



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

CY 2022 ESRD PPS Proposed Rule

Presentation Transcript

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Karen

VanBourgondien: Good afternoon everyone. Thank you for joining us. My name is Karen VanBourgondien. Our speaker today is Dr. Delia Houseal.

Before we begin, let me just cover a few housekeeping items. First, the slides are available on CMS.gov. I will place the direct link in the chat box. We will also have a word-for-word transcript as well as a recording of this event available at the same site in the next few weeks.

Again, 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 will be covering some general information as it relates to the rulemaking process.

First though, the learning objectives for this presentation are listed here.

I will discuss with you some of the statutory and legislative components related to the rulemaking cycle. Delia will be discussing the proposals put forth in the proposed rule and the rationale behind these decisions. Lastly, we will discuss how and where to comment, as well as where to access resources.

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

Please refer to the proposed rule, located in the *Federal Register*, to clarify and provide a more complete understanding of the modifications and proposals to the program which Delia will discuss. We have placed the direct link to this document to the proposed rule here on this slide.

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

Here, you'll see references and 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.

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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. It 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 Health and Human Services Secretary; iron management; bone mineral metabolism; and vascular access, all 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, CMS applies 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.

To clarify how policy is decided, let's discuss the rulemaking process in very basic terms. Now, this is a high-level overview of rule development for ESRD QIP. Prior to issuing the proposed rule each year, CMS uses a process to draft proposals for the ESRD QIP.

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The drafting process includes a rigorous series of reviews within CMS, Health and Human Services, and the Office of Management and Budget of the policy proposals that CMS plans to include in the proposed rule.

When the proposed rule is published, CMS provides the public with a 60-day opportunity to submit comments on the proposals in that rule. This comment period allows facilities and the general public the opportunity to provide their feedback on the proposals included in the proposed rule.

The final rule is drafted after CMS has reviewed and considered all public comments received during that 60-day comment period. This draft is also subject to CMS, Health and Human Services, and the Office of Management and Budget review prior to publication.

The public comments are taken very seriously by CMS. So, please submit comments, and I will walk you through that process towards the end of the presentation.

Now, without any further ado, let me turn things over to our speaker, Delia, and she will discuss the proposals. Delia?

Delia Houseal:

Thank you, Karen. First, let us discuss updates to the Extraordinary Circumstance Exceptions, or ECEs, issued for this program in response to the COVID-19 Public Health Emergency, as well as system-related issues.

On March 22, 2020, in response to the COVID-19 Public Health Emergency, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare quality reporting and value-based purchasing programs.

On March 27, 2020, we published a supplemental guidance memorandum that described the scope and duration of the ECEs we were granting under each Medicare quality reporting and VBP program. Each of these ECEs relieved these providers and facilities of their obligation to report data for Q4 of calendar year 2019, Q1 and Q2 of calendar year 2020, but we stated that we would score such data if optionally reported.

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In September 2020, the IFC updated the ECE we granted in response to the COVID-19 Public Health Emergency for the ESRD QIP and several other quality reporting programs.

In the IFC, or the Interim Final Rule with Comment Period, we updated the 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 Q4 calendar year 2019 NHSN data if the facility actually reported the data by the March 31, 2020, deadline but did not notify CMS that it would do so. Additionally, we finalized that facilities would not have the option to opt-out of the ECE we granted with respect to Q1 and Q2.

At that time, we welcomed public comments on our policy to update our regulations, and we will respond to the public comments we received in the Calendar Year 2022 ESRD PPS Final Rule.

In November of 2020, we launched the ESRD Quality Reporting System, also known as EQRS. This system contains the functionalities of multiple applications into one global application.

The transition to EQRS supports efforts to consolidate the functionalities of the CROWNWeb, ESRD QIP System, and REMIS applications into a single system, and aims to provide ongoing support to the ESRD user community to foster accurate and timely monthly data submission. This migration eliminates the need for multiple user accounts and will in the long-term also improve the overall user experience and reduce burden due to enhanced navigation features.

Since the launch of EQRS, several critical data submission issues have been identified that impact the overall quality and accuracy of data available to support the implementation of ESRD QIP. As such, we suspended all clinical data submissions into EQRS to allow time to resolve the issue.

Based on our assessment, the data submission issues only impact ESRD QIP, Dialysis Star Ratings, Dialysis Facility Compare, and data submitted for ESRD Network quality improvement activities.

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We have analyzed the data submission issues and believe that the data systems issues have been resolved.

We recognized that these operational systems issues would prevent facilities from submitting ESRD QIP clinical data until the data systems issues are resolved. Therefore, we are announcing a blanket extension of the remaining calendar year 2020 clinical reporting deadlines. Under this extension, facilities will have until September 1, 2021, to submit ESRD QIP clinical data for calendar year 2020. These are data for September 2020, October 2020, November 2020, and December 2020.

We believe this reporting extension aligns with the time estimated for resolution of our operational systems issues and will give dialysis facilities nearly seven weeks to submit their data to EQRS.

We proposed the blanket extension because we believe that the system issues experienced during the initial implementation of the EQRS could potentially impact the accuracy and reliability of the data reported. We were also concerned that facilities may be unfairly penalized because the current systems issues may impact the quality of the data.

In our next section, we will discuss some proposed flexibilities in response to the COVID-19 Public Health Emergency.

In previous rules, we have identified the need for flexibility in our quality measurement programs to account for changing conditions that are beyond the control of participating facilities or practitioners. We identified this need because we would like to ensure that participants in our programs are not affected negatively when their quality performance suffers for reasons not due to the care provided, but instead due to external factors. A significant example of an external factor is COVID-19.

The COVID-19 pandemic has had, and continues to have, significant and enduring effects on health care systems around the world, and affects care decisions, including those made on clinical topics covered by the ESRD QIP's measures.

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As a result of the COVID-19 Public Health Emergency, dialysis facilities could provide care to their patients that meets the underlying clinical standard but results in worse measured performance, and by extension, payment penalties in the ESRD QIP.

We are also concerned that regional differences in COVID-19 prevalence during the performance period for payment year 2022 have directly affected dialysis facilities' measure scores on the ESRD QIP for payment year 2022.

To assist in dealing with the effects of COVID, we are also proposing to adopt a policy for the duration of the COVID-19 Public Health Emergency which will enable us to suppress the use of ESRD QIP measure data for all facilities if we determine that circumstances caused by the COVID-19 Public Health Emergency have affected those measures and the resulting total performance scores. In developing this proposed policy, we considered what circumstances caused by the COVID-19 Public Health Emergency would affect a quality measure significantly enough to warrant its suppression in a value-based purchasing program.

Based on these considerations, we developed a number of Measure Suppression Factors that we believe should guide our determination of whether to propose to suppress ESRD QIP measures for one or more payment years that overlap with the COVID-19 Public Health Emergency. We are proposing to adopt these Measure Suppression Factors for use in the ESRD QIP and, for consistency, several other VBP programs.

We believe that these Measure Suppression Factors will help us evaluate measures in the ESRD QIP and that their adoption in the other VBP programs will help ensure consistency in our measure evaluations across programs.

We have proposed a total of four suppression factors. The first three are seen on this slide.

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The fourth suppression factor can be viewed on this slide. We also considered alternatives to this proposed policy that could fulfill our objective to not penalize dialysis facilities for measure results that are distorted due to the COVID-19. As an alternative to the proposed quality measure suppression policy, we also considered not suppressing any measures under the ESRD QIP. However, this alternative would mean assessing dialysis facilities using quality measure data that have been significantly affected by the COVID-19 pandemic.

We intend for this proposed policy to provide short-term relief to dialysis facilities when we have determined that one or more of the Measure Suppression Factors warrants the suppression of an ESRD QIP measure from facilities participating in the program.

We believe that a significant deviation in measured performance that can be reasonably attributed to the COVID-19 PHE is a significant indicator of changes in clinical conditions that affect quality measurement. Similarly, we believe that a measure may be focused on a clinical topic or subject that is proximal to the disease, pathogen, or other health impacts of the Public Health Emergency.

As has been the case during the COVID-19 pandemic, we believe that rapid or unprecedented changes in clinical guidelines and care delivery, potentially including appropriate treatments, drugs, or other protocols, may affect quality measurement significantly and should not be attributed to the participating facility positively or negatively. We also note that scientific understanding of a particular disease or pathogen may evolve quickly during an emergency, especially in cases of new diseases or conditions.

Finally, we believe that, as evidenced during the COVID-19 pandemic, national or regional shortages or changes in health care personnel, medical supplies, equipment, diagnostic tools, and patient case volumes or case mix may result in significant distortions to quality measurement.

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We believe that these Measure Suppression Factors will help us evaluate measures in the ESRD QIP and that their adoption in the other VBP programs will help ensure consistency in our measure evaluations across programs.

In response to the PHE for the COVID-19 pandemic, we have conducted analyses of the fourteen current ESRD QIP measures to determine whether and how COVID-19 may have impacted the validity of these measures. Based on our analysis, we have concluded that COVID-19 has so severely impacted the validity of four measures that we cannot fairly and equitably score these measures for the payment year 2022 program year. As such, we have proposed several policies to avoid unfairly penalizing facilities.

Based on our analysis, we are proposing to suppress the following measures for the payment year 2022 program year for all ESRD QIP participants: Standardized Hospitalization Ratio Measure, or SHR; the Standardized Readmission Ratio Measure, or SRR clinical measure; the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems, the ICH CAHPS; and the Hemodialysis Vascular Access Long-Term Catheter Rate.

The reasons for this proposal are COVID-19 affected different regions of the country at different rates depending on factors like time of year, geographic density, state and local policies, and health care system capacity.

Because of the increased hospitalization risk associated with COVID-19 and the Medicare dialysis patient population, we are concerned that these regional differences in COVID-19 rates may lead to distorted hospitalization rates such that we may not reliably measure national performance. We are concerned that the COVID-19 Public Health Emergency affects measure performance on the current SHR clinical measure such that we would not be able to score facilities fairly or equitably.

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We are proposing suppression of these measures for the payment year 2022 program year, rather than remove it, because we believe that the SRR clinical measure is an important part of the ESRD QIP Program measure set.

Due to the EQRS system issues, and additionally, due to the impact of the COVID-19 Public Health Emergency on four of the payment year 2022 ESRD QIP measures, we are proposing a special rule to modify the scoring methodology such that no facility would receive a payment reduction for PY 2022.

Under this special rule for payment year 2022, which we would codify, we propose to codify the policy to apply a payment reduction of 0 percent in a payment year when CMS does not calculate or award a TPS to any ESRD facilities and to codify the application of this policy for payment year 2022. However, we would provide confidential feedback reports to dialysis facilities on their payment year 2022 performance to ensure that they are made aware of the changes in performance rates that we have observed. We also intend to publicly report payment year 2022 data where feasible and appropriately caveated.

Although we considered if there may be any alternative data sources for the measures impacted by these EQRS system issues, we concluded that this was not feasible.

First, all 14 ESRD QIP measures for payment year 2022 are impacted by these system issues. Although certain measures do not require that facilities submit clinical data into EQRS, we use EQRS data to determine whether a facility has treated a sufficient number of patients in order to meet the measure's minimum patient case threshold necessary to calculate the measure for ESRD QIP.

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We ultimately decided to propose the special rule because not only do these system issues impact all ESRD QIP measures, which could lead to distorted performance scores and unfair penalties, but we also want to provide facilities with the business certainty they need regarding their payment year 2022 payments.

Under our current policy, we retain all ESRD QIP measures from year to year unless we propose through rulemaking to remove them or otherwise provide notification of immediate removal if a measure raises potential safety issues

In the 2017 ESRD PPS, we stated that our modified SHR clinical measure would incorporate 210 prevalent comorbidities into our risk adjustment calculation, as our analyses suggested that incorporating prevalent comorbidities would result in a more robust and reliable measure of hospitalization. We also explained that data used to calculate the SHR clinical measure are derived from an extensive national ESRD patient database.

In November of 2020, the NQF completed its most recent review of the SHR clinical measure and renewed the measure's endorsement. As part of this review, the NQF endorsed updating the prevalent comorbidity adjustment, which would group 210 individual ICD-9 prevalent comorbidities into 90 condition groups. The updated prevalent comorbidity adjustment would also limit the source of prevalent comorbidities to inpatient claims. The switch to using only Medicare inpatient claims to identify prevalent comorbidities is due to the lack of Medicare outpatient claims data for the growing Medicare Advantage (MA) patient population.

The NQF stated its concern that Medicare Advantage patient prevalent comorbidities would be systematically biased. These MA patient prevalent comorbidities would only be populated by Medicare inpatient claims, as compared to non-MA patient prevalent comorbidities that would be populated by Medicare claim sources.

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The updated NQF-endorsed SHR clinical measure would also include updates to the risk adjustment method of the measure, which include a prevalent comorbidity adjustment, the addition of MA patients and a MA indicator in the model, updates to parameters of existing adjustment factors and re-evaluation of interactions, and an indicator for a patient's time spent in a skilled nursing facility.

This update is proposed beginning with payment year 2024.

We believe that adopting these updates would be consistent with our stated goal of evaluating opportunities to more closely align ESRD QIP measures with NQF measure specifications. The SHR clinical measure seeks to improve patient outcomes by measuring hospitalization ratios among dialysis facilities, and we believe that these updates would result in a more reliable and robust SHR clinical measure.

We seek comment on this proposal to update the SHR clinical measure specifications.

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

The Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year.

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, as required.

We recently codified definitions for the terms “achievement threshold,” “benchmark,” “improvement threshold,” and “performance standard” in our regulations.

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Under our current policy, calendar year 2022 would have been the performance period and CY 2020 will be the baseline period for the payment year 2024 ESRD QIP.

However, under the nationwide ECE 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. We are concerned that it will be difficult to assess levels of achievement and improvement if the performance standards are based on partial year data.

As a result, we are proposing to calculate the performance standards for payment year 2024 using CY 2019 data, which is the most recently available full calendar year of data we can use to calculate those standards. Due to the impact of CY 2020 data that is excluded from the ESRD QIP for scoring purposes, we believe that using calendar year 2019 data for performance standard setting purposes is appropriate.

Consistent with our established policy, we would continue to use the prior year's numerical values for performance standard, achievement threshold, and benchmark if the most recent full calendar year's final numerical values are worse.

We welcome public comments on this proposal.

Due to the impact of COVID 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. As I spoke a moment ago, it may be difficult to assess levels of achievement and improvement if the performance standards are based on a partial year of data.

Shown here is the Performance Standards for the payment year 2024 ESRD QIP Clinical Measures if the proposal to use calendar year 2019 as the Baseline Period is finalized. However, if the policies are not finalized, the payment year 2022 ESRD QIP payment would be as implemented in accordance with our current policy, as well as the payment reduction ranges finalized in the Calendar Year 2020 ESRD PPS Final Rule.

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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, or TPS, that is at or above the minimum Total Performance Score (mTPS) that we establish for the payment year.

We have defined the minimum Total Performance in our regulations with respect to a payment year, the TPS that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

For payment year 2024, 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 note that the minimum Total Performance Score in this rule is based on data from the calendar year 2019 baseline period instead of calendar year 2020 baseline period, and this would be for payment year 2024 because we have proposed to use calendar year 2019 as the baseline period for that payment year.

Our current policy, which is codified, also implements 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.

For all measures except the SHR clinical measure, the Standardized Readmission Ratio (SRR) clinical measure, and the STrR reporting measure, measures with less than 11 patients for a facility were not included in that facility's Total Performance Score.

For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least five patient-years at risk and 11 index discharges, respectively, in order to be included in the facility's TPS. For the STrR reporting measure, facilities were required to have at least 10 patient-years at risk in order to be included in the facility's TPS.

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Each facility's TPS was compared to an estimated minimum Total Performance Score and an estimated payment reduction table that were consistent with the proposals. Facility reporting measure scores were estimated using available data from calendar year 2019. Facilities were required to have at least one measure in at least two domains to receive a Total Performance Score.

If we do not finalize the proposed update to our performance standards policy, then we would update the minimum Total Performance Score for payment year 2024, as well as the payment reduction ranges for that payment year in the Calendar Year 2022 ESRD PPS Final Rule using data from calendar year 2020.

To estimate whether a facility would receive a payment reduction for payment year 2024, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates are calculated using the most recent data available in accordance with the policies proposed in this proposed rule.

On this slide, you can see our current measure domains and the Total Performance Score for payment year 2025. Under our current policy, we assign the Patient and 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.

We continue to believe that 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. Under this policy, we would adopt calendar year 2023 as the performance period and calendar year 2021 as the baseline period for the payment year 2025 ESRD QIP.

In this proposed rule, we are not proposing any changes to this policy.

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At this time, we do not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures for the payment year 2025 ESRD QIP. We intend to publish these numerical values, using calendar year 2021 data, in the Calendar Year 2023 ESRD PPS Final Rule.

In the Calendar Year 2019 ESRD PPS Final Rule, we finalized the continued use of existing performance standards for the Screening for Clinical Depression and Follow-Up reporting measure, the Ultrafiltration Rate reporting measure, the NHSN Dialysis Event reporting measure, and the MedRec reporting measure. We will continue use these performance standards in payment year 2025.

We will now change our focus to another area of extreme importance.

Persistent inequities in health care outcomes exist in the United States, especially among Medicare patients. In recognition of these disparities and the importance of closing the health equity gap, we request information on expanding several related CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for dialysis facilities, providers, and patients.

As part of an ongoing effort across CMS to evaluate appropriate initiatives to reduce health disparities, we are seeking feedback on strategies to close health equity gaps for the ESRD population. This RFI contains four parts.

The Background is the section that provides information on existing statements describing our commitment to health equity and existing initiatives with an emphasis on reducing disparity.

Next is the current CMS Disparity Methods. In this section, we describe the methods, measures, and indicators of social risk currently used with the CMS Disparity Methods.

Then, there is discussion of future potential stratification of quality measure results.

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This section describes four potential future expansions of the CMS Disparity Methods, including future potential stratification of quality measure results by dual eligibility; future potential stratification of quality measure results by race and ethnicity and Improving Demographic Data Collection; and the potential creation of an ESRD Facility Equity Score to synthesize results across multiple social risk factors.

The last portion is our solicitation of public comment. This section specifies 11 requests for feedback on the topics specified in this RFI.

We have mentioned multiple times in our time today about the effects of COVID-19 on health care. On March 25, 2021, the Biden administration announced a new partnership with dialysis facilities to provide COVID-19 vaccinations directly to people receiving dialysis and healthcare providers in dialysis facilities.

We believe it is important to incentivize and track vaccination in dialysis facilities through quality measurement in order to protect health care workers, patients, and caregivers, and to help sustain the ability of these facilities to continue serving their communities throughout the Public Health Emergency and beyond.

Therefore, we are seeking public comment on adding two new measures to the ESRD QIP: the COVID-19 Vaccination Coverage Among Healthcare Personnel and the COVID-19 Vaccination Coverage for Patients in End-Stage Renal Disease Facilities.

Under CMS' Meaningful Measures Framework, the COVID-19 vaccination measure would address the quality priority of Promoting Effective Prevention and Treatment of Chronic Disease through the Meaningful Measures Area of Preventive Care. We believe facilities should track the level of vaccination among their patients and healthcare providers as part of their efforts to assess and reduce the risk of transmission of COVID-19 within their facilities.

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We also believe that publishing the vaccination rates will be helpful to many ESRD patients, including those who are at high-risk for developing serious complications from COVID 19, as they choose facilities from which to seek treatment.

The COVID-19 vaccination measure and the COVID-19 patient vaccination measure were both included on the publicly available list of Measures under Consideration for December 21, 2020, also known as the MUC list.

The Measure Applications Partnership Hospital Workgroup recognized that the proposed measures represent a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the ESRD QIP measure set by providing transparency about an important COVID-19 intervention to help prevent infections in health care providers and patients.

The MAP workgroup stated that collecting information on COVID-19 vaccination coverage among health care providers and ESRD patients and providing feedback to facilities will allow facilities to benchmark coverage rates and improve coverage in their facility. They further noted that reducing rates of COVID-19 in health care providers and ESRD patients may reduce transmission among a patient population that is highly susceptible to illness and disease and reduce instances of staff shortages due to illness. The Measure Applications Partnership offered conditional support for rulemaking contingent on CMS bringing the measures back to the MAP once the specifications are further refined.

We are also interested in public comment on data collection, submission, and reporting for the COVID-19 vaccination measure for health care providers and the COVID-19 vaccination measure for patients. For example, we are considering requiring reporting for these measures on an annual basis for the performance period for each calendar year corresponding to the associated payment year, and the reporting period would be January 1 through December 31, annually.

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Based on the measures currently being developed by the CDC that were submitted to the MAP, facilities would report the measures through the National Healthcare Safety Network web-based surveillance system.

We also seek public comment from stakeholders on other ways to collect data on COVID-19 vaccination rates at dialysis facilities for ESRD QIP purposes and their associated costs and burdens.

On to the next important request for feedback. CMS aims to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. As part of this modernization of our quality measurement enterprise, we are issuing this Request for Information (RFI). The purpose of this RFI is to gather broad public input solely for planning purposes for our transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future rulemaking, as necessary.

With regard to the goal of moving to digital quality measurement by 2025, we acknowledge providers within the various care and practice settings covered by our quality programs may be at different stages of readiness. Therefore, the timeline for achieving full digital quality measurement across our quality reporting programs may vary.

Reporting quality data via EHRs, or electronic health records, remains burdensome, and our current approach to quality measurement does not readily incorporate emerging data sources such as patient-reported outcomes (PRO) and patient-generated health data (PGHD).

In May 2020, we finalized interoperability requirements in the CMS Interoperability and Patient Access final rule to support beneficiary access to data held by certain payers.

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At the same time, the Office of the National Coordinator for Health Information Technology, or ONC, finalized policies in the ONC 21st Century Cures Act final rule to advance the interoperability of health IT as defined in section 4003 the Cures Act, including the “complete access, exchange, and use of all electronically accessible health information.”

We believe the emerging data standardization and interoperability enabled by APIs will support the transition to full digital quality measurement by 2025 and are committed to exploring and seeking input on potential solutions for the transition to digital quality measurement as described in this RFI.

CMS seeks input on future elaboration that would define a dQM as a software that processes digital data to produce a measure score or measure scores.

We also note that dQMs are intended to improve the patient experience including quality of care, improve the health of populations, and/or reduce costs. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs (medical devices and wearable devices), patient portals or applications (for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources.

We do seek comment on the potential definition of dQMs and feedback on how leveraging advances in technology to access and electronically transmit interoperable data for dQMs could reinforce other activities to support quality measurement and improvement.

To enable this transformation, we are considering further modernizing the quality measurement enterprise in four major ways displayed on this slide.

These changes would enable us to collect and utilize more timely, actionable, and standardized data from diverse sources and care settings to improve the scope and quality of data used in quality reporting and payment programs, reduce quality reporting burden, and make results available to stakeholders in a rapid-cycle fashion.

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We are seeking comment on the advancing of digital quality measurement. Please refer to the proposed rule for more clarifying details on our inquiries.

We plan to continue working with other agencies and stakeholders to coordinate and to inform any potential transition to dQMs by 2025.

While we will not be responding to specific comments submitted in response to this RFI in the CY 2022 ESRD PPS Final Rule, we will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

Again, we refer you to the proposed rule for details on our discussion today. 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 mentioned that throughout the presentation today. So, please comment. CMS does look forward to hearing from you, and this is your opportunity to be involved in the decision-making for this program.

For your information, this is a brief overview of the public role in the rulemaking cycle. CMS writes proposals and brings them forward in the proposed rule. The document is posted publicly in the *Federal Register*. The comment period then opens. CMS reviews all comments. The comments and the final decision on the proposals is then put forth publicly in the final rule which is also posted in the *Federal Register*.

To be assured consideration, comments must be submitted no later than August 31st. CMS cannot accept comments by fax transmission and does encourage submission of comment by electronic means.

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However, you may also submit comment via regular mail, by express mail, or overnight mail. There are separate addresses for those types of mails. So, you may resource the specified address found in the proposed rule. Please allow sufficient time for mailed comments to be received before the close of the comment period.

To find the proposed rule, you will start at the *Federal Register* home page, [FederalRegister.gov](https://www.federalregister.gov). To access the Calendar Year (CY) 2022 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Proposed Rule, specifically, from the [FederalRegister.gov](https://www.federalregister.gov) home page, you will enter CMS-1749-P in the search box. You can see that here on this slide. Then, click the magnifying search icon.

This will take you to the initial publication page and you will click on the title of the rule that you see here in blue.

This will then direct you to the proposed rule. If you simply scroll down on this page, you will be able to read this rule in its entirety. However, you may also choose the PDF icon on the right. That will allow you to view and download a PDF version of the rule. To submit a comment electronically, you will click on the Summit A Formal Comment icon in green and you can see that towards the top right hand side.

This will redirect you to the [regulations.gov](https://www.regulations.gov) website where you will be able to submit a comment. Here you see the top part of that page. You can enter your comment and add a file, if you wish, and you will scroll down that page.

Enter your information. Fill in the necessary information and make sure you click on the “I read and understand the statement above” box. The Submit Comment box will not turn green unless that box is selected. Once complete, you will simply click the Summit Comment button.

So again, please comment. CMS does look forward to hearing from you about the proposals discussed here today.

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Here is a list of hyperlink resources for information, some of which we discussed today. There is also a direct link to the proposed rule in the Federal Register. You can see here, the last selection on the chart. That link will take you directly to the proposed rule.

Delia, thank you so much for spending time with us today to go over the rule. It is always nice to have CMS keep us up-to-date on all these important program updates. So, thank you again. Thank you to all of you for joining us. We appreciate your time. Thank you and have a great day.