



## End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

### **CY 2021 ESRD Prospective Payment System Final Rule: ESRD QIP Finalized Proposals**

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**Karen**

**VanBourgondien:** Good afternoon, everyone. Thank you for joining us today. My name is Karen VanBourgondien. Our speaker today is Dr. Delia Houseal. For those who are not aware, Delia is the program lead for the End-Stage Renal Disease Quality Incentive Program.

Before we begin, let me just cover a few housekeeping items. First, the slides are available on [CMS.gov](https://www.cms.gov). I will place the direct link in the chat box shortly. We will have also, in addition to the slides, a word-for-word transcript as well as a recording of this event available shortly. Second, Delia will be going over the finalized proposals for the Calendar Year 2021 ESRD PPS Final Rule as it relates to QIP. After the presentation portion, Delia will be taking questions from the QA box and responding verbally to those questions. If you would like to address a question to Delia related to the finalized policies she will be discussing today, please place that question in the QA box and she will try to get to as many questions as possible. Now, without any further delay let me turn things over to Delia. Delia?

**Delia Houseal:** Greetings. Thank you and welcome to our annual webinar on the Calendar Year 2021 ESRD PPS Final Rule. My name is Dr. Delia Houseal, the ESRD QIP Program Lead, and I will also be your presenter.

The learning objectives for this presentation are listed here. I will discuss with you some of the statutory and legislative components related to the ESRD QIP rulemaking cycle. We will discuss the finalized proposals put forth in the final rule and the rationale behind these proposals. Lastly, we will discuss where and how to access resources.

Before we begin, I'd like to make certain that the content covered on today's call should not be considered official guidance. This webinar is only intended to provide information regarding program requirements.

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Please refer to the final rule, located in the *Federal Register*, to clarify and provide a more complete understanding of the modifications to the program we will be discussing. We have placed the direct link to this document here on this slide.

Before we get into the finalized proposals, let's briefly go over some statutory foundations and legislative drivers surrounding the rulemaking process.

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, TPS, 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 stipulates that ESRD QIP must include measures specific to the conditions treated with oral-only drugs. These measures are required to be outcome-based, to the extent feasible.

Here on this slide is an overview of the statutory requirements for ESRD QIP. Under MIPPA, ESRD QIP is responsible for selecting measures that will address anemia management; dialysis adequacy; patient satisfaction, as specified by the HHS Secretary; iron management; bone mineral metabolism; and vascular access, all as specified by the HHS 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.

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In addition, CMS is required to apply an appropriate payment percentage reduction to facilities that do not meet or exceed established total performance scores

Lastly, CMS is required to publicly report results through various websites. Facilities are also required to post their performance score certificates within 15 days of their availability. So, let's discuss the finalized changes that affect the Payment Years 2023 and 2024.

Let's begin the discussion with the proposal we made to update the scoring methodology for the Ultrafiltration Rate, or UFR, reporting measure. This measure assesses the number of months for which a facility reports all data elements required to calculate ultrafiltration rates for each qualifying patient.

In the CY 2021 ESRD PPS proposed rule, we proposed to update the current Ultrafiltration Rate reporting measure scoring methodology.

This change will modify the scoring methodology for the Ultrafiltration Rate reporting measure so that facilities would be scored based on the number of eligible patient-months, as opposed to facility-months. The new formula is seen here on this slide.

Now, let's discuss the rationale for replacing this methodology.

We believe that the proposed patient-month scoring methodology is more objective because it scores facilities based on the percentage of eligible patient-months across the entire performance period for which they will report all UFR data elements. This methodology will give facilities more flexibility to receive credit for UFR reporting throughout the 12-month performance period.

Also, calculating the measure rates using the patient-month scoring methodology better supports our goal of assessing performance on whether the facility is documenting UFR for its eligible patients, which we believe will lead to better patient-level outcomes.

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Additionally, this change is consistent with our plan to re-evaluate our reporting measures for opportunities to more closely align them with National Quality Forum, NQF, measure specifications. Additionally, the UFR reporting measure scoring methodology will make the scoring methodology for that measure consistent with the scoring methodology we are using to calculate the Medication Reconciliation, MedRec, reporting measure. CMS believes that the utilization of this patient month scoring methodology for both the MedRec and the Ultrafiltration Rate reporting measures better reflects our intent to score facilities based on actions taken by the facility that impact patient experiences.

We received several comments in support of this change, and we agree that the proposed change in methodology is more outcomes focused and better supports our goal of assessing performance on whether the facility is documenting UFR for its eligible patients, which we believe will ultimately lead to better patient-level outcomes. We also agree that the update will give facilities more flexibility to receive credit for UFR reporting throughout the 12-month performance period.

After considering the comments we received, we are finalizing our proposal to update the scoring methodology for the Ultrafiltration Rate reporting measure as proposed, beginning with PY 2023.

In the CY 2021 proposed rule, we also made a clarification of the timeline for facilities to make changes to their NHSN Bloodstream Infection, or BSI, clinical measure and NHSN Dialysis Event reporting measure data for purposes of the ESRD QIP.

Under our current policy for the NHSN BSI clinical measure and NHSN Dialysis Event reporting measure, facilities are required to submit monthly data on a quarterly basis, and each quarter's data are due three months after the end of the quarter.

In our proposal, we noted that facilities may make changes to their quarterly NHSN data for purposes of the ESRD QIP at any point up until the applicable quarterly submission data deadline.

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We also clarified that any changes that a facility makes to its data after the deadline that applies to those data will not be included in the quarterly permanent data file that the Centers for Disease Control and Prevention, or the CDC, generates for purposes of creating the annual CMS ESRD QIP Final Compliance File. I want to reiterate this point because we have received several inquiries regarding this during our preview periods. So again, any data that are submitted, or edited, after the quarterly deadline will not be included in the calculation for the ESRD QIP performance scores.

So, why are the data not included? After each quarterly data submission deadline, the CDC takes a snapshot of the facility's data for the quarter and creates a permanent data file. Each quarterly permanent data file is aggregated together to create the annual CMS ESRD QIP Final Compliance File, which the CDC transmits to CMS for purposes of determining whether the facility has met the reporting requirements for these measures.

CMS became aware that the NHSN system does not prevent facilities from making changes to their data for purposes of CDC surveillance after the applicable ESRD QIP quarterly submission deadline has passed. This clarification is to note that any changes in data that are submitted after the deadlines would be only for the purposes of CDC, and not their data for purposes of the ESRD QIP. We thank the commenters for their support with this clarification.

In the CY 2021 proposed rule, we stated that one of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and Total Performance Scores are accurate. The ESRD QIP currently includes two validation studies for this purpose: CROWNWeb, which is now referred to as the End Stage Renal Disease Quality Reporting System, or EQRS, data validation study and the NHSN validation study.

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For the NHSN validation study, we previously finalized that a sample of 300 facilities will be selected for the NHSN validation study each year, and that each facility will be required to submit 20 patient records per quarter for each of the first two quarters of the calendar year, for a total of 40 records. However, in the Calendar Year 2021 ESRD PPS proposed rule, we proposed to change this requirement and allow facilities selected to participate in the NHSN validation study to submit a total of 20 patient records for the applicable calendar year. We also proposed to allow facilities to submit patient records from any two quarters during the year, as long as all of the records are from no more than two quarters.

We stated that this revised approach would reduce facility burden by decreasing the required number of patient records and allowing more flexibility for facilities to choose what records to submit. We stated our belief that the reduction in patient records still provides an adequate sample size for the validation and this would still meet the CDC's recommended sample estimate to achieve the 95 percent confidence level precision and a one percent margin of error.

After considering public comments, we are finalizing our proposal to update the records submission requirements for the NHSN data validation study as proposed, beginning with PY 2023.

Here you will see a summary of these finalized proposals. First, we updated the scoring methodology for the Ultrafiltration Rate reporting measure so that facilities are scored based on the number of eligible patient-months, instead of facility-months. We also clarified both the reporting requirements for the NHSN Bloodstream Infection measure, as well as the NHSN validation study. Lastly, we changed the number of records a selected facility is required to submit for the NHSN validation study.

We discussed at the beginning of the presentation the legislative drivers of this program which require the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP.

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The performance standards must include levels of achievement and improvement and must be established prior to the beginning of the performance period for the year involved.

In the CY 2021 ESRD PPS proposed rule, we stated our continued belief that 12-month performance and baseline periods provide us with sufficiently reliable quality measure data for the ESRD QIP. We also previously finalized our proposal to automatically adopt a performance and baseline period for each year that is one year advanced from those specified for the previous payment year.

For example, for Payment Year 2023, the performance period is CY 2021 and the baseline period is CY 2019. For PY 2024, the performance period is CY 2022 and the baseline period is CY 2020. The performance standards must include levels of achievement and improvement and must be established prior to the beginning of the performance period for the year involved. We recently codified definitions for the terms “achievement threshold,” “benchmark,” “improvement threshold,” and “performance standard” in our regulations.

At this time, CMS does not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures because we do not have CY 2020 data.

In the most recent proposed rule, we stated our intent to publish these numerical values, using calendar year 2020 data, in the Calendar Year 2022 ESRD PPS Final Rule. However, we acknowledge that calendar year 2020 data may be impacted by the nationwide Extraordinary Circumstances Exception (ECE) we granted to facilities in response to the COVID-19 PHE, or Public Health Emergency, which excluded data from the first and second quarter of calendar year 2020. We are considering ways to address this and will provide further guidance in the Calendar Year 2022 ESRD PPS Proposed Rule.

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Under our current policy, we assign the Patient & Family Engagement Measure Domain a weight of 15 percent of the Total Performance Score, the Care Coordination Measure Domain a weight of 30 percent of the Total Performance Score, the Clinical Care Measure Domain a weight of 40 percent of the Total Performance Score, and the Safety Measure domain a weight of 15 percent of the Total Performance Score.

In the Calendar Year 2020 ESRD PPS Final Rule, we finalized a policy to use the measure weights we finalized for payment year 2022 for the payment year 2023 ESRD QIP and subsequent payment years, and also to use the payment year 2022 measure weight redistribution policy for the payment year 2023 ESRD QIP and subsequent payment years.

We do not propose any updates to these policies. Under our current policy, a facility must be eligible to be scored on at least one measure in two of the four measure domains in order to be eligible to receive a Total Performance Score.

Under our current policy, a facility will not receive a payment reduction for a payment year in connection with its performance for the ESRD QIP if it achieves a total performance score that is at or above the minimum Total Performance Score, also known as the TPS, that we establish for the payment year. The policy is also to implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the minimum Total Performance Score.

In the proposed rule, for payment year 2023, we estimated, based on available data, that a facility must meet or exceed a minimum Total Performance Score of 57 in order to avoid a payment reduction. We noted that the minimum Total Performance Score estimated in the Calendar Year 2021 ESRD PPS Proposed Rule was based on data from calendar year 2018 instead of the payment year 2023 baseline period because calendar year 2019 data were not yet available.

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We have now finalized the payment reductions that will apply to the payment year 2023 ESRD QIP using updated calendar year 2019 data. The minimum Total Performance Score for payment year 2023 will be 57, and the finalized payment reduction scale is shown here.

This concludes our discussion on the finalized proposals for this rulemaking cycle.

Before we end our time today, I would like to address the Interim Final Rule with Comment Period. This rule was released in September and essentially revises regulation to strengthen CMS' ability to enforce compliance requirements for reporting information related to COVID-19.

I would like to touch on a few highlights regarding this rule. The IFC3 revised regulation in response to the Public Health Emergency, PHE, related to COVID-19.

Based on the current and projected increases in the COVID-19 incidence rates in the United States, observed fatalities in the older adult population, and the impact on health workers who are at increased risk due to treating special populations, it is CMS' belief that certain regulations should be reviewed and revised, as appropriate, to offer additional flexibilities in furnishing and providing services to combat the Public Health Emergency for COVID-19 and to address and minimize the unique impact of the Public Health Emergency on other regulatory provisions.

The comment period ended on November 2, 2020.

We continue to believe that the ESRD QIP data we have excepted serves multiple purposes, including allowing us to understand the impact of COVID-19 on the quality of ESRD care provided to Medicare beneficiaries and supporting the continued analysis and evaluation of ESRD quality data submitted to EQRS. However, we were concerned about the national comparability of these data due to the geographic differences of COVID-19 incidence rates and hospitalizations, along with different impacts resulting from different state and local law and policy changes implemented in response to COVID-19.

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For these reasons, we adopted two updates to our current ECE policy for the ESRD QIP. First, we updated our regulations to state that a facility has opted out of the ECE for COVID-19 with respect to the reporting of fourth quarter 2019 NHSN data if the facility actually reported the data by the March 31, 2020, deadline, but it did not notify CMS that it would do so. Additionally, we removed the ability of facilities to opt-out of the ECE we granted with respect to Q1 and Q2 2020 ESRD QIP data.

These updates do not require facilities to complete any forms or submit any additional information to receive an ECE; therefore, the program does not anticipate any change in burden associated with this IFC.

That concludes our discussion of the finalized proposals.

**Karen**

**VanBourgondien:** Thank you, Delia. On slide 26, we do have some general resources for your review. The ServiceNow QA tool link is there, the final rule. You can see other resources available as well.

Of course, we do have an acronyms list should you need it. Again, we really appreciate everybody's time joining us today. Arbor and Delia, we really appreciate you.

Until next time, that concludes our presentation for today. Everybody, have a great day! You can disconnect.