ESRD QIP: Proposed Rule for Payment Year 2021 Listening Session

Moderated by: Aryeh Langer
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Table of Contents

Announcements & Introduction 2
Presentation 2
ESRD QIP Overview 3
CY 2018 ESRD PPS Proposed Rule: ESRD QIP Proposals 4
Proposal for Payment Year 2021 Program 6
Programmatic Initiatives for Public Comment 7
Participating in the Comment Period 8
Resources 8
Question & Answer Session 9
Additional Information 10

Operator: At this time, I would like to welcome everyone to today's Medicare Learning Network® Event. All lines will remain in the 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 & Introduction

Aryeh Langer: Thank you very much, Dorothy. As you just heard, my name is Aryeh Langer from the Provider Communications Group here at CMS, and I'm your moderator for today's call. I'd like to welcome you to this Medicare Learning Network call on the End-Stage Renal Disease Quality Incentive Program, or ESRD QIP.

During today's call, you will learn about provisions in the calendar year 2018 ESRD Prospective Payment System proposed rule including plans for the program in payment years 2019, '20, and '21. The agenda will be covered shortly.

Before we get started, you received a link to the presentation in your confirmation email. The presentation is available at the following URL: go.cms.gov/npc. Again, that URL is go.cms.gov/npc.

I would like to point out that, on slide number 2, you will find a list of acronyms that will be used during today's presentation. As participants have requested in past calls, we have included this in the beginning of the slide deck.

At this time, I would like to turn the call over to Tamyra Garcia from CMS.

Presentation

Tamyra Garcia: Good afternoon to you all. As Aryeh stated, my name is Tamyra Garcia, and I am the deputy director of the Division of Value, Incentives, and Quality Reporting in CCSQ. First, we would like to thank you all for joining us this afternoon and welcome you to the calendar year 2018 End-Stage Renal Disease Prospective Payment System Proposed Rule Medicare Learning Network Event.

Today, we have Delia Houseal, our program and policy lead, along with Joel Andress, our resident ESRD measures lead, and Celeste Bostic, our technical expert nursing consultant, providing you with pertinent information on the calendar year 2018 proposed rule.

We hope that you come away from this call more knowledgeable of the calendar year 2018 proposals and with extremely important questions to ask us, whether it be on the line today or via the comment period.

Right now, I'm going to turn it over to Delia Houseal, our ESRD QIP lead, to go on ahead and get us started. Thank you.

Delia Houseal: Awesome. Thank you, Tamyra. So today, we are going to provide an overview of the calendar year 2018 ESRD Prospective Payment System Notice of Proposed Rulemaking in which we have proposed policies and measures for payments years 2019 to 2021 of the ESRD QIP.

We'll also be providing a summary of the formal public comment process and then open it up for discussions – for questions as time permits.

While we will try to answer as many questions as possible, please note that Federal regulations prevent us from answering any specific questions or addressing your opinions about the proposed rule which was published in the *Federal Register* at the beginning of July. However, we encourage you to share your ideas and questions on the proposed rule itself by participating in the formal comment period that is now ongoing.

If you need additional information after this session, I invite you to review the online resources identified at the end of the presentation, and any questions that remain can always be sent to our mailbox, esrdqip@cms.hhs.gov. After participating in this webinar, we hope that you will be able to locate the calendar year 2018 ESRD QIP proposed rule text and identify our policy proposals.

You should also be able to identify how and when to submit public comments on the rule. So let's get started with a legislative overview of the program.

ESRD QIP Overview

On slide 7, you'll see here that the ESRD QIP was authorized by the Social Security Act, which was added by section 153(c) of the Medicare Improvements for Patients and Providers Act of 2008, also known as MIPPA. The act was also amended by protecting access to Medicare act – by the Protecting Access to Medicare Act of 2014, or PAMA, to include additional statutory requirements for the program, such as the inclusion of measures that are specific to conditions treated with oral-only drugs.

The overall purpose of the program is to incentivize and encourage improvements in the quality of care provided in outpatient dialysis facilities by adjusting payments of up to 2 percent for facilities that do not meet performance standards on selected measures.

The table on slide 8 lists the finalized measures and performance periods for payment year – payment years 2019 and 2020. Comparing the two payment years, you will see that we've added three new measures in payment year 2020. We added the Standardized Hospitalization Ratio clinical measure to our Clinical domain and the Ultrafiltration Rate to our Reporting Measures domain. Additionally, in payment year 2020, we replaced the Mineral Metabolism reporting measure with the Serum Phosphorus reporting measure.

Slide 9 provides an overview of the process CMS uses to develop ESRD QIP rulemaking. As you can see here, we start out by conducting a series of strategic planning sessions which result in the development of draft proposals for various payment years. Next we share our proposals with various components throughout HHS and refine and/or modify our proposals based on the feedback given. After we've completed the internal clearance process, we publish the proposed rule in the *Federal Register* and provide stakeholders, such as yourself, with 60 days to provide feedback and comments on our proposals as well as suggest approaches that

you would like to see in the program. In this way, facilities and the general public have an opportunity to influence policies governing each payment year. After we review and respond to comments, we draft our final proposals to share with other HHS components, and once cleared, we publish the final ruled – rule in the *Federal Register*.

I'd like to note that public comments are taken very seriously at CMS. In the past, comments have led to various changes and/or the removal of our – of some proposals. So again, I'd like to reiterate that it's very important for you to participate in the comment period and share any thoughts and recommendations that you have on how the ESRD QIP can best serve the needs of patients with ESRD.

With that overview in mind, we will turn our attention to the ESRP QIP proposals published in the calendar year 2018 ESRD PPS proposed rule. I'll present proposals for payment years 2019 and 2020, and then I'll turn it over to my colleague Dr. Joel Andress to present proposals for payment year 2021.

CY 2018 ESRD PPS Proposed Rule: ESRD QIP Proposals

On slide 11, you'll see our only proposal for payment year 2019. In this proposal, we present our plans to simplify the Performance Score Certificate. Over the last few years, the PSC has expanded significantly as the program has grown in complexity and in the number of measures and as the number of measures has increased. Additionally, we've heard several concerns from consumer advocacy groups that the current layout and amount of information included might create more confusion for patients and their families.

To address some of these concerns, we are proposing to streamline the content, simplify the language, and make the document more readable. Specifically, we are proposing to retain basic facility information, the facility TPS and the national average TPS in future versions of the Performance Score Certificate.

We also plan to continue releasing the document in both English and Spanish. We believe that these changes will make it much easier for consumers to understand the PSC and reduce facility burden by decreasing the number of pages that must be printed and publicly displayed.

We encourage you along with patients, family members, caregivers, and other stakeholders, to comment on our proposal to simplify the PSC and let us know if there are other ways in which you believe that it can be improved.

In the next few slides, we will discuss five specific elements of the proposed rule that would impact payment year 2020. We've listed them here for you on slide 12.

Our first proposal for payment year 2020, here on slide 13, discusses the way that CMS determines eligibility for individual ESRD QIP measures. In this proposal, we are clarifying how we determine eligibility by the number of months the facility is open starting with the first day of the month following the facility CCN Open Date.

In the calendar year 2017 ESRD PPS Final Rule, we inadvertently included incorrect information for certain measures. So in this proposal, we are seeking to apply this current policy in a uniform way to payment year 2020 measures.

The proposed rule includes a table that shows how our current policy should apply to those measures with respect to minimum data requirements, CCN Open Dates, and small-facility adjusters. I'd also like to reiterate that this proposal does not change the methods we use to determine a minimum number of cases for measure eligibility or change how we score the measures.

Slide 14 addresses another area that we're looking to update. Currently, we have an Extraordinary Circumstances Exception policy that permits a facility to request an exemption from ESRD QIP measure eligibility and scoring for a defined amount of time. Our current policy requires a facility to be closed completely in order for an ECE to be approved and only permits the CEO to authorize the request.

With this proposal, we are looking to update our ECE policy to align with other CMS Value-Based Purchasing programs and to provide more flexibility in our ECE policy. Specifically, we are proposing to allow a facility to designate personnel who could sign the ECE request form submitted to CMS. In addition, we want to expand the grounds under which an ECE can be requested to include those times when the facility's operations are significantly affected for reasons beyond its control. For example, the ECE would now cover situations when a facility's ability to report data by a particular submission deadline is affected due to an unresolved issue with the CMS data system. To date, CMS has been able to establish a suitable workload – workaround or extend the deadline in question in most situations. With that being said, we do recognize the possibility – that the possibility exists that we may be unable to establish a workaround, and we want to provide a basis for requesting an ECE should that event come to pass.

Finally, we are also proposing to remove the requirement that a facility must be closed completely in order for an ECE to be approved.

On slide 15, we address our proposal to alter the method by which CMS selects the 35 facilities to participate in the National Healthcare Safety Network data validation study. Specifically, CMS wants to adjust the sampling method to ensure that a more representative sample of the facility data is included. Also, given that our sample size is relatively small for this pilot, we'd like to increase the probability that facilities at risk for underreporting are selected to participate in the validation study.

Consistent with previous rules, slides 16 through 18 provide the estimated performance values.

We – here we look at the achievement thresholds, benchmarks, and performance standards for payment year 2020 clinical measures. We've also released the data file we used to calculate these values on the Public Reporting and Certificates page of the ESRD QIP section on cms.gov.

Using this information, we also estimated that the minimum Total Performance Score for payment year 2020 will be 61 points, as shown ahead on slide 18. The finalized performance values and minimum Total Performance Score will be included in November's final rule using the most recently available data.

Now that we've highlighted the proposed changes to payment year 2019 and payment year 2020, we'll address the proposals for the payment year 2021 – excuse me – program. And for that discussion, I'm happy to turn it over to Dr. Joel Andress. Joel?

Proposal for Payment Year 2021 Program

Dr. Joel Andress: Thank you, Delia. Good afternoon. This is Joel Andress. We'll start with discussing CMS's plan for 2021 focusing on the three measures we proposed to either revise or replace to keep pace with evolving national quality reporting standards.

We'll start the discussion on slide 20 with the proposed measure set. You may notice that the structure of the measure set continues from what we finalized for payment year 2020. The domain and subdomain weighting in calculating the TPS remains unchanged, and the measures themselves remain mostly the same with the exception of the revision or replacement measures noted with a gold star here on slide 20. And we'll be discussing those in the next two slides.

Further, we're proposing to continue using the measure score – scoring methods in payment year 2021 that we've employed for the last several years, including the application of achievement and improvement scoring for clinical measures and the measure-specific scoring methods for the Reporting Measure domain. Because CMS proposes to retain the payment year 2020 scoring structure, we are not devoting a lot of presentation time to it. If you're interested in the – in detailed overview of scoring, please take a look at the Payment Year 2020 Final Rule National Provider Call materials, which we've posted on the Educational Resources page of the ESRD QIP section of cms.gov and to the *CMS ESRD Measures Manual* posted on the Measuring Quality page.

On slide 21, we discuss our proposed replacements for the two current Vascular Access clinical measures. These new measures were developed at the – with the assistance of a technical expert panel in 2015 and reflect a number of changes recommended by that panel. The core changes to these measures are that they will now become all-patient measures. They will no longer be restricted solely to Medicare beneficiaries.

We are also incorporating additional exclusion criteria reflecting patients with conditions that result in limited life expectancy where the placement of a fistula or a graft may not be appropriate and may not be clinically appropriate for the patient.

We are also adjusting the Fistula measure—the new Standardized Fistula Rate—for conditions with – where – which may lead to a low rate of success for fistula placement, which may reflect that a graft is more appropriate for placement with the patient. This is intended to provide appropriate levels of clinical flexibility to physicians in treating their patients.

The primary purposes of these alterations are to respond to a number of comments from stakeholders regarding the existing fistula measures and to reflect advances in the state of knowledge and access placement for dialysis patients.

On slide 22, we're – you'll see we're also proposing to revise the Standardized Transfusion Ratio clinical measure. This revision addresses some concerns that were raised by the National Quality Forum's Renal Standing Committee about the previous measure with respect to variability in hospital coding practices.

The revised definition of transfusion events now excludes inpatient transfusion events that include only 038 or 039 revenue codes without an accompanying ICD-9 or -10 procedure or value code. And the purpose of this is to address the National Quality Forum's concerns and provide for less variability to the measure that is a consequence of differences in hospital coding practices rather than the quality of care provided by the dialysis facilities.

On slide 23, you'll see another illustration of the proposed payment year 2021 program highlighting the proposed changes, identifying the domain weights, and reinforcing that the ESRD QIP will continue to use a hundred-point TPS scale centered around the minimum TPS with payment reduction percentages continuing to be set at 10-point increments.

From this point, we'll move on to a discussion of some overall programmatic initiatives that CMS would like public comment about. And for that, I'll turn the discussion back over to Delia.

Programmatic Initiatives for Public Comment

Delia Houseal: Great. Thanks, Joel. So beginning on January 1st, 2017, renal dialysis services provided by renal dialysis facilities as defined under section 1881(b)(14)(B) of the Social Security Act are also covered and reimbursed for individuals with AKI. Consequently, in this proposed rule, we are confirming our statutory authority to collect data on this patient population. And while we have the ability to collect data on this population and believe that it is important to monitor and measure the quality of care furnished to these patients, we also recognize the unique needs of this population and would like to gather additional data on the population to assess the feasibility of developing measures before including this population in ESRD QIP.

In this proposed rule, we are reiterating that facilities are not required to report AKI patient data for any of our measures in ESRD QIP. This also includes the NHSN BSI clinical and reporting measures.

We are also seeking comments from stakeholders about whether and how to include AKI patients in ESRD QIP measures in the future.

Slide 25 addresses CMS's focus on social-risk factors and how they impact Value-Based Purchasing programs.

To follow up on findings from the ASPE report published last December, we continue to examine how beneficiaries' socioeconomic status impacts the effectiveness of their care and the extent to which that has the potential to affect facility scores.

We are very interested in the community thoughts on how ESRD QIP measures can reduce disparities and how we can alter risk adjustment methods to better account for these risk factors.

So this concludes our high-level overview of ESRD QIP elements in the calendar year 2018 ESRD PPS proposed rule. So now, I will turn it over to my colleague Mrs. Celeste Bostic. Celeste?

Participating in the Comment Period

Celeste Bostic: Thanks, Delia. Now that we have reviewed our proposals, we will now go over the process for participating in the comment period.

On slide 27, we provide an overview of the process that CMS follows in creating and implementing Federal regulations. In past years, the comments that CMS received helped to shape the final rule and they sometimes reflected significant differences from the proposed rule as a result of those comments. For example, in the payment year 2015 proposed rule, it included Hypercalcemia as a clinical measure. However, CMS changed course in the final rule due to the feedback it received as a part of the comment process. Therefore, your participation in the process is essential in creating the best possible program for measuring facility performance in providing quality care to the ESRD population. Again, please note that the comment period will end on August 28th, 2017.

The most convenient way to submit a comment is online via regulations.gov. On slide 28, we provide a screenshot of that home page. You can use the search box to navigate to the rule and the comment portion. There are several search terms that successfully return the proposed rule as a result, including the file name, as pictured here, as well as "calendar year 2018 ESRD PPS," which is a portion of the proposed rule formal title.

Slide 29 identifies the methods to submit comments on the proposed rule. If you choose to use regulations.gov, you can search for the rule as described and use the Comment Now button to submit your comment. You can also upload files as a part of your comment. Your state, ZIP Code, country, and your category, whether you're submitting as an individual or a health care professional, are now required fields. You must also disclose whether you are submitting the comment on behalf of a third party as well as that organization's name. We've also listed the resources for additional help in using the system.

Of course, you do not have to use the online interface to submit comments, and you can utilize the alternative methods noted here on slide 29. Please be sure to allow time for transit and delivery to prevent any delays if you choose to use the alternative methods.

Whichever comment method you choose, be sure to include a reference to the file number from the previous slide, CMS-1674-P, in your correspondence.

And with that, I'll turn the presentation back over to Aryeh Langer to open the question-and-answer session.

Resources

Aryeh Langer: Thank you, Celeste. In a moment, we will take your questions. Before we do, I'd like to refer to slide 31 and remind you that, due to the Administrative Procedure Act, we are unable to provide additional

information on the proposed rule and we encourage you to submit comments or questions through the formal comment submission process, as described.

I would also like to point out that, on slide 32, you will find useful links to resources for more information, including the proposed rule, ESRD QIP CMS webpage, and others.

Okay, Dorothy, we are now ready to begin our question-and-answer session. As a reminder, this event is being recorded and transcribed.

Question & Answer Session

Operator: To ask a question, please star followed by the number 1 on your touch-tone phone. To remove yourself from the queue, press the pound key. Remember to pick up your handset before asking your question to assure clarity. Once your line is open, state your name and organization. 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. If you have more than one question, press star 1 to get back into the queue, and we will address additional questions as time permits. Please hold while we compile the Q&A roster.

Please hold while we compile the Q&A roster. Your first question comes from the line of Robert Brown.

Robert Brown: Hello. I'm Dr. Robert Brown. I'm the chairman of Network Number One Regional Board. And my question really is a statement for the listeners. I assume that you can – they can hear my voice. Is that correct?

Aryeh Langer: Yes, sir.

Robert Brown: Then, because you're not really going to answer them – and I would like to point out for the other listeners that we are happy that you've seen that AV grafts are important access aids to avoid catheters. And one question is whether this should be added to years 2019 and 2020 in addition to '21 rather than just looking at fistulae, particularly given the elderly nature of our population.

Also, we might mention that we facilities don't control these things entirely. We get patients, and they have accesses often. So if they have grafts, that's still useful, and the same thing occurs in the infection rates. For instance, the infection rates for catheters are 10 times what they are for other patients. So a particular unit that has a lot of catheters is going to have higher infection rates, essentially double counting. They suffer from catheter, as many urban units have, and from infection rates. So we would urge the listeners to consider asking for infection rates only in catheter patients since we don't control diabetic feet, etc., and good care depends on giving good catheter care that units can give rather than total care. That's my statement. Thank you.

Aryeh Langer: Thank you very much.

Operator: As a reminder, if you would like to ask a question, please press star, then the number 1 on your telephone keypad. To remove yourself from the queue, press the pound key.

Dr. Joel Andress: Good afternoon. This is Joel responding to Robert. So thanks, first of all, for your comments regarding the measures. We're always looking for ways to improve on the measure set.

With regard to your question about the process for implementing the measures for 2019 and 2020, I think there's a legal process involved in trying to put forward proposals for that. So I can't speak to that too much here. I can say that we present them on the timeline that we do because, not only are there legal requirements in terms of going through the rulemaking process, but there are also issues with regard to the timeline and implementation within the QIP system and also providing you with advance notice of what our requirements for the ESRD QIP are going to be.

Certainly, we – I'm gratified to know that you think these measures are worthwhile to the extent that you would like us to consider implementing them more quickly. And I think we'll certainly do our best to respond to any additional concerns you may have about them in the future.

With regard to additional measures and the future measure set, I don't think we can respond any more than to say that we are interested in your feedback. And if you have evidence supporting a particular measure, for instance, infections only in catheter patients, then we'd certainly be interested in talking with you more about that and discussing with you any evidence around it. So thank you.

Operator: Again, if you would like to ask a question, please press star, then the number 1 on your telephone keypad. To remove yourself from the queue, press the pound key. Your next question comes from the line of Maile Robb.

Maile Robb: Hi. My name is Maile Robb. I am a patient SME. I'm from Network 15. And I just want to encourage CMS to keep involving patients as much as they can. We're the ones that are in the units every day dealing with these illnesses. And we appreciate the involvement that we had, but we would definitely appreciate more involvement. Thank you.

Dr. Joel Andress: Maile, this is Joel again. Thank you for letting us know. I think we've been making efforts to expand our involvement of patients certainly in our measure development and policy development efforts. But we're also looking for ways in which we can get more patients involved. Currently, we, on a fairly annual basis, send out calls for nominations for patients to be involved in our technical expert panels that help us develop measures. We also try to get input on the implementation of our measures from patients. If you have any recommendations regarding how that might be occurred, then I think it would not be too far afield to suggest that you can submit a comment to us, and we'd be happy to take a look at that and see what ways we can try to engage with you further. But thank you for reaching out.

Operator: And there are no further questions. I will turn the conference back over to Aryeh Langer.

Additional Information

Aryeh Langer: Okay, thank you very much. Please reference the slide deck for information on submitting comments on the proposed rule. For more information on MLN Events and resources, please see slide 33.

Again, my name is Aryeh Langer. I'd like to thank our presenters here at CMS and also thank you all on the phones for participating in today's Medicare Learning Network Event on the ESRD QIP. Have a great day, everyone.

Operator: Thank you for participating in today's conference call. You may now disconnect.