Ratings. And the biggest thing is that we want to be transparent and consistent across all the sites as much as possible. And for that purpose, we are coordinating the release of the sites. As we said, our site rolls out in October, and we will also have the Hospital Compare and Nursing Home ...

Dr. Kate Goodrich: Home Health.

Elena Balovlenkov: Home Health Compare will be coming out late fall.

So, let's look at the slide – at this slide 17 on the Star Rating. We need to talk about the timeline. The Star Ratings will be displayed for each facility on DFC and we will also be updating them annually. And we'll give you some more information for that later in the presentation. What is most important for those of you on the phone, I'm sure, is that the Star Ratings will be included in the preview reports beginning next week. So starting on July 15, 2014—next week—you will be able to look at the ratings and that you will have an opportunity, as we'll talk about further in the presentation, to provide comments. You'll also be able to ask additional questions during today's presentation. And that the Star Ratings will be publicly reported on the Dialysis Facility Compare website starting in October 2014. And let me repeat that again, public reporting will occur for the Star Ratings on the DFC website beginning October of this year.

Slide 19. So, what do these ratings look like? The Star Ratings are based on the quality measures that are currently reported on the Dialysis Facility Compare website. They're

the measures that are used to assess patient health outcomes and also processes of care. Each dialysis facility is given a rating between one and five stars:

- Five stars are rated much above average quality,
- Four stars, above average quality,
- Three stars, average quality,
- Two stars, below average quality, and
- One star, much below average quality.

Next slide. Now, we know that people are very interested in how the methodology was obtained, so I will now turn the presentation over to Chris Harvey, research analyst from the University of Michigan. Chris?

Star Ratings Methodology

Christopher Harvey: Thank you Elena. So I will be discussing the Star Rating methodology, including the measures used and the algorithm used to give ratings between one and five stars. Finally, I will discuss some of the preliminary results using this methodology.

We start on slide 21. As discussed, the Star Ratings uses the DFC quality measures in its calculation. Here, 9 of the 11 measures available on the website are used. The first three quality measures used are standardized ratios. These represent adjusted ratios of actual events compared to expected events based on the makeup of the dialysis facility. Standardized transfusion ratio is abbreviated ST_{Tr}R, the standardized mortality ratio, SMR, and the standardized hospitalization ratio, SHR. The rest of the measures measure the percentage of patients that surpass the specified threshold.

There are three measures that measure percentage of patients who had enough waste removed from their blood for different patient modalities. These three measures look at percentage of patients with Kt/V values greater than 1.2 for adult hemodialysis patients, Kt/V greater than 1.2 for pediatric hemodialysis patients, and Kt/V greater than 1.7 for peritoneal dialysis patients. These measures are combined to create one measure for enough waste removed in the blood from dialysis patients, which will be described later in the presentation.

The last three measures are percentage of adult dialysis patients who had hypercalcemia, percentage of adult dialysis patients who received treatment through AV fistula, and percentage of adult patients who had a catheter left in their vein longer than 90 days for their regular hemodialysis treatment. The two measures not used measure urea reduction ratio and hemoglobin. These measures have percentages that are topped out with national averages of 99 percent and less than 1 percent, respectively. As most – as almost all facilities have the same values for these measures, it is difficult to use them to differentiate facilities.

Continuing on to slide 22, we discuss the weighting of the quality measures. Since the Star Rating is based only on the outcomes described by the quality measures, it was

important to investigate the best unbiased way to combine the measures to create fair ratings. A simple method would have been to give all of the measures equal weight. However, we explored weighing some of the measures differently so that specific aspects of quality were not over weighted. For instance, if four related quality measures measure a certain aspect of care and only one quality measure measures a second different aspect of care, a simple average of the five quality measures would count the first aspect of care much more heavily than the second in an overall rating.

Just because more quality measures measure specific aspects of care does not mean that this quality is necessarily more important. Therefore, we look to group quality measures that measure similar aspects of the facility and give equal weights to these groups rather than equal weights to individual measures. These groups come from an analytical method called factor analysis that identifies groups of correlated measures. After factor analysis, the correlation structure of the individual measures is investigated to confirm that these groups make sense.

Moving on to slide 23, we discuss the transformation of the measures. Before we perform the factor analysis to group the measures, we first combine the three Kt/V dialysis adequacy measures into a single value. As described in the measures, dialysis adequacy measured by Kt/V is reported on DFC separate for a child HD, adult HD, and adult PD modalities. So that we do not give equal importance to these separate measures when proportion of patients differ vastly in a facility by modality, a single measure is calculated as the weighted average of measures for the three groups based on patient months spent in a facility for each type of patient.

The seven final measures—the combined Kt/V measure, and the six other measures—were then standardized so that distribution of measured values did not affect the importance of the measure. This was done by transforming measure values into ranks ranging from zero to 100 that follow a normal distribution with a mean of 50. These normal ranks are abbreviated as nRanks. These resulting rank values are directly comparable in scale (zero to 100), distribution (normal), and directionality (higher values indicate better performance).

Moving on to slide 24, we give an example of the standardization. At the top of the diagram we have a measure where higher percentage achieving a threshold is better. Distribution is initially skewed right. The bottom of the diagram shows the nRanks after standardization. They range from zero to 100, are distributed normally, and higher values indicate better performance. The arrows represent how facility measure values change before and after this normalization. Before using this method all measures are equally influential based on their ranks compared to other facilities.

Continuing on to slide 25, we discuss the grouping of measures. We now use systematic empirical methods, specifically factor analysis, to identify groups or domains of correlated quality measures. For the preliminary analysis, we used January 2014 DFC-released data. Based on the factor loadings of this data and the correlation structures of the measures, we created three groupings of measures. First, we called the

standardized outcomes, SHR, SMR, STrR domain. The second grouping contained AV fistula and catheter measures and was called Other Outcomes 1 – AV fistula, tunneled catheter. Finally, the last grouping contained Kt/V and hypercalcemia measures and was called Other Outcomes 2 – Kt/V and hypercalcemia.

It is important to note that measures in the same grouping may not be very similar clinically, but performance of groups' measures are correlated within facilities. Therefore, groupings may represent underlying qualities signifying good performance and facilities. Treating groupings as underlying factors is a common interpretation of the results analysis. The naming of groupings here is intentionally vague as these domains may change after the addition of new measures in future years.

Scoring and Ranking Facilities

We now discuss the scoring of facilities. Facilities must be scored and then ranked before Star Ratings can be allocated. We start discussing the scoring on slide 27.

After the domains or groups are created, these groups are given equal weight in creating a final score to rank all facilities. First, domain scores are scored by averaging the standardized values for the measures in that domain. If a facility is missing any measure in the domain, a mean value of 50 is used for that measure in calculating the domain score. This limits one measure from being too influential on a domain when others are suppressed. Additionally, if a facility is missing values for all measures in a domain, the domain score is not calculated and the facility is not given a Star Rating. This gives a domain score between zero and 100 for each facility.

Next, the final score is created by averaging the domain scores. For PD-only facilities, only two domains are needed for a rating as Other Outcomes 1. AV fistula and tunneled catheter measures, are not relevant for PD-only facilities. For all other facilities, all three domain scores are averaged to make a final score. Again, if a facility is missing a needed domain score, the final score is not calculated and the facilities do not receive a Star Rating. The resulting final score for each facility is between zero and 100.

Continuing on to slide 28, we discuss the assignment of Star Ratings. After final scores are calculated and facilities are ranked based on final scores, we assign stars to facilities based on these ranks. Here, the top 10 percent of facilities are given a rating of five stars, 20 percent of facilities are given a rating of four stars, the middle 40 percent of facilities are given a rating of three stars, 20 percent are given a rating of two stars, and the bottom 10 percent of facilities are given a rating of one star.

Ratings are assigned in this manner to make exceptional ratings more difficult to achieve. Additionally, fixed percentages of facilities are in each category to eliminate unwanted drift in percentages over time.

We now discuss preliminary results of the ratings starting on slide 30. Given this methodology, we showed the preliminary results for the January 2014 release data containing 6,033 facilities. We carried out analyses to examine missing measures and

ratings, correlations between measures within domains, and relationships between Star Ratings and original values of the quality measures.

Result of missing ratings and measures are on slide 31. In investigating missing data, we tabulate the number of facilities with zero to seven missing measures (second column). We then show the number and percentage of unrated facilities based on the number of measures missing. We can see that among facilities with two or less missing measures, there are very few unrated facilities. However, we see that among facilities with many missing measures, the majority of facilities are unrated. In total, most facilities—81 percent—had all measures available and only 9 percent are unrated. The result of the most recent release of data show similar results.

The correlation of measures is discussed on slide 32. We tabulate the correlations between original measure values. The shaded areas are the measures in three domains. We see that for any given measure, the highest correlated measures are in the groups defined by factor analysis, strengthening the validity of our empirical groupings.

Finally, the relationship between Star Rating and measured values is presented on slide 33. Here we see that the average measured values are systematically better with higher Star Ratings in all cases. For example, lower values of SMR are better. We see that average SMR values decrease with improved Star Rating. Similarly, high percentage of patients with AV fistula is better. And this is – and this average percentage is systematically higher with higher Star Rating.

On slide 34 we finally give a summary of the rating methodology used. Domains are first created using factor analysis and the correlation of measures. Then we create domain scores by averaging standardized values for measures within a given domain. Averaging these domains, or two for PD-only facilities, we obtain a final score where we rank all of the facilities by. Finally, using these rankings, we allocate five and one stars to 10 percent of facilities, four and two stars to 20 percent, and three stars to the middle 40 percent of facilities.

At this point, we have finished the discussion of the methodology of the Star Rating System, and I would like to pass the presentation back over to Elena.

Future Plans for Star Ratings

Elena Balovlenkov: Thank you Chris. So we're on slide 35 and what we're going to do now is talk about the future plan for the maintenance of a Star Rating and future updating using input from our consumer groups, our stakeholders.

As addressed in the slide, the methodology used today that Chris just went over for us will be used to update the quality measure groupings and to maintain the ratings annually and to incorporate new or potentially revise DFC quality measures. The other thing that CMS is considering is adding other elements other than quality measures in the future for inclusion into the Star Rating.

CMS, as we said earlier, really wants your feedback on these methods and also when we're talking about including other quality measures or including other elements. Perhaps, grievance issues could be infection, could be lots of different measures. We're interested in getting your feedback of potential elements that could be included in the future for the Star Rating project, so please don't hesitate to share those with us.

Slide 37, so let's talk about what comes next. As stated earlier, on slide 38, the Facility Star Ratings will be available on the Dialysis Facility Compare Preview Report starting next week. Dialysis Facility Compare Preview Report as well as the technical document documentation will be available on the dialysisreports.org website beginning July 15th. The comment period goes from July 15th through August 15th.

Now if you missed the August 15th deadline and send us a comment August 16th, trust me, we'll take it. You know, we do understand that people oftentimes have time constraints and time gets away from you. You know, we're really interested in your feedback. So while we do believe that we want the predominance of all comments between that comment period, please feel free to reach out to us if all of a sudden something comes up that you have a question about. Also, if you have any general comments on the Star Rating System methodology, you can contact UM-KECC directly and that website is also provided, dialysisdata@umichigan.edu.

I'd like to turn the call over to Hazeline right now.

Keypad Polling

Hazeline Roulac: Thank you Elena. So we're going to open the call up for questions and answers, but before we do – for our question-and-answer session, but before we do, at this time we will pause for a few minutes to complete keypad polling so that CMS has an accurate account of the number of participants on the line with us today. Please note, there will be a few moments of silence while we tabulate the results.

I'm ready to start polling.

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.

Once again, please stand by while we complete the polling. Thank you. I'll now turn the conference back over to Hazeline.

Question-and-Answer Session

Hazeline Roulac: Thank you Holley. Elena would like to now introduce the panels that will be responding to your questions.

Elena Balovlenkov: Thank you Hazeline. Before we begin the question-and-answer session, I'd like to introduce our expert panel from CMS and from the University of Michigan. From CMS, we have myself, as I said, Elena Balovlenkov. I'm the Technical Lead for the Dialysis Facility Compare website. I have Dr. Alan Levitt, Medical Officer from the Quality Measurement and Health Assessment Group. I also have Joel Andress, Lead for the ESRD Measure Development in the Division of Chronic and Post-Acute Care. From the University of Michigan, we have Chris Harvey, the research analyst who presented today, and we also have Ji Zhu, Professor of Statistics.

So, we'd like to open up the call to questions and answers.

Hazeline Roulac: OK. Thank you, Elena. I would like to remind everyone that this call is being recorded and transcribed. I ask our speakers that before you respond to a question that you identify yourself for the transcriptionist. And for people asking questions, please state your name and the name of your organization. In an effort to get to as many questions as possible, we ask that you limit your question to one. If you would like to ask a followup question or have more than one question, you may press pound 1 to get back into the queue and we'll address additional questions or comments as time permits.

All right, Holley, you may open the call up for questions and comments.

Operator: To ask a question, press star 1 on your touchtone phone. To remove yourself from the queue, please press the pound key. Again, to ask a question, press star 1. Please 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.

And your first question will come from the line of Karen Glass.

Karen Glass: Yes, hello. My name is Karen Glass, I am with Liberty Dialysis. I had a question for Chris in regards to slide 27 please, where he was talking about if a facility is missing any measure in the domain, you're going to use a value of 50 for that measure in calculating the domain score. Could you be a little bit more specific in what that means? The first domain has the three, has the largest components in it. So can you use that one as an example, please?

Christopher Harvey: Yes, no problem. Thank you for your question. And this is Chris from UM-KECC. So in the first domain, we have SMR, STTrR, and SHR. And so, after these measures are normalized, they range from zero to 100, follow normal distribution with mean and median of 50. So if a facility only has SMR but STTrR and SHR are missing, we still want to give them a domain score. So say the facility gets a 100 score

for SMR but STrR and SHR are missing. Well if we give them a score of 100 for that domain, we're basically assuming that STrR and SHR are also 100. So in order for one measure not to be too influential, we give the other measures the median or average value so that the domain score still shows the facility did better than average but we sort of regress to the middle so that one measure isn't too influential.

Hazeline Roulac: Thank you, next question.

Operator: Your next question will come from the line of Alex Furman. Alex, your line is open.

OK, that question has been withdrawn. And your next question will come from Mahesh Krishnan.

Mahesh Krishnan: Hello, this is Mahesh Krishnan, Vice President for Clinical Innovation and Public Policy at DaVita. Thank you for the opportunity and the information that you presented. I have a general question, maybe for Kate, Elena, and Joel. The methodology, as currently described, is significantly different than that used for the QIP, specifically some of the measures that are being even discussed to be removed are topped out or different in the proposed rule than what you are proposing here in terms of UR and hemoglobin.

And then secondly, with regards to the use of some of these other measures like the standardized transfusion ratio or standardized hospitalization ratio, which is related to SRR, we do have significant concerns around the use of the 2728 data, which is being used to adjudicate the comorbidities. Our internal research has shown that there's significant variation and regional variation in the quality of accuracy of some of that data. And then also the data is only obtained when the patient first starts dialysis and doesn't accommodate incremental comorbidities that may be accumulated over that.

So in the sphere of all of that, just, Elena, you had mentioned the ability to comment on the methodology, although it seems like the methodology's already fixed. Just want to get your reaction to that. And then lastly, given a 1-month timeline, it will be helpful to get a corporate access to do the comparison because in 1 month – we're currently in the process of initiating the paper process of gathering signatures and approvals for all 2,200 facilities, but it's unlikely that we'll complete that aggregation to even do a meaningful comment prior to that. Thank you.

Elena Balovlenkov: Thank you for your question. I'm going to let Joel answer it because, as you know, he works closely both on the QIP and works with me on DFC. The one thing I do want to point out before he answers this question is that QIP is totally separate from DFC.

Joel, do you want to take the call, please?

Joel Andress: Certainly, thank you. This is Joel Andress. The one – the first thing I want to point out is that the QIP is intended for Value-Based Purchasing among facilities. The assessment of facilities and the completion of the performance score is intended to inform facility performance and to address payment. The goal of DFC is substantially different. And I think the methodology here reflects that. The goal here is to provide meaningful information distinguishing the quality performance of facilities for patients who visit the Dialysis Facility Compare website.

And so we did not begin the development of the methodology and intending to mirror the QIP except to – we did analyze variation QIP scores with the variation Star Rating and we found generally that facilities that had – that receive a payment penalty were more likely to receive a lower Star Rating. So they do concord to some extent.

In terms of the concerns that you've raised here for the 2728 data and for the use of specific measures, I think those would be best responded to in writing. We're certainly going to make provision for responses for those concerns. So I would encourage you to submit those in writing rather than us trying to address them on the phone call here today.

Mahesh, did I hit everything there or did I miss one of your ...

Mahesh Krishnan: Yes, the only other one, Joel, is the data component. So is there a way for us to get the data feed because of the 1-month time period to adjudicate all of these and gather comments? We're going to spend thousands of man- hours just gathering the data from each one of our clinics because there's no corporate aggregation ...

Elena Balovlenkov: That's one of the things, Mahesh, we're talking about is the fact that we will take comments after the comment period because we do realize that for some people it is going to be difficult to do it within that 30-day timeframe. So please, don't hesitate at all to contact us on any concerns that you have.

Joel Andress: OK, and one other point I do want to make – the methodology for the Star Rating is set for the October only. We will be reconsidering the methodology as it currently stands in future years on an annual basis. So any comments that you provide now or that you provide over the course of the – of the next year will be taken into consideration as we consider that. And that reconsideration will include potentially retiring measures, adding new measures, or restructuring how the Star Ratings are scored. First of all, all of those things are up for comments and we certainly welcome any thoughts, considerations, or concerns with what we presented to you here.

Hazeline Roulac: OK, thank you for your question. Next question.

Casey Parrotte: One second. I'm sorry, this is Casey Parrotte, UM-KECC. Just to clarify, these reports are being posted on dialysisreports.org, which does allow for corporate access through the permission process the same way that other reports on dialysisreports.org allow for corporate access. So there is the ability to get corporate access to the data.

Mahesh Krishnan: OK, great. Thank you.

Hazeline Roulac: Thank you, next question.

Operator: Your next question comes from the line of Glenda Payne.

Glenda Payne: Hi, thank you. Elena, very nice job. My question has to do with pediatric facilities and whether or not they would have a Star Rating. And if so, would they only have one “whole domain” and part of a second one since the vascular access domain does not apply to them?

Elena Balovlenkov: I want to thank you for your compliment. I appreciate it. And also, thank you for your comment. I'd like to have University of Michigan answer that.

Christopher Harvey: Thanks for your question. This is Chris again from UM-KECC. So, PD-only facilities ...

Glenda Payne: Pediatrics, pediatrics.

Christopher Harvey: Oh, pediatric facilities. Can you please repeat the question because I heard it as PD?

Glenda Payne: Oh, I'm sorry. Pediatric facilities, will they participate in the Star Rating System? And if so, will their rating be based on just a standardized ratios plus the adequacy, which is essentially the only one of these criteria that applies to them?

Joel Andress: So this is Joel Andress. We don't have special provisions put in place for the scoring for pediatric facilities. So, the answer to your question is that if the pediatric facility has a score for all three domains, then it would receive a Star Rating score. If it does not, then it will not receive a Star Rating for the year. And that's not distinguished by pediatric facility, it's a blanket statement at this time for all facilities.

Glenda Payne: But on slide 21 the parameters for the quality measures, many of them, in fact, one, two, three, four, five of them say percentage of adult patients. So there's only the standardized measures and the percentage of pediatric patients, hemo patients with adequacy. And so that's only the first measure – I've forgotten what we're calling it – and then part of one of the outcome measures that's even, they're eligible for.

Elena Balovlenkov: Glenda, can I do this, can I ask that you submit the question in writing and that we give you a more in-depth response directly?

Glenda Payne: Absolutely. Thanks.

Elena Balovlenkov: Thank you very much.

Hazeline Roulac: Thank you. Next question, please.

Operator: Your next question will come from the line of Raymond Cavazos.

Raymond Cavazos: Hi, this is Raymond Cavazos. I'm with the Children's Hospital of San Antonio. And the question I have is where your data comes from. Is this only Medicare patients? Does this – is this data that comes off of CROWNWeb? And I'm just asking because coming from a pediatric facility, when you use measures that just come from Medicare-eligible patients, that really skews our numbers.

Valarie Ashby: Hi. This is Valarie Ashby from UM-KECC. The data on Dialysis Facility Compare comes from a variety of sources. There are several measures that are Medicare-only patients, and those include the standardized transfusion ratio, the Kt/V measures, and the fistula and the catheter measures, and the hospitalization measure. The hypercalcemia measure comes from CROWNWeb, and the SMR comes from a variety of data sources. So it really depends on the measure specifically, and more information about each of these measures is found on the website specifically. So it really depends on the measure specifically in terms of the measures itself.

Raymond Cavazos: OK, thank you.

Operator: And your next question will come from the line of Gina Marinilli.

Katrina Russell: Hi, this is actually Katrina Russell on behalf of the NRAA. Gina Marinilli set up our call. I've got a comment and then a question.

Your earlier reference to the QIP score, you know, we are required to publicly report our QIP score to our patients. And I'm afraid that our Medicare beneficiaries, all of our patients, are going to find it very confusing to have this Five Star as well as the QIP. So I just wanted to comment on that.

The question is, will there be an opportunity for providers to comment on lower scores? In certain cases, there are actually pretty good reasons to explain why a facility might have lower scores. For example, I have a facility that's considered a special care unit and all of our high acuity nursing home patients are at that facility and we struggle to have really good scores there. So I'm just wondering, is there an opportunity to allow the provider to provide public comment on the score?

Elena Balovlenkov: Hi, this is Elena Balovlenkov from CMS. Two things – One, when you talk about the comment period, absolutely, anyone can comment on the score. That's one of the reasons why we have the preview period and we also have preview periods in ongoing years. However, fortunately or unfortunately, one of the things that's important to CMS is that when a patient has a high acuity or lower acuity, we're not in a position to say that there can be different standard quality of care provided or different outcomes based on the acuity of the patient. But we absolutely will take any comments if you believe that, you know, there's a difference that should be occurring in the methodology based on your QIP, please feel free to share that with us.

And then when you talk about posting the QIP scores, your total performance scores for the community to see, one of the things that we're very confident about is the facilities' and the networks' abilities to educate the consumers about what the differences are. And when we have patients who get online on the website and are looking at quality, we have a technical description that will be on that website that will explain to the patient how Star Ratings are to be used, that they're not used in isolation. They discuss with their family, discuss with their nephrologist to help them determine what type of facility they would be – they would like to attend to receive care. And also that we do not tie the QIP scores to the DFC scores on the DFC website. The posting of the QIP scores – we believe that that is part of an educational initiative that's been ongoing with the facilities for a number of years since the QIP scores have existed. So we feel pretty comfortable that the two can be kept separate.

Joel, you wanted to add something?

Joel Andress: Sure. And I just wanted to make sure – there's been a couple of comments that's suggesting it's not necessarily clear. When we're talking about the preview period, we – when we provide you with your Five-Star Rating, it is going to be incorporated in the same report that you receive on a quarterly basis for Dialysis Facility Compare. So the same comment period, the same opportunity to preview the Star Rating will be available that has always been there for Dialysis Facility Compare reports.

Katrina Russell: OK, thank you.

Hazeline Roulac: Your next – next question, please.

Operator: And the next question will come from the line of Deborah Halinski.

Deborah Halinski: Hi, this is Deborah Halinski. I'm from Winthrop University Hospital. Probably just a comment, really, to the panel that with this calculating of scores and reporting of the Five-Star status, my concern is that CMS may not be giving people enough time to smooth out – like one system, like CROWNWeb, for instance. So that when there are upgrades or changes to CROWNWeb, we frequently see that we have discrepancies in our data that need to be fixed before, you know, we can move on. And my concern is that the same thing may happen with this Five-Star Rating.

Joel Andress: So – yes, I'm sorry, this is Joel Andress again. I think we understand that the system is new and that it's something that facilities aren't going to be entirely familiar with at first. We're anticipating that the Star Rating itself will be a work in improvement as we move on. So one of the reasons that we have this call and we're inviting comments both here and/or in the preview period is because we anticipate that there may, in fact, be issues that we are not aware of at this time. And we're hoping to get your input to help us identify those and improve the Star Rating as a public reporting system. So – but as you say, that may be true, and we're hoping that you can help us to identify those issues and deal with them appropriately.

Deborah Halinski: Thank you.

Hazeline Roulac: Thanks for your question. Next question.

Operator: And your next question will come from the line of Tanya Soffer.

Tanya Soffer: My question was actually answered. Thank you.

Operator: All right. And your next question will come from the line of Kathy Lester.

Kathy Lester: Hi, this is Kathy Lester. I'm a consultant to Kidney Care Partners. And I think we've heard a lot of concerns today about the methodology and the fact that it really doesn't align with the QIP. And I appreciate that they're two different programs, but the patients that we work with have learned how the QIP operates and now you're asking them to learn another program. And it just seems that since CMS is interested in stakeholder feedback and that there are may be some serious concerns about the methodology being used to calculate these stars and that it is inconsistent with the QIP, I'm wondering why CMS would not maybe take the opportunity to revise the methodology or to adjust those stars or even perhaps delay the launch in October to make sure that the system, when it does go live, is correct.

Elena Balovlenkov: Hi, this is Elena from CMS. I guess the big thing for me is the use of the word correct because the Five-Star Rating is correct for the Five Star System. It is not a payment system. It is completely different from the Quality Improvement Program, and while we do understand that there may be questions about whether or not QIP ratings are included in the Five Star, we feel pretty comfortable that that can be explained.

And one of the things that it's important to understand is, as you noticed when we did the Star Rating methodology, we used the measures that have existed on DFC for a period of time so that we did not introduce any new measures. We introduced measures that we believe are valid and that the community is aware of. And that by saying that getting the program correct, we do believe that the intent for the consumer of being able to go to a website, to look at the information about the measures, to see a star value, a visual value with an explanation of what that means, that that intent has been met by using the factor methodology.

But, again, we will take a look at it and we are really excited about the fact that people are saying, "Hey, you need to look at this again." But we really do want to stress the fact that QIP is very separate from DFC Star Rating initiative. And, again, you know, please send in your comments and we're also taking notes during this call, and we're willing to look at things again. But as for what stands right now, please keep clear that QIP is not DFC.

Hazeline Roulac: Thanks for your comment. Next question.

Operator: OK. And your next question will come from the line of Kimberly Pettit.

Kimberly Pettit: Hi, my name is Kimberly Pettit. I'm from Tampa General Pediatric Dialysis. And my question was, is there a minimum number of patients that you have to, eligible patients that you have to have to be included in this? Being a pediatric unit, we probably have three or maybe four adult patients. So, I'm trying to figure out if we would still be getting scores on those measures or not?

Elena Balovlenkov: I'd like to have Michigan answer this call.

Valarie Ashby: Sure. This is Valarie Ashby from U of M-KECC. Each measure has a required number or minimum number of patients. For the percentage based measures, that minimum is 11. For the standardized measures, it really depends on the expected number of deaths in the facility or the expected hospitalizations or transfusions. That methodology is shown on the website on dialysisreports.org for more information. But easily, I can tell you that for the percentage-based measures, you have to have at least 11 patients for a measure to be calculated for the facility.

So on the website, if a measure does not meet the minimum threshold for a specific measure, "Not Available" is shown. And the reason given is that there were not enough patients in the facility to show a measure. If the Star Rating is not calculated because the measures weren't there, then it's just not rated.

Kimberly Pettit: OK, thank you very much.

Operator: And your next question comes from the line of ESRD Network 14.

Male: Our question has already been answered.

Operator: Thank you. And the next question will come from the line of Cindy McGee.

Cindy McGee: Hi, I also have a question on the methodology. My question is, I know you utilize the bell curve, and usually with quality measures, we have a goal to look at or, you know, the highest rating. Again, I was just – maybe it's just a comment in regard to the methodology.

Elena Balovlenkov: You go...

Joel Andress: Hello, this is Joel Andress. That's essentially correct. We have actually learned, had some experiences with Nursing Home Compare, which uses a Star Rating System, with regard to how, for instance, thresholds are established for establishing the rating system. And that was part of the – that was part of what led us to the current methodology. If you have concerns about the use of the distributions as we presented them here, or if you have recommendations related to specific thresholds or performance benchmarks in mind, we'd certainly be willing to take a look at those in consideration of future development of the methodology.

Cindy McGee: Thank you.

Hazeline Roulac: Thanks for your comment. Next question.

Operator: And the next question will come from the line of Dr. Eduardo Lacson.

Dr. Eduardo Lacson: Hi, this is J.R. Lacson from Fresenius. My question is, one of the criteria that you use is appropriateness of the measure for Five Star Rating, recognizing that not all measures are appropriate. In the first group where you have standardized measures, you can pick any one mortality hospitalization or transfusion rates. The one formerly used is observed versus expected or divided by expected, and the expected rates are calculated by models, which have 95 percent confidence limits. What that says is within that 95 percent confidence limit, if one is 2 and the other end is 10, 2 and 10 may be part of just the same value because the estimated number of deaths or number of hospitalizations are not exact.

So when you release this data on the Dialysis Facility Compare, you release it as expected or both ends worse than expected or better than expected. When you transform this into a ranking system, a facility that has a rank of 0.99 and a rank that's 1—1 may have anywhere from difference of 35 points to 70 points in the ranking. And you're going to give a star value to that, which is not appropriate to the fact of how the measure is calculated.

So I would like to ask comment and for a reexamination of using this process for the standardized measures. Now the other two corollary problems to this is the problem of small numbers, and that was the case earlier. If you have only four adult patients and one of them gets hit by the bus, you could essentially go out of your comfort zone and be down to the 10- and 1-Star range for that particular measure or at least the bottom of that particular measure. And if you have 99 patients and you have one patient hit by a bus, it may have a totally different affect. And so, I just wanted to kind of make that point and see if there's a way that that could be addressed. Thank you.

Elena Balovlenkov: Joel?

Joel Andress: This is Joel Andress. Hi, JR. So I think that we are aware of the statistical issues that you're raising. This is dealt with in some ways with the methodology by combining the use of all three measures together, by assuring that the Star Rating will not depend on any one single measure but uses a confluence of quality measures.

We retain, as Valarie mentioned earlier, we retain the same limitations on small numbers of patients in order to ensure that facilities with small populations of patients for individual measures, including the standardized measures, are not included in the measure assessment.

I think to get into more depth with this, you know, we would probably need to take a written comment from you and respond to it in writing, given the complexity of the issues involved here. We are certainly aware of what you're raising and then I don't think we

ignored that. But getting into it in too much depth here, I think, would be potentially problematic.

So, if – well, I'll say that I'll invite you to submit written comments. Again, if you want more than the 30 days to submit the writing, and this, of course, goes for anyone here, then we certainly will be willing to entertain the concerns as we're reevaluating the methodology in future years.

Dr. Eduardo Lacson: OK, thank you Joel. And I do think you addressed the mitigation portion in part for the small numbers. But the – in the written comment, I will be, again, asking about how you're going to rank facilities differently within the 95 percent confidence limit when in reality they fall within what would've been an expected rate.

Joel Address: OK, I will ...

Eduardo Lacson: And that's going to be the gist of my comment. Thank you.

Joel Address: All right.

Hazeline Roulac: Thank you.

Joel Address: All right. And we'll certainly respond to that and we'll do so in writing and in a way that's publicly available.

Operator: All right. And your next question will come from the line of Teresita de Guzman.

Female: I'm calling from the line of Teresita de Guzman. My question is about the patients with catheter more than 90 days. Some patients have other comorbidities that will prevent the catheter being removed within the 90-day period. So how do we account for those who cannot be removed? You know, they can – because of other medical conditions, they can't get AV fistula created within that timeframe. So it makes it impossible for them to be removed from catheter within the 90-day period. So, how do I account for those?

Elena Balovlenkov: Chris, can you take that question?

Valarie Ashby: Hi, this is Valarie from U of M-KECC. So the measure – the percentage of patients who had catheter in their vein longer than 90 days, that is the current NQF measure that has been approved for the DFC site. Certainly, we would welcome your questions and comments about patients with comorbidities as we are always evaluating our measures. But that is the current measure that is on our site and shown for this type of – on the DFC site.

Female: So in other words, even though it's not the patient's fault or the facility's fault, you still count it against them.

Valarie Ashby: If the patient has been on a catheter for more than 90 days, then, yes, that is, that particular patient is counted in the numerator as being on a catheter for more than 90 days.

Female: OK, sorry. It doesn't matter what the reason is?

Valarie Ashby: Yes, we currently do not adjust for that measure. It is just a percentage of patients. It's not an adjusted measure.

Female: OK.

Joel Address: And excuse me, this is Joel Address ...

Hazeline Roulac: Thank you.

Joel Address: ... I just want to also say that if you have specific concern with regard to how we're counting patients with that measure, we would certainly accept that as a comment as well. As Valarie says – said, we are always reevaluating our measures and reconsidering how they're constructed to improve their validity for the patient population. So if you believe you've identified exclusions or risk adjustments or some other modifications to the measure that may be important, then we certainly want to hear that in your comments.

Female: OK. So you're going to – you're suggesting we send a written comment.

Joel Address: Yes.

Elena Balovlenkov: That's correct.

Joel Address: Yes, please.

Female: OK, thank you so much.

Operator: And your next question will come from the line of Susan Witzel-Kreuter.

Susan Witzel-Kreuter: Thank you, hello. Actually, my comment is more of a comment. It's that I'm concerned as a social worker that these Star Ratings might create a situation where clinics will be cherry-picking patients rather than accepting these patients that were just discussed, such as the patient with a catheter that can't be replaced by a fistula.

Elena Balovlenkov: I'd like to thank you for your comment. And one of the things that I will point out is that CMS has a robust grievance-collection system where patients are encouraged, who believe that they are not being selected or being specifically selected based on certain criteria, that the patient does have the opportunity to file a grievance either with their facility or at the network and that that will be investigated. Because one of the things that CMS is very serious about is monitoring access to care and monitoring cherry-picking and/or as the other colloquial term is lemon-dropping or excluding

patients from admission to a facility based on criteria that exist for that patient. It is something that we do monitor through the Patient Contact Utility and through the grievance system. But, thank you.

Joel Andress: And I would also just note that with the implementation of the QIP, this has already been a concern for CMS. So, while I agree that there may in fact be some risk for this occurring with the Star Rating, I think the additional risk, on top of that already experienced as a consequence of the QIP, is likely to be minimal. Nevertheless, we will be on the lookout for any evidence of those kinds of issues.

Susan Witzel-Kreuter: My concern isn't just about the clinics choosing patients, it's about the patients who are in that condition not being able to voice their own concerns and make that phone call to lodge complaints or have advocates for them that can do so.

Elena Balovlenkov: One of the things that CMS has been doing for the past year is we've implemented a new grievance system, the Patient Contact Utility, that is being used to track grievances. And one of the new processes that have changed, that if you check the cms.gov website, the DFC website, that patients can now call the network directly if they have concerns relative to their access to care and are afraid to bring this issue up at the facility level. And this could also occur with discharge planners calling the network if they believe that a patient is being discriminated against in access to care issues. So CMS is very aware of this and very sensitive to this issue. And we appreciate your comment, and it's something that we really do take very seriously. So, thank you.

Susan Witzel-Kreuter: Thank you.

Operator: And your next question will come from the line of Robert Sepucha.

Robert Sepucha: All right, thanks for doing the call. I just want to confirm something I heard earlier. It seems to be getting conflicting messages. On the one hand, we are encouraged to submit comments for the next month and that you'll look at these comments closely. But then I have heard several times with the methodology, no matter what the comments say, the methodology for this year is fixed. Any comment has nothing to do with what will be published in October but for future years. Is that correct?

Joel Andress: Yes. To clarify, this preview period, regardless of what comments we receive, we would not have enough time to modify Star Rating – the Star Rating for October. So instead, what we will be looking to do is just to take the comments that we receive as a result of this comment period or even outside of it and take into consideration as part of next year's process when we begin to take another look at the Star Rating at that point.

Essentially, what will be happening on an annual basis is that after our update of the Star Ratings in October, we will begin to look at the methodology for next year, to consider whether or not there are additional measures that need to be added, new domains that need to be included within the ratings, or if the statistical structure and scoring of the Star

Rating needs to be reconsidered. And a critical part of that reconsideration from year to year will be your comments as they're submitted. So while it is true that it will not impact the Star Rating methodology for this year, it very much has the potential to impact the Star Rating methodology for next year and future years.

Robert Sepucha: Seriously, nontransparent process for the inaugural year of the Star Rating, but thank you for your response.

Hazeline Roulac: Thanks for your question. Next one.

Operator: All right, and your next question will come from the line of Heather Dauler.

Heather Dauler: Hi, thank you. I just wanted to clarify what I believe I heard Elena saying when we were speaking about publicly disseminating or telling the patients the difference between the QIP and the Star Rating System. I believe I heard Elena say that she was confident in the network and the facilities' ability to differentiate the two for the patients. Is it then CMS's expectation that all of the networks and all of the providers and facilities will proactively work with patients to ensure they have an understanding of each system?

Elena Balovlenkov: Hi, this is Elena. One of the things that's important is, remember, the QIP has been around for a number of years now so that facilities and/or the networks I know have done a lot of education with facilities helping facilities understand and develop teachings tools for patients to understand the QIP. So by now, if you're not a new patient, the majority of the patients should understand how to interpret the total performance score that is posted in a facility.

And by the facilities working with the networks to say, "OK, so how do I explain this to the patient and encourage them that if they have any questions to use the DFC site to look at if, let's say, it's a transient patient going on vacation and they're saying, 'I'm going to Florida and I'm trying to figure out where I should get my mom to dialyze within 25 miles of where I'm going to be staying.'"

Then it's very easy for the social worker or someone to sit down with the patient and say, "OK, let's pull up DFC and look at, you know, what's the geographical location. Let's look at the quality ratings for these areas." And to help a patient select an area where they want to have their family member dialyzed. So we do see them as two totally different systems.

Hazeline Roulac: Well, thank you for your question. Next question.

Operator: And your next question will come from the line of Diane Crafton.

Diane Crafton: Hi, this is Diane Crafton, Wheeling Renal Care. I have, I guess, a comment, and we have submitted comments in the past related to this subject, our medical director in fact, regarding the DFR transfusion ratio.

At one of our facilities we have a single patient who has a significant GI bleed issues – sent three, four times a year for ablation, not under our care at all, care provider, GI physician, numerous admissions, numerous transfusions, and those are all being accounted against us so that we are actually showing on the DFR as worse than expected for transfusion. Our medical director drafted comments indicating that it was related to a specific patient and that we had no opportunity to correct this. We have no opportunity to change it.

So, I guess my question is, having already submitted the comment and not received any written comment in response, it doesn't seem like there was any opportunity moving forward to adjust the standardized transfusion ratio so that a facility with one patient such as this one would not be indicated on your website as substandard. Am I missing something?

Elena Balovlenkov: This is Elena Balovlenkov. I have a comment before I have Joel answer your question. One of the things that we're looking at doing differently this time, and I talked with our group director about this, is creating a consolidated question document and coordinating the questions that we may have 50 people saying the same thing different ways. Actually, we're going to have a mechanism where any comments that we receive, we will post publicly so that, you know, that CMS and Michigan, we looked at the comments and that we will be responding.

And then our assumption is that if you have the question, that maybe 10 other people in the community that have that same question, and we want to be able to provide consistent answers as much as possible to everyone. So we will, for the comments we receive, be creating a consolidated question document with responses for the public. Joel?

Joel Andress: So I'll just say this, if you've already provided us with a comment on this and you haven't received a response for it, then I would ask you to simply copy/paste, send it again, and we'll incorporate it in that document.

The issue I think to hand is not necessarily the reporting methodology so much as the measure specifications themselves. So I think where we probably look at what you're describing is in maintenance of the measure specifications directly and we want to consider whether or not this is a case in which an exclusion might be appropriate. So I would ask you – I realize it's not – it's probably not your preference, but if you can submit that comment again, we'll take a look at it and we will get you a written response to your concern.

Diane Crafton: Thank you. We would appreciate a written response. Thank you very much.

Elena Balovlenkov: Thank you.

Operator: And your next question will come from the line of Lana Chambers.

Lena Chambers: Hi, this is Lena. I have a question and I just want to make sure I'm understanding it properly. If we did the QIP and we passed it with no penalties and we were unscathed in the process, is it true to say that the Star Rating may or may not reflect that? Like if we did good with QIP, is it possible for us to get like three stars or less or four? How does that compare, because it seems like you can do good on one end but still possibly be penalized on another end.

Joel Andress: This is Joel Andress. So in constructing this, as we've said, we did not construct this to be parallel directly with the QIP. So there are measures that are incorporated in the Star Rating which are not part of the QIP. So, of course, performance there may cause variation in the overall assessment. As well, the methodological approach for setting what Star Rating a facility receives is distinct from the benchmark and threshold approach that the QIP – that the QIP scores possess.

That having been said, in producing this methodology, as I said earlier, we did look at how QIPs – the QIPs penalties were distributed across the Star Ratings, and I don't have those results in front of me right now. But generally speaking, there – if you were – if you had received a penalty, then – if you had received one of the larger penalties, then you are certainly in a one- or two-star facility. I think there were some facilities that received a penalty and scored higher, but there was not – I'm going to free fall here – there was not a great deal of overlap between penalties and, say, the four- and five-star ratings.

So, while it is possible that there would be facilities that did not receive a QIP penalty but received a rating below four or five, it would be unlikely if you had received a penalty to achieve a higher score. Any variation that you're looking at, we're probably looking at the facts that we're using different measures for the assessment and the thresholds. That is for the Star Rating is using a different methodology.

Lana Chambers: OK, thank you.

Operator: And your next question comes from the line of Susan Senich.

Susan Senich: Hello, Susan Senich, North Central Pennsylvania Dialysis Clinic. This is a softball. Since patient satisfaction is something that we're working on, do you think the CAHPS results are ever going to be an element in the Star System?

Elena Balovlenkov: One of the things that we're looking for as we started within the presentation is that, while the ratings that are going to be posted for the preview period and for public comment – for public release in October are based strictly on the composite of the measures that are found on the DFC website currently, that we will be accepting comments for other measures or elements that could be included. And it could be grievances, it could be survey and CERT results, it could be seven, it could be any number of things. So that if you have something that you would like to recommend, please send it to us in a public comment because we're always looking for new and innovative valid ways to be able to evaluate the work that's being done in the community.

Joel Andress: And then – this is Joel again. As Kate mentioned earlier, one of the guiding principles for measure development and public reporting the measures is the CMS Quality Strategy, which has identified six particular domains of care. One of those is patient engagement. So certainly, we are interested in measures that address issues of patient satisfaction and patient experience of care.

In terms of whether or not the CAHPS measure, for instance, would become part of the Star Rating, that's something that we haven't decided at this current time, but we will be taking into consideration later on. I do know from working with the QIP, for instance, that the CAHPS data are not yet available for implementation on DFC. So we would have to wait there, particularly at least until there were sufficient data available to have anything to report.

Hazeline Roulac: Thanks for your question. We'll take one more question.

Operator: OK, your last question will be a followup from Dr. Eduardo Lacson.

Dr. Eduardo Lacson: Hi, J.R. Lacson again. Just wanted to ask, because the DFC has been there for many years and the QIP has been there for many years, and now we have this Five Star Program that appears to be, you know, a high priority to roll out this year, if there were indeed serious issues with some of the methodology, what is the driving force behind the requirement to make sure it's rolled out this year? Why can't it wait next year? Is it a regulatory issue? Is it a policy issue? Because if patients have gone on without this, I believe it can wait another year for the methodology to be more examined and to be more precise and to be more appropriate to reflect quality rather than just numbers for potentially just numbers sake? Thank you.

Elena Balovlenkov: J.R., hi, it's Elena Balovlenkov. It's actually a two-part answer. One, we do a lot of consumer testing here at CMS to find out what they think of the website and the information that the government is providing. And so this is actually being driven by two things.

One, the consumer has been asking at our consumer touch points that they want a way to better understand what quality means at a dialysis center. They don't drill down and get into the weeds with the numbers. So we have had multiple comments where patients have asked, "So how am I supposed to decide if a dialysis facility is giving good care or not, whether this is somewhere I should be?" You can't just go by whether or not a patient or a family member files a grievance.

And the other thing being is, this is part of the mandate for the Affordable Care Act, that we improve our public reporting and improve our transparency in a way that consumers can have an easy way to understand how to evaluate quality at the community level at the facilities. And while we are planning right now – we have the preview period next week. You know, we're seriously going to look at people's comments, you know, to see whether or not you all think we've gotten it right. We feel comfortable in what we've

done, but we again are open to listen to what people have to say. But as to what's driving it, it actually is in response to our meetings from the community.

Dr. Eduardo Lacson: OK. And since it's the community that's driving it, if there's a sufficient response back from the community to say, "Can we please hold on and review the methodology," could that potentially ...

Elena Balovlenkov: What I can tell you is that ...

Dr. Eduardo Lacson: Or, that's impossible at this point?

Elena Balovlenkov: I can't tell you whether it's possible or impossible, that's above my pay grade. But I will tell you that, you know, Dr. Goodrich, Dr. Conley are very interested in our comments from the stakeholders, and we will absolutely bring this up at that level to discuss the comments that we get back from our providers. We do take comments from our providers very seriously, we do respond to them, just as we take the comments from our consumers. So, you know, I will absolutely make sure that it's discussed.

Dr. Eduardo Lacson: Yes, ma'am. Well, thank you very much. I'm sorry I ask questions in all candor and I make comments in all candor, and I thank you for your response.

Elena Balovlenkov: Thank you.

Additional Information

Hazeline Roulac: So, that is our last call for today. We want to thank you very much for all of your questions and your comments. If you have general questions or comments concerning the Star Rating System methodology for Dialysis Facility Compare, please refer to slide 38 for the email address where you can submit those. An audio recording and written transcript of today's call will be posted to the MLN Connects Call website. We will release an announcement in the MLN Connects Provider eNews when these are available.

On slide 42 you will find information and a URL to evaluate your experience with today's call. Evaluations are anonymous, confidential, and voluntary. We hope that you will take a few moments to evaluate your MLN Connects Call experience.

Again, my name is Hazeline Roulac. I'd like to thank our presenters and also thank our listeners for participating in today's MLN Connects Call on the Dialysis Facility Compare Rollout of Five Star Rating. Have a great day, everyone.

Elena Balovlenkov: Thank you.

Operator: Thank you for your participation on today's call. You may now disconnect.

This document has been edited for spelling and punctuation errors.

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