



Outpatient Quality Program Systems and Stakeholder Support Team

CY 2023 ESRD PPS Proposed Rule Presentation Transcript

Moderator

Karen VanBourgondien, RN, BSN
Outpatient Quality Program Systems and Stakeholder Support Team

Speaker

Delia Houseal, PhD, MPH
ESRD QIP Program Lead
Division of Value, Incentives & Quality Reporting (DVIQR)
Centers for Medicare & Medicaid Services (CMS)

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Karen

VanBourgondien: Hello, everyone. Thank you for joining us. My name is Karen VanBourgondien. Today we are fortunate to have Delia Houseal with us to go over the ESRD PPS proposed rule as it relates to ESRD QIP. Dr. Delia Houseal is the ESRD QIP Program Lead. Before I hand things over to Delia, I'm just going to cover some general information.

The learning objectives for this presentation are listed here. Today we'll be discussing with you some of the statutory and legislative components related to the rulemaking cycle. Delia will discuss the proposals put forth in the proposed rule and the rationale behind these decisions. Lastly, we will discuss how and where to submit comments, and we'll have some additional resources as well.

Let's briefly go over some statutory foundations and legislative drivers surrounding the rulemaking process.

So, here you'll see references to the foundational legislative drivers of the ESRD QIP, which was enacted by the Medicare Improvements for Patients and Providers Act of 2008, otherwise known as MIPPA.

The intent of the ESRD QIP is to promote patient health by providing a financial incentive for renal dialysis facilities to deliver high-quality patient care. To do this, CMS is authorized to apply payment reductions of up to 2 percent if a facility does not meet or exceed the minimum Total Performance Score as set forth by CMS.

The ESRD QIP was supplemented by language included in the Protecting Access to Medicare Act of 2014, also known as PAMA, which it stipulates that ESRD QIP must include measures specific to the conditions treated with oral-only drugs, and these measures are required to be outcome-based, to the extent feasible.

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Here on this slide is an overview of the statutory requirements for ESRD QIP. Under MIPPA, ESRD QIP is responsible for selecting measures that would address: anemia management, dialysis adequacy, patient satisfaction, iron management, bone mineral metabolism, and vascular access. All are as specified by the Health and Human Services Secretary.

CMS is required to establish performance standards that apply to individual measures, specify the performance period for a given payment year and develop a methodology for assessing total performance of each facility based on performance standards for measures during a performance period. In addition, apply an appropriate payment percentage reduction to facilities that do not meet or exceed the established total performance scores. Lastly, CMS is required to publicly report results through various websites. Facilities also are required to post their performance score certificates within 15 days of their availability.

I'd like to make certain that the content covered on today's call should not be considered official guidance. This webinar is intended to provide information only. Please refer to the proposed rule, located in the *Federal Register* to clarify and provide a more complete understanding of the modifications and proposals for the program which Delia is getting ready to discuss. We have placed the direct link to the proposed rule in the Federal Register here on this slide. So, without any further delay, let me hand things over to Dr. Delia Houseal to discuss the proposals. Delia?

Delia Houseal:

Awesome! Thank you, Karen. Again, welcome to our calendar year 2023 ESRD PPS proposed rule webinar. I will now go over a high-level overview of our proposals.

We have determined that circumstances caused by the Public Health Emergency due to COVID-19 have significantly affected the measures and resulting performance scores. As a result, in this rulemaking cycle, we are proposing to suppress the Standardized Hospitalization Ratio clinical measure, the Standardized Readmission Ratio clinical measure, the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems clinical measure, the Long-Term Catheter Rate clinical measure,

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the Percentage of Prevalent Patients Waitlisted, clinical measure, and the Kt/V Dialysis Adequacy Comprehensive clinical measure for payment year 2023. We are proposing to use calendar year 2019 data to calculate performance standards for the payment year 2023 ESRD QIP. We are also proposing to begin expressing the Standardized Hospitalization Ratio, or SHR, clinical measure and Standardized Readmission Ratio, or SRR, clinical measure results as rates, beginning with the payment year 2024 ESRD QIP.

For the payment year 2025 ESRD QIP, we are proposing to add the COVID-19 Vaccination Coverage among Healthcare Personnel measure to the ESRD QIP measure set. We are also proposing to convert the Standardized Transfusion Ratio, or STRR, reporting measure to a clinical measure beginning in payment year 2025 and are also proposing to express the measure as a rate to align with the proposals to express the SHR and SRR clinical measure results as rates. In addition, we are proposing to convert the hypercalcemia clinical measure to a reporting measure, beginning in payment year 2025. Furthermore, we are proposing to create a new Reporting Measure domain and to re-weight current measure domains, beginning in payment year 2025.

This proposed rule also includes requests for information on several important topics, including potential quality measures for home dialysis, the expansion of our quality reporting programs to allow us to provide more actionable and comprehensive information on health care disparities across multiple variables and new care settings, and on the possible future inclusion of two potential social drivers of healthcare screening measures. I will be discussing these proposals with you, but I highly encourage you to read the rule yourself for a more complete understanding and to capture the details of what we have put forth.

Let's begin with proposals that will impact payment year 2023.

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In the calendar year 2022 ESRD PPS final rule, we finalized a measure suppression policy for the duration of the COVID-19 Public Health Emergency. We stated that we identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating facilities' control. We identified this need because we would like to ensure that facilities are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors, such as the COVID-19 Public Health Emergency. COVID-19 has had significant negative health effects—on individuals, communities, nations, and globally and, impacts of the pandemic continued to accelerate in 2021 as compared with 2020.

We are proposing to suppress the six measures seen here. The SHR clinical measure, SRR clinical measure, ICH CAHPS clinical measure, Long-Term Catheter Rate clinical measure, PPPW clinical measure, and the Kt/V Dialysis Adequacy Comprehensive clinical measure for payment year 2023. We are concerned that the COVID-19 Public Health Emergency would continue affecting measure performance such that we would not be able to score facilities fairly or equitably on it for payment year 2023. However, we are proposing to continue to collect the measure's data from participating facilities so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future.

We also propose to continue providing confidential feedback reports to facilities as part of program activities to ensure that they are all are made aware of the changes in performance rates that we occur. We intend to publicly report payment year 2023 data where feasible and appropriately caveated. We are proposing to suppress these measures under our previously finalized measure suppression policy because we have determined that circumstances caused by the Public Health Emergency due to COVID-19 have significantly affected the measures and resulting performance scores.

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We remain concerned that the COVID-19 Public Health Emergency would continue affecting measure performance on the measures. Data may also reflect a rapid and unprecedented change in healthcare personnel, as staffing shortages may have had an impact on some of the top box rating scores. We are concerned that these regional differences in COVID-19 rates have led to distorted hospitalization rates such that we could not reliably make national, side-by-side comparisons of facility performance.

We believe that suppressing these measures for the payment year 2023 would address concerns about the potential unintended consequences of penalizing facilities for deviations in measure performance resulting from the impact of the COVID-19 Public Health Emergency.

Our goal is to continue resuming the use of all measure data for scoring and payment adjustment purposes beginning with the payment year 2024 ESRD QIP. We understand that the Public Health Emergency for COVID-19 is ongoing and unpredictable in nature, and we would continue to assess the impact of the PHE on measure data used for the ESRD QIP.

In addition to the proposal to suppress measures, we are proposing to update the minimum Total Performance Score and payment reduction scale to reflect our proposal to suppress six measures for payment year 2023, which is almost half of the current ESRD QIP measure set. We are also proposing to amend our current regulation to state that the definition of the minimum Total Performance Score does not apply to payment year 2023.

The proposed re-calculated minimum Total Performance Score for payment year 2023 would be 80. If one or more of our measure suppression proposals is not finalized, then we would revise the minimum Total Performance Score for payment year 2023, so that it includes all measures that we finalize for scoring in payment year 2023.

With respect to performance standards, our current policy is to automatically adopt a performance and baseline period for each year that is one year advanced from those specified for the previous payment year.

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Under this policy, calendar year 2021 is currently the performance period and calendar year 2020 is the baseline period for the payment year 2023 ESRD QIP. However, under the nationwide Extraordinary Circumstance Exception that we granted in response to the COVID-19 Public Health Emergency, first and second quarter data for calendar year 2020 are excluded from scoring for purposes of the ESRD QIP. Accordingly, in the calendar year 2022 ESRD PPS final rule, for payment year 2024, we finalized calculating performance standards using calendar year 2019 data due to concerns about using partial year data. Therefore, we are proposing to calculate the performance standards for payment year 2023 using calendar year 2019 data, which are the most recently available full calendar year of data we can use to calculate those standards.

Due to the impact of calendar year 2020 data that are excluded from the ESRD QIP for scoring purposes, we believe that using calendar year 2019 data for performance standard setting purposes is appropriate. We are also concerned that it would be difficult to assess performance standards for payment year 2023 based on partial year data. We believe that this may skew achievement and improvement thresholds for facilities and therefore may result in performance standards that do not accurately reflect levels of achievement and improvement.

Although the lower performance standards would be substituted with those from the prior year, the higher performance standards would be used to set performance standards for certain measures, even though they would be based on partial year data. We continue to be concerned that this may create performance standards for certain measures that would be difficult for facilities to attain with 12 months of data. Our goal is to continue resuming the use of all measure data for scoring and payment adjustment purposes beginning with the payment year 2024 ESRD QIP. We certainly appreciate your comments on the proposals we just discussed.

Now, let's move on to our proposals that impact payment year 2024, which include proposed updates to the SHR and SRR clinical measures.

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In the calendar year 2019 ESRD PPS final rule, the SHR clinical measure and the SRR clinical measure each accounted for 14 percent of the Total Performance Score. In calendar year 2019, with average weights of more than 15 percent (after reweighting of missing measures), the SHR clinical measure and the SRR clinical measures were the two measures with the largest weight in calculating the Total Performance Score for each facility.

We are updating the technical specifications to revise how we express the results of the SHR clinical measure and the SRR clinical measure so that those results are expressed as Risk-Standardized Hospitalization Rates and a Risk Standardized Readmission Rate, respectively. In light of these concerns, we are updating the technical specifications manual to change the scoring methodology for the SRR clinical measure and the SHR clinical measure such that a facility's results are expressed as a rate in the performance period that is compared directly to its rate in the baseline period. We believe these changes are technical in nature because they do not substantively change the measures themselves and, therefore, are not required to be implemented through rulemaking. This will begin with payment year 2024 for ESRD QIP.

Stakeholders have previously expressed concern that the SHR clinical measure and the SRR clinical measure are difficult to interpret and track facility performance over time when expressed as ratios, and have recommended expressing those ratios as rates when scoring. Another concern stakeholders have raised is that ratios are difficult to understand and to determine how to use these ratios for quality improvement efforts.

Our analysis found that expressing the SHR clinical measure and SRR clinical measure results as rates would reflect the same level of measure performance as expressing those results as ratios, and we believe that expressing the measure results rates would help providers and patients better understand a facility's performance on the measures and would be more intuitive for a facility to track its performance from year to year. Further, this proposed update would also more closely align with the measure result calculation methodology for the ESRD QIP with that used in the Dialysis Facility Compare Star Ratings Program.

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For the payment year 2025, we have several updates to program requirements. In this next section, we will discuss our proposal to adopt the COVID-19 Vaccination Coverage among Healthcare Personnel reporting measure, our proposal to convert the STrR reporting measure to a clinical measure, and our proposal to convert the hypercalcemia clinical measure to a reporting measure.

We will begin with the COVID-19 vaccination measure as COVID-19 has had significant negative health effects—on individuals, communities, and the nation as a whole. To address the COVID-19 pandemic, we believe that it is important to incentivize and track Healthcare Personnel vaccination for COVID-19 in dialysis facilities through quality measurement. Therefore, we are proposing to add the COVID-19 Vaccination Coverage among Healthcare Personnel reporting measure to the program beginning with payment year 2025 ESRD QIP. As I stated, CMS believes that it is important to incentivize and track healthcare personnel vaccination for COVID-19 in dialysis facilities through quality measurement and finalized proposals to include COVID-19 Healthcare Personnel vaccination measures in quality reporting programs for other care settings. We also believe that publishing the healthcare personnel vaccination rates would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID-19 such as dialysis patients, as they choose facilities to seek treatment.

Under CMS' Meaningful Measures Framework, the COVID-19 Healthcare Personnel Vaccination measure would address the quality priority of Promoting Effective Prevention and Treatment of Chronic Disease through the Meaningful Measure Area of Preventive Care. The COVID-19 Healthcare Personnel Vaccination measure is a process measure developed by the Centers for Disease Control and Prevention to track COVID-19 vaccination coverage among Healthcare Personnel in non-long-term care facilities such as dialysis facilities.

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The denominator is the number of healthcare personnel eligible to work in the dialysis facility for at least one day during the reporting period excluding persons with contraindications to COVID-19 vaccination that are described by the CDC. The numerator is the cumulative number of healthcare personnel eligible to work in the dialysis facility for at least one day during the reporting period and who have received a complete vaccination course against COVID-19 using an FDA-authorized or approved vaccine for COVID-19.

We are proposing quarterly reporting deadlines for the ESRD QIP and a 12-month performance period. Facilities would report the measure through the NHSN web-based surveillance system. Facilities currently use the NHSN web-based system to report two ESRD QIP measures, the NHSN Bloodstream Infection clinical measure and the NHSN Dialysis Events reporting measure. To report this measure, we propose that facilities would collect the numerator and denominator for the COVID-19 healthcare personnel vaccination measure for at least one self-selected week during each month of the reporting quarter and submit the data to NHSN before the quarterly deadline to meet ESRD QIP requirements.

While it would be ideal to have healthcare personnel vaccination data for every week of each month, we are mindful of the time and resources that facilities would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable snapshot of vaccination levels among a facility's healthcare personnel while balancing the costs of reporting. If a facility submits more than one week of data in a month, the most recent week's data is used to calculate the measure, as we believe the most recent week's data will provide the most up-to-date information.

We would publicly report the most recent quarterly COVID-19 healthcare personnel vaccination coverage rate as calculated by the CDC. You can access specifications for this measure by using the link here on the slide. I do encourage you to access the resources with regard to this proposed new measure to obtain a more complete understanding of its specifications.

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We are also proposing to convert the STrR reporting measure to the revised STrR clinical measure using the revised specifications that were endorsed by the National Quality Forum, or NQF. We believe that previous validity concerns have been adequately examined and addressed, that dialysis facilities have had sufficient time to gain experience with the updated measure, and converting back to the STrR clinical measure would be consistent with our intent to more closely align with NQF measure specifications where feasible.

In addition to our proposal to convert the STrR reporting measure to a clinical measure, we are also proposing to update the scoring methodology for the STrR clinical measure so that facilities that meet previously finalized minimum data and eligibility requirements would receive a score on the STrR clinical measure based on the actual clinical values reported by the facility, rather than the successful reporting of the data.

We are also proposing to express the proposed STrR clinical measure as a rate, rather than as a ratio. These proposals, if finalized, would begin in payment year 2025.

Previously, commenters raised concerns about the validity of the modified STrR measure finalized for adoption beginning with payment year 2021. Specifically, that due to the new level of coding specificity required, many hospitals were no longer accurately coding blood transfusions. The commenters further stated that because the STrR clinical measure was calculated using hospital data, the rise of inaccurate blood transfusion coding by hospitals had negatively affected the validity of the STrR measure. The NQF renewed its endorsement of the STrR clinical measure after performing a review based on updates we made to the measure's specifications to address coding and validity concerns. Under the revised STrR clinical measure, inpatient transfusion events are identified using a broader definition.

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We believe that the updates would result in identification of a greater number of inpatient transfusion events compared to the previously implemented STrR clinical measure. In addition, the revised STrR clinical measure would effectively mitigate a provider coding bias. Converting the STrR clinical measure to be expressed as a rate would help providers and patients better understand a facility's performance on the measures and would be more intuitive for a facility to track its performance from year to year. We believe that expressing STrR measure rate results as a rate would not result in significantly different ESRD QIP scores. This approach would also align with our proposed clinical updates to the SHR clinical measure and the SRR clinical measure.

In recent years, we have received numerous public comments expressing concern about the role and weight of the hypercalcemia clinical measure in the ESRD QIP. Taking into account persistent concerns expressed by stakeholders, we are currently examining the continued viability of the hypercalcemia clinical measure as part of the ESRD QIP measure set. We are proposing to convert the hypercalcemia clinical measure to a reporting measure beginning in payment year 2025 while we explore possible replacement measures that would be more clinically meaningful for purposes of quality improvement.

We are also proposing to update the scoring methodology so that facilities that meet previously finalized minimum data and eligibility requirements would receive a score on the hypercalcemia reporting measure based on the successful reporting of the data, rather than the actual clinical values reported by the facility. Facilities would be scored using the equation shown here, beginning in payment year 2025. If finalized, the hypercalcemia reporting measure would be in our proposed Reporting Measure domain, which I will discuss with you in a few moments. Again, we welcome your comments on this proposal.

Many stakeholders have indicated that they believe the measure is topped out, pointing out that the NQF has placed the measure in Reserve Status because of high facility performance and minimal room for improvement.

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As a result, the ability to distinguish between meaningful differences in performance between facilities is substantially reduced because small random variations in measure rates can result in different scores. Others have expressed concern about whether the Hypercalcemia clinical measure is the best measure in the bone mineral metabolism domain to impact patient's outcomes.

Although the hypercalcemia clinical measure is not considered topped out based on our previously adopted methodology, we believe that it is very close to being topped out based on the available data and are concerned that small differences in measure performance may disproportionately impact a facility's score on the measure.

As I covered earlier, a patient's lasting clinical conditions due to COVID-19 could also impact a facility's performance on the ESRD measure set. As we continue to evaluate the effects of COVID-19 on the ESRD QIP measure set, we have observed both short-term effects on hospital admissions and readmissions. For some patients COVID-19 continues to have lasting effects. In order to adequately account for patient case mix, we are further modifying the technical measure specifications for the SHR and SRR measures to include a covariate adjustment for patient history of COVID-19.

This inclusion of the covariate adjustment for patient history of COVID-19 would be effective beginning with the payment year 2025 program year for the SHR clinical measure and the SRR clinical measure, and we would also apply this adjustment for purposes of calculating the performance standards for that program year. We are also considering whether it would be appropriate to add a covariate adjustment for patient history of COVID-19 to the STrR clinical measure, beginning with payment year 2025, and will announce that technical update, if appropriate, at a later date. We believe these changes are technical in nature because they do not substantively change the measures themselves and, therefore, are not required to be implemented through rulemaking.

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Currently, ESRD QIP measures are weighted and distributed across four measure domains: Patient & Family Engagement, Care Coordination, Clinical Care, and Safety. We are proposing to create a new Reporting Measure domain which would include the four current reporting measures in the ESRD QIP measure set, as well as the proposed COVID-19 Healthcare Personnel Vaccination reporting measure and the proposed hypercalcemia reporting measure.

As we are proposing to convert the STrR reporting measure to a clinical measure, as a result, we are proposing that the proposed STrR clinical measure would be placed in the Clinical Care Measure domain. We are also proposing to update the domain weights and individual measure weights in the Care Coordination domain, Clinical Care domain, and Safety domain accordingly to accommodate the new Reporting Measure Domain and individual reporting measure.

We take numerous factors into account when determining appropriate domain and measure weights, including clinical evidence, opportunity for improvement, clinical significance, and patient and provider burden. We have reassessed the impact of the ESRD QIP measure domains and domain weights on Total Performance Scores, and we believe it is necessary to increase incentives for improving performance by increasing the weights on measures where there is the most room for improvement, especially on patient clinical outcomes. We believe this would help to address concerns regarding the impact of individual measure performance on a facility's TPS, while also further incentivizing improvement on clinical measures.

Here is a view of the current domains and weights on the left side of the screen and what we are proposing on the right. To summarize the pie chart on the right, or proposed domains and weights, the Care Coordination domain will still have the SHR, SRR, and PPPW measures. However, the PPPW weight will increase to 6.00. The Clinical Care Measure domain will decrease to 35 percent and Ultrafiltration will no longer be in that domain. The Safety Measure Domain will also decrease to 10 percent and will only contain the NHSN BSI Measure.

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The Patient and Facility Engagement Measure Domain's overall weight remains at 15 percent and still only contains the ICH CAHPS. The proposed added domain, the Reporting Measure domain, will have a 10 percent weight and contain the Clinical Depression and Follow-Up Measure, Hypercalcemia, Ultrafiltration Rate, MedRec, NHSN Dialysis Event, and the new COVID-19 Healthcare Personnel Vaccination measure. Again, we would like your feedback on these proposals regarding domains and weights.

We define the terms "achievement threshold," "benchmark," "improvement threshold," and "performance standard" in our regulations.

Earlier we discussed the performance standards for payment year 2023 with regard to our proposal to express as Risk-Standardized Hospital Rate and Risk-Standardized Readmission Rate measures. We also discussed the minimum Total Performance Score changes if the six measures proposed to be suppressed is finalized. For the six measures we are proposing to suppress, we would continue to use calendar year 2019 data as the baseline period for those measures. We believe that this is consistent with our established policy to use the prior year's numerical values for the performance standards if the most recent full calendar year's final numerical values are worse. For the measures that we are proposing to suppress for payment year 2023, this would result in no measure data that could be used for calendar year 2021 baseline period. Therefore, this would result in worse performance standards for those suppressed measures in payment year 2025.

In this proposed rule, we are estimating the performance standards for the payment year 2025 clinical measure using data from calendar year 2019, which is the most recent data available. We intend to update these standards for the non-suppressed measures, using calendar year 2021 data, in the calendar year 2023 ESRD PPS final rule.

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For payment year 2025, based on available data, a facility must meet or exceed a minimum Total Performance Score of 55 in order to avoid a payment reduction. We note that the minimum Total Performance Score estimated in this proposed rule is based on data from calendar year 2019 instead of the payment year 2025 baseline period of calendar year 2021 because calendar year 2021 data are not yet available. Under our current policy, a facility that achieves a Total Performance Score below 55 would receive a payment reduction based on the Total Performance Score ranges.

We intend to update the minimum Total Performance Score for payment year 2025, as well as the payment reduction ranges for that payment year, in the calendar year 2023 ESRD PPS final rule.

That concludes the discussion on proposals. We do hope you will comment and provide your feedback on the proposals. We will include these comments in the final rule.

In addition to the proposals we just discussed, we are also requesting information on several topics. I am just going to touch on these briefly here today. However, I do encourage you to access the proposed rule as the document goes into quite a bit of a detail on these topics and requests for information. We do look forward to your feedback on these requests for information.

We are seeking comments on strategies to monitor and assess the quality of care delivered to patients who receive dialysis at home. We are also seeking comments on how to support more equitable access to home dialysis across different ESRD populations. There are two general types of dialysis; hemodialysis, in which is done in an in-center facility, and peritoneal dialysis, which commonly occurs at a patient's home. We believe that increasing rates of home dialysis has the potential to not only reduce Medicare expenditures, but also to preserve or enhance the quality of care for ESRD beneficiaries. In fact, recent studies show substantial support among nephrologists and patients for dialysis treatment at home.

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We believe it is important to screen patients with ESRD for social drivers of health that can negatively impact health outcomes and contribute to avoidable hospitalizations. Significant and persistent health disparities in the United States result in adverse health outcomes for people with ESRD. As a result, we do request information on the potential for future inclusion of two social drivers of health measures. Specifically, the Screening for Social Drivers of Health Measure and the Screening Positive Rate for Social Drivers of Health Measure.

The goal is to lay the groundwork for potential future measures that focus on the development of an action plan to address these social drivers of health, including efficiently navigating patients to available resources and strengthening the system of community-based supports where resources are lacking.

We are exploring potential future inclusion of social drivers of health screening measures to the ESRD QIP. Therefore, we are seeking public comment on adding a new measure to the ESRD QIP measure set in the next rulemaking cycle.

We believe these measures would be helpful to many patients who need additional care coordination but may experience reluctance in seeking assistance due to concerns for personal stigmatization. Under our Meaningful Measures Framework, the Screening for Social Drivers of Health measure would address the quality priority of Promoting Effective Prevention and Treatment of Chronic Disease through the Meaningful Measures Area of Management of Chronic Conditions. We are committed to achieving equity in healthcare outcomes for our beneficiaries by supporting healthcare providers' quality improvement activities to reduce health disparities, enabling beneficiaries to make more informed decisions, and in promoting healthcare provider accountability for healthcare disparities. We discussed the impact of these disparities on patients with ESRD in our request for information on closing the health equity gap in the calendar year 2022 ESRD PPS proposed rule.

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Measuring healthcare disparities and reporting these results to healthcare providers is a cornerstone of our approach to advancing healthcare equity. There are several key considerations that we intend to consider when advancing the use of measurement and stratification as tools to address healthcare disparities and advance healthcare equity. We seek input on key considerations in five specific areas that could inform our approach. Again, this is a very brief overview and we do solicit public input on these topics. As I have said during this presentation, CMS does want your feedback and we appreciate your comments.

Now I will turn it over to my colleague, Karen, to provide you with information on how to submit comments on the rule.

Karen

VanBourgondien: Thank you, Delia. CMS has asked for comments and feedback from all of you and Delia has also mentioned that several times throughout the presentation. So please comment. CMS does look forward to hearing from you and this is your opportunity to be involved in the decision-making process for this program.

For your information, this is a brief overview of the public's role in the rulemaking cycle. CMS writes proposals and brings them forward in the proposed rule. This document is publicly posted in the *Federal Register*, and the comment period opens. CMS reviews all comments, and the comments and the final decisions on the proposals is then put forth publicly in the final rule which is also posted in the *Federal Register*. To be assured, comments must be submitted no later than August 22, 2022. CMS cannot accept comments by fax transmission. They do encourage submission of comment by electronic means which I'm going to cover here in just a second. However, you can submit your comment by regular mail, or express mail, or overnight mail. They are separate addresses which you can find in the proposed rule. So please allow sufficient time for any mailed comments to be received by the close of the comment period, which again you can see here on the slide is August 22.

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So, let's talk about finding the rule and commenting specifically. You can find the rule again published in the *Federal Register* and that link is here. If you want to view a PDF version of the proposed rule, we also have the link here and the ESRD QIP-specific information, that section and the page number are also listed here on the slide.

To begin the commenting process, from the direct *Federal Register* link that we also have here on the slide, select the PDF option that will provide you with a PDF version of the proposed rule. To begin the commenting process from the same page, from the direct *Federal Register* link, the page we were just on, instead of selecting the PDF icon, you will select that green Submit a Formal Comment box next to the red arrow. This will redirect you to regulations.gov. That website is where you're actually going to submit your comment.

Here you're seeing the top part of that page. You can enter your comment and add a file, if you choose to do so. Then, you're going to scroll down that page.

You're going to enter your information. Fill in the necessary information and make sure that you click on: "I read and understand the statement above." The Submit Comment box will then turn green, but it won't turn green unless you select "I read and understand the statement above." Then, once you check that box, you can click on the Submit Comment button. That is all there is to it, to comment. Again, please do comment. CMS does look forward to hearing from you and your opinion on the proposals that Delia went over today.

So, here are a list of hyperlink resources of information, some of which we've discussed. There is also a direct link to the proposed rule again here in the *Federal Register*. Delia, again thank you so much for spending time with us today to go over the rule. It's always nice to have CMS keep us all up-to-date on these important program updates. So, thank you again. Also, thanks to all of you for joining us. Thank you and have a great day.