



## CY 2019 ESRD PPS Proposed Rule Call

**Moderated by: Leah Nguyen**  
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Operator: At this time, I would like to welcome everyone to today's Medicare Learning Network® Event. All lines will remain in a listen only mode. 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 Leah Nguyen. Thank you, you may begin.

## Announcements & Introduction

Leah Nguyen: I am Leah Nguyen from the Provider Communications Group here at CMS, and I am your moderator today. I'd like to welcome you to this Medicare Learning Network Call on the End Stage Renal Disease Quality Incentive Program, also referred to as ESRD QIP.

During this call, learn about proposals for the ESRD QIP in the calendar 2019, ESRD Prospective Payment System, or PPS final rule. This call will not include a question and answer session.

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](https://go.cms.gov/npc), again that URL is [go.cms.gov/npc](https://go.cms.gov/npc).

At this time, I'd like to turn the call over to Delia Houseal from the Center for Clinical Standards and Quality.

## Presentation

Delia Houseal: Thank you, Leah, and good afternoon to you all. As Leah stated, my name is Delia Houseal and I am the ESRD QIP program lead. First, we would like to thank all of you for joining us this afternoon and welcome you to the calendar year 2019 ESRD QIP Proposed Rule Medicare Learning Network Event. Unfortunately, my colleague James Poyer was unable to join the call, however he sent his warmest regards. We hope that you come away from this call more knowledgeable about the proposals and also how to express your opinions and concerns about them during the comment period that runs through September 10th.

Slide 4. So, today we are going to provide an overview of the calendar year 2019 ESRD QIP Perspective Payment System notice of proposed rulemaking, in which we have proposed policies and measures for payment years 2021 and 2022 of the ESRD QIP. We also have one proposed measure that would not take effect until payment year 2024 but for which we would need to start collecting data as soon as next year. We'll also be providing a summary of the formal public comment process, and please note that federal regulations prevent us from answering any specific questions or addressing your opinions about the proposed rule at this time. Instead 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 as always, questions that remain can be sent to the Q&A tool on Quality Net. If your question involves your facility specifically, then please continue to contact us using our program mailbox at [ESRDQIP@CMS.HHS.gov](mailto:ESRDQIP@CMS.HHS.gov). After participating in this webinar, we hope that you will be able to locate the calendar year 2019 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 proposed rules.



## ESRD QIP Legislative Drivers

So let's get started with the legislative overview of the program on slide 6. Here on slide 6 you'll see that the ESRD QIP was authorized by the Social Security Act which is added by Section 153C of the Medicare Improvements for Patients and Providers Act of 2008, also known as MIPPA. The Act was also amended 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 ESRD QIP is to incentivize and encourage improvements in the quality of care provided in dialysis facilities by adjusting payments of up to 2 percent for facilities that do not meet performance standards on selected measures.

On slide 7 you'll see a summary of our statutory requirements. Here you'll see that the ESRD QIP is responsible for selecting measures that address a variety of high priority areas. We are also required to establish performance standards and specify the performance period for any given payment year. We're also required to develop a methodology for assessing the total performance of each facility and applying any — and applying the appropriate payment percentage reduction for those facilities that do not meet or exceed total performance scores. Lastly, we are required to publicly report those results through websites such as DFC and CMS.gov and also require that a facility post their performance score certificate.

And slide 8 provides an overview of the rule development process. By issuing a proposed rule, CMS proposes clinical and reporting measures for a given payment year. We also propose the score mechanisms that we want to include for that payment year. Then, we provide the public with a 60-day opportunity to comment on the proposals and suggest approaches it would like to see in the program. This way we give facilities and the general public an opportunity to influence policy governing each payment year. Also would like to reiterate that public comments are taken very seriously by CMS. In the past, comments have led to the postponement of implementing measures, and those measures are stronger when they were implemented in future years due to the input received. So, it's very important that you participate in the comment period and share your thoughts on how the ESRD QIP can best serve the needs of — the needs of patients with ESRD.

## CMS Meaningful Measures Objectives

Next slide...With the foundation of the ESRD QIP in mind, we now want to take a few minutes to see how the program interacts with another major CMS initiative — Meaningful Measures.

So on slide 10 here, we discuss the objectives of the new initiative. Under Meaningful Measures, CMS identifies the highest priorities for quality, measurement, and improvement, and assesses only those core areas that are most critical to providing high quality care and improving individual outcomes. Recognizing that the importance of measurement must be balanced with the administrative burden it can sometimes cause for providers, CMS has developed an approach that focuses on streamlining measures around high impact areas. Drawn from work completed by the National Quality Forum, the National Academy of Medicine, and the Healthcare Payment Learning and Action Network as well as feedback from you guys — we refer to these high impact areas as Meaningful Measures.

The illustration on slide 11 provides a general overview of the Meaningful Measure areas in each of its 6 categories. They are concrete, quality topics which reflect core issues that are most vital for high quality care



and better patient outcomes. And so for on this slide you'll see that some of those include "Promoting Effective Communication and Coordination of Care," "Making Care Affordable," and so forth and so on. Later we will describe why this initiative matters to ESRD patients.

On slide 12 we identify some expected positive outcomes of the Meaningful Measures initiative. Every proposal is carefully measured against these benefits to ensure that patients along with their families and providers are able to focus on what matters to them. In addition to focusing on measures that matter, CMS is also a careful steward of public funds, and strives to achieve cost savings where possible, and reduce in burden — financial, administrative, and effort — for both patients and their provider.

Slide 13 illustrates how CMS intends to use Meaningful Measures to put patients first within the context of CMS strategic goals, with the ultimate outcome of better patient outcomes.

On slide 14 — slide 14 shows a strong relationship between the complexities of living with ESRD and the Meaningful Measure areas that support them. ESRD patients and their families face daunting challenges each and every day, and their providers and clinicians recognize the need to focus on what really matters: quality care and outcomes for patients rather than unnecessary paperwork. As we all know, ESRD is a devastating and complex disease that impacts all areas of a patient's life and beneficiaries with ESRD are among the nation's sickest and most vulnerable citizens. Topics of special interest to the ESRD population include promoting the effective prevention and treatment of chronic disease; making care safer by reducing harm caused by the delivery of care; and promoting effective communication and coordination of care. As you'll see throughout this presentation, CMS proposed a number of changes in the program to better reflect and align with the Meaningful Measures initiative.

ESRD is an excellent use case for operationalizing the Meaningful Measures Initiative —why—because the quality of life for beneficiaries with ESRD is affected significantly by the decisions and treatment options available for them. The Meaningful Measures Initiative comes to life with ESRD patients and their families, providing a framework for humane quality care with outcomes to which both providers and patients can agree.

### **Operationalizing Meaningful Measures**

And so now we'll move in to how the Meaningful Measures Initiative influenced the proposals that CMS included in the proposed ruling. So, here on slide 16 you'll see that the ESRD QIP has long been interested in refining its measure-set, even before the Meaningful Measures Initiative was begun. These proposals reflect CMS' ongoing interest in getting to measures that matter, putting patients over paperwork, and freeing providers to take care of their patients as much as possible. You'll see that we propose retiring three measures that are widely performed among ESRD facilities and for which there is little room for improvement, along with a forth in favor of an existing measure that is more strongly associated with the desired patient outcomes.

We welcome comment on two new measures related to transplant — one for incident patients and one for prevalent patients. CMS believes these measures will complement existing efforts by dialysis facilities in evaluating their patients for transplant. There can be little doubt that a successful transplant leads to a tremendous improvement in a patient's quality of life. CMS also proposes to allow existing measure removal factors with those of other quality programs, and to add a new factor that will be used to evaluate measures in the ESRD QIP measure set — again, to assure that we focus on measures that truly matter.



With that, let's move into a brief overview of the proposals and the rules for each applicable payment year. Each payment year will have its own section in this presentation to explore those proposals in greater detail.

For slide 18, note that the calendar year 2018 rule finalized policies for payment year 2021, but in this year's rule we proposed to make modifications starting in payment year 2021, in part to implement the Meaningful Measures principals at the earliest opportunity by removing measures and changing the payment year structure accordingly. We also proposed to update our data validation strategies in a number of ways as we'll detail later on in the presentation.

On slide 19 we propose the measure set and structure of the new payment year 2022, including adding two new measures. As mentioned, we'll go into this information in greater detail in subsequent slides.

And then we proposed to establish an additional transplant measure to take effect for payment year 2024. Because the measure requires three years' worth of data, we felt it necessary to push back its inclusion in the QIP measure set until payment year 2024. This way, data collection on this measure will begin in calendar year 2019 after and if this policy is finalized later this year.

### **Proposed Modifications to PY 2021**

Now that we have a general idea of the proposals in each payment year, we'll now go into a detailed discussion regarding the proposals starting on slide 22. I've talked a lot about Meaningful Measures and the importance in the overall initiative of patients over paperwork, but in addition to adding measures that matter, CMS recognizes that there are times when a particular measure no longer for fulfills its intended purpose, and in fact may be at odds with the spirit of Meaningful Measures. This slide discusses a new factor that CMS proposes to apply when deciding whether to remove a given measure. We propose to add a new measure removal factor to the ESRD QIP starting on payment year 2021 so that we can remove measures where the cost outweigh the benefits of the measures' continued use in the program. CMS is proposing to update the measure removal criteria which will now be referred to as "factors" to align with Meaningful Measures. Two existing factors will be combined, and a new one will be added. The new proposed measure removal factor is whether the costs associated with the measure outweigh the benefits of its continued use. This factor would be used beginning with payment year 2021.

Consistent with our factors for retiring measures, and with the Meaningful Measures initiative, slide 23 identifies four reporting measures that we intend to retire. As we will see, retiring a measure is not always a bad thing, and in many cases means that facilities are already doing such an outstanding job that further improvement cannot be measured. For example; for healthcare personnel influenza vaccination, facility performance has been consistently high and it's a widespread clinical practice. Likewise, 90% percent of facilities have achieved the maximum score for pain assessment and follow up which indicates a wide-spread clinical practice. Facilities scored also — facilities also scored consistently high in anemia management in 2016, which indicates that there is little room for improvement. Also CMS believes that the standardized transfusion ratio clinical measure, or STRR, reflects the strong and more meaningful association between hemoglobin levels and subsequent transfusion events, which carries significant risks to a patient's health and which can have negative implications for future transplantation. And finally, the serum phosphorus reporting



measure is proposed for retirement because the hypercal — excuse me—because the hypercalcemia clinical measure is considered to be a superior measure of bone mineral metabolism.

Slide 24 builds on the proposed removal of those four measures by accounting for their absence in the program's organization and scoring methods. When we remove the reporting measures, we propose to remove the reporting domain, and relocate the remaining reporting measures and structure the domains by Meaningful Measure categories instead of measured types. Slides 28 to 30 will illustrate what these changes look like.

Slide 25 describes the proposed changes to the start date for new facilities to report data for the ESRD QIP, and the method we intend to use to validate the data that facilities enter into CROWNWeb and NHSN. We wanted to make the requirements clear for new facilities, and as always we want to achieve the most reliable results possible. We also proposed to make the CROWNWeb study a permanent feature of the ESRD QIP.

As mentioned earlier, along with removing the reporting measures we propose to change the structure of our measures domain.

Slide 26 lays out the division of the current clinical measure domain into three separate domains. The Patient and Family Engagement domain aligns with the Meaningful Measures Initiative to strengthen an engagement. The Care Coordination domain aligns with the Meaningful Measures topic area to promote communication and coordination of care, and the Clinical Care domain aligns with the Meaningful Measures area related to chronic disease management.

One consequence of proposing to eliminating the reporting measures domain and splitting up the clinical measure domain, is resetting domain weight for measure scores making up the Total Performance Score, or TPS.

Slide 27 also points out our proposed minimum eligibility standards. A facility must have a score in at least one measure in each of two domains in order to receive a TPS.

With all of that information in mind, slide 28 begins our illustrative recap of how these proposals would change payment year 2021. We start with how payment year 2021 is currently constructed based on last year's rule making. You see three—here you see three measured domains. The Clinical Measure domain has two sub domains and accounts for 75% percent of the TPS. The Safety Measure domain account for 15% percent of the TPS. And the Reporting Measure domain accounts for 10% percent of the TPS.

On slide 29 we see a significantly different picture reflecting the proposed changes. The Reporting domain is no longer available, the Safety domain is essentially unchanged and still makes up 15% of the TPS, the Clinical Measure domain has to split into three domains, the Clinical Care domain which makes up 40% percent of the TPS; the Care Coordination domain includes the one measure from the Reporting Measure domain to be retained and now the domain makes up 30% percent of the TPS; finally we have the Patient and Family Engagement domain which makes up the remaining 15% percent of the Total Performance Score.

On slide 30 we see how these changes impact the scoring method we finalized earlier. The box on the left



contains the measures and domain from the previous slide, and the middle column shows the new domain weights. The right-hand column demonstrates the same payment reduction ranges already finalized. The proposals do not change the minimum TPS that forms the basis for the reduction.

Another issue we wanted to address in the proposed rule is the burden posed on new facilities in reporting data. As shown on slide 31; under our current policy, a facility begins reporting data on the first day of the month following its CCN Open Date. In this rule we propose delaying that collection so that reporting starts four months following the CCN Open Date. For example, a facility with a CCN effective date of January 15th, 2019 would be required to begin collecting data for purposes of the ESRD QIP beginning with services furnished on May 1st, 2019.

And finally, for payment year 2021, we propose updating our ESRD QIP data validation activity. The table on slide 32 shows our current policies and the NHSN expansion that we're proposing. For payment year 2021 we propose to expand the number of facilities from 35 to 150, and to increase the number of records requested for each of the first two quarters of the performance period from 20 –excuse me— from 10 to 20 patient records. For payment year 2022 we proposed to expand the number of participants to 300 facilities. CROWNWeb is not listed here because we are not proposing a change in the number of participating facilities or the records that they provide but rather to note that we propose making the activity a permanent part of our program.

#### **Proposed Modifications to PY 2022 and PY 2024**

Now that we've discussed the proposals for payment year 2021, we can turn our attention to payment years 2022 and 2024. Here on slides 34 and 35 we detailed the proposed PPW measure or percentage of Prevalent Patients Waitlisted measure. Here it aligns with the Meaningful Measures category of effective communication and coordination. CMS admitted the measure to the Measures Application Partnership or MAP in 2017 for consideration as part of the pre-rule making process. We plan to use data sources from CROWNWeb as well as the Organ Procurement and Transplant Network which is a public/private partnership established by the National Organ Transplant Act of 1984 to calculate the measure. We also released more details about this and other proposed measures on the ESRD QIP technical specifications page on CMS.gov. We provided a URL at the end of this presentation to help you find those documents.

Continuing on slide 36 and 37, we detailed the proposed Medication Reconciliation measure, also known as MedRec measure. As we all know ESRD patients are especially vulnerable to medication-related problems and this measure aligns with the Meaningful Measures priority area of making care safer by reducing harm caused by health care delivery. Again, medication management is a critical safety area for all patients but especially for patients with ESRD who also prescribed 10 or more medications simultaneously and take an average of 17 to 25 doses per day. They also have a variety of co-morbid conditions, and have multiple healthcare providers and prescribers and undergo frequent medication regimen changes. And lastly, we know that medication related problems contribute significantly to the approximately \$40 billion dollars in public and private funds spent annually on ESRD care in the US.

So for patients with chronic kidney disease alone, this figure is about \$10 billion dollars. So again, all this data really highlights the importance of the medication — of the MedRec measure.

On slide 38 we illustrate how those two proposed measures would fit into the domain structure, again based on



our proposed changes for payment year 2021. PPW is shown as part of the Care Coordination domain and MedRec is added to the Safety domain. Please note that the proposed domain weights remain unchanged.

Here on slide 39 you can see the scoring and payment reduction method we propose to apply. Note that we won't be able to calculate a minimum TPS until the 2020 rule making, because it will be based on data of — it will be based on 2009 facility performance data.

The last proposal we will discuss is on slide 40, which is a Transplant Waitlist Ratio for Incident Dialysis Patients, also known as SWR. The measure will require three years of data to score properly, so we choose to propose it now in order to begin collecting the information we need starting next year. Note that CMS has done something similar before the hospital value-based purchasing program proposed and finalized on event measures several years in advance for the same reason. We also want to note that this measure aligns with the meaningful measures category of effective communication and coordination.

With our review of the proposed rule in mind, in this section we will share some guidance and recommendations for participating in the comment period for the proposed rules. please note that the rule includes some proposed changes not reviewed in this presentation, so we encourage you to please be sure to refer to the proposed rule for complete information.

### **Participating in the Comment Period**

Slide 42 provides an overview of the process CMS follows in creating and implementing federal regulation. We emphasize the period in which the public may provide input on proposed rules. In past years the comments the CMS received have helped shape the final rules and they sometimes reflect significant differences from the proposed rules as a result of those comments. As an example, the payment year 2015 proposed rule included hypercalcemia as a critical measure, but based on your feedback CMS changed course in the final rule and finalize — and hypercalcemia measure was finalized for payment in 2016 — excuse me — and so the hypercalcemia measure that was finalized for payment in 2016 was adjusted in part to address the issues that commenters raised the previous year. Therefore, again your participation in the process is essential in creating the best possible program for measurable facility performance and providing quality care to the ESRD population. Again, please note that the comment period will end on September 10th, so we encourage all of you to enter comments as soon as possible.

On slide 43 you will see that the most convenient way to submit a comment is online, via [regulations.gov](https://www.regulations.gov). You can use the search box to navigate the rule and the comment portion. We were able to use several search terms that successfully returned the proposed rule as a result, including the file number as pictured 1691-P, as well as calendar year 2019 ESRD PPS, which is part of the proposed rule formal title. If you choose to use [regulations.gov](https://www.regulations.gov), you can use the Comment Now button to submit your comment as illustrated on slide 44. You can also upload files as part of your formal comments.

Of course, you do not have to use the online interface to submit comments — you can deliver your comments in hard copy format if you prefer, the text of the proposed rule includes information on how to do so. Please be sure, however, to allow time for transit and delivery to prevent any delays. More information can be found at the very beginning of the proposed rules. Whatever comment method you choose, please be sure to include a reference to the file number CMS-1691-P on all correspondences.



Finally, here a few important dates that we'd like for you to keep in mind this year. The payment year 2019— I am sorry—excuse me—the payment year 2018 payment reductions are currently being applied. We are also currently in our payment year 2019 preview period, with an end-date of September the 5th, 2018 at 11:59 PM Pacific time. We are also currently in our payment year 2020 performance period which spans from January 1st to December 31st of 2018, and as all of you are aware — we are currently in our calendar year 2019 rule making cycle. We published our proposed rule on or around July 11th. The 60-day comment period ends September 10th, and we are expecting to publish our final rule around early November of this year. Around mid-December we are planning to have the payment year 2019 PSCs available for download; we'd also like to remind you of our requirement to post the PSC within 15 business days. And lastly, the payment year 2019 payment reductions will be effective beginning January 1st, 2019.

Again, CMS appreciates your cooperation, input, and recommendations, and we encourage you to submit any questions or comments that you have via the forms mentioned earlier.

So here on slide 46 we provide, again, just a high level overview of some of the ESRD critical dates and milestones. Given the overlap of the rule-making process and the scoring process, it's easy to see that a lot of activity impacting multiple payment years happen at the same time. This graphic illustrates what's going on with the program as we speak; so right now we're in the midst of payment implications from the payment year 2018 program, the 30-day preview period; an opportunity for facilities to review their ESRD QIP scores for payment year 2019 is underway. Additionally, we have the performance period under way for payment year 2020, and later this year we will finalize the rules for payment year 2021, 2022 and 2024, and that final rule will also include achievement methods values for measuring payment year 2021 clinical measures and other changes to payment year 2021 as discussed earlier in this presentation. In this way, we're hoping that this slide allows you to see how ESRD QIP— to see how ESRD QIP spans across multiple years.

## Resources

On slide 47 we provide a list of hyperlink resources for information that referenced in our discussion; and with that I will turn the call back over to Leah to close out today's presentation. Again, we'd like to thank you all for joining us, and we look forward to reading your comments.

## Additional Information

Leah Nguyen: Thank you very much Delia. That ends the presentation for today's call. An audio recording and transcript will be available in about two weeks at [www.CMS.gov/npc](http://www.CMS.gov/npc). Again, my name is Leah Nguyen; I would like to thank our presenters and also thank you for participating in today's Medicare Learning Network Event on ESRD QIP. Have a great day everyone.

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