Calendar Year (CY) 2021 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Proposed Rule

Presentation Transcript

Speaker

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Delia Houseal: Greetings, and welcome to the *Calendar Year (CY) 2021 End Stage Renal Disease (ESRD) Prospective Payment System Proposed Rule* webinar. This webinar will focus on proposals that impact the End Stage Renal Disease Quality Incentive Program, or ESRD QIP. My name is Dr. Delia Houseal, and I am the ESRD QIP Program Lead. And I'll also be your presenter for today's webinar.

Please note the acronyms that we will be using throughout the presentation. Although we do define terms as we go, we have them here for your reference.

The learning objectives for this presentation are listed here. I will be discussing with you some of the statutory and legislative components related to the ESRD QIP rulemaking cycle. We will discuss the proposals put forth in the proposed rule, and, lastly, we will discuss how to submit comments. CMS absolutely encourages submission of comments. It is your opportunity to be involved in program-related policy.

Before we begin, I'd like to make certain that it is clear that the content of this presentation should not be considered official CMS guidance. Please refer to the proposed rule, located in the *Federal Register* to clarify and provide a more complete understanding of the proposals we will be discussing.

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

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 ESRD QIP was supplemented by language included in the Protecting Access to Medicare Act of 2014, otherwise known as PAMA.

So, as you can see, 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 two percent if a facility does not meet or exceed the minimum Total Performance Score, or TPS, as set forth by CMS.

Here, you can see that the ESRD QIP is responsible for selecting measures that address a variety of high priority areas, including anemia management, dialysis adequacy, patient satisfaction, iron management, bone mineral metabolism, and vascular access.

CMS is required to establish performance standards and specify the performance period for any given payment year. We're also required to develop a methodology for assessing the total performance of each facility and applying the appropriate payment reduction for those facilities that do not meet or exceed the established minimum total performance score.

Lastly, we are required to publicly report those results through websites such as DFC, or *Dialysis Facility Compare*, and CMS.gov.

To clarify how policy is decided, let's discuss the rulemaking process in very basic terms. 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 ESRD QIP. The drafting process includes a rigorous series of reviews within CMS, HHS, and OMB of the policy proposals that CMS plans to include in the proposed rule.

When the proposed rule is published, we provide 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 the 60-day comment period. This draft is also subject to CMS, HHS, and OMB review prior to publication. The public comments are taken very seriously by CMS. Please submit your comments. I will walk you through this process later in the presentation.

The ESRD QIP fosters improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by CMS. This proposed rule proposes several updates for the payment years 2023 and 2024.

Now, let us begin with our discussion of proposals.

CMS is proposing to replace the current Ultrafiltration Rate (UFR) reporting measure scoring equation with the equation seen here, beginning with PY 2023. With this change, facilities would be scored based on the number of eligible patient-months, instead of facility-months.

In the CY 2017 ESRD PPS Final Rule, we adopted the Ultrafiltration Rate reporting measure. The measure assesses the number of months for which a facility reports all data elements required to calculate ultrafiltration rates for each qualifying patient. It is based upon the NQF-endorsed Avoidance

of Utilization of High Ultrafiltration Rate, which assesses the percentage of patient-months for patients with an ultrafiltration rate greater than or equal to 13 ml/kg/hr.

This proposal would modify the scoring methodology for the Ultrafiltration Rate reporting measure. Again, facilities would be scored based on the number of eligible patient-months, instead of facility-months.

We believe that this proposed change would make the UFR reporting measure more flexible for facilities unable to obtain information on certain patients. Additionally, this is more consistent with the NQF measure upon which it is based.

The use of patient-months for the Ultrafiltration Rate reporting measure is also consistent with the scoring methodology we are using for the MedRec reporting measure. Updating the scoring to patient-months, rather than facility-months, would more accurately reflect the patient experience that the reporting measure is intended to capture by addressing the fact that patients may require varying amounts of time in treatment within the annual ESRD patient population.

The scoring updates would also more closely with CMS's goal to focus on outcomes-based measures, as the new specifications will score facilities based on the extent to which data is reported for each patient. We encourage you to comment on this proposal.

Moving on now, CMS wishes to provide clarification of the timeline for facilities to make changes to their NHSN Bloodstream Infection 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 that each quarter's data would be due three months after the end of the quarter.

After each quarterly reporting deadline, the Centers for Disease Control and Prevention, or 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.

In this proposed rule, we are emphasizing the three-month review and correction period, between the end of the quarter and the submission deadline for that quarter, that facilities have to update data reported to NHSN, and we reiterate the inability for CMS to accept any changes after the three-month review and correction period.

Although facilities can make changes to their data at any point prior to each of these quarterly submission deadlines, and facilities can make changes to their data after these quarterly submission deadlines for purposes of CDC surveillance, facilities cannot make changes to their data for purposes of the ESRD QIP after any of these quarterly submission deadlines. New or revised data that a facility submits to the NHSN after a quarterly data submission deadline will not be reflected in the quarterly permanent data file generated by the CDC that is then used to create the annual CMS ESRD QIP Final Compliance File.

In this proposed rule, we are proposing to change the number of records a facility is required to submit for the NHSN validation study to a total of 20 records across two quarters.

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. The NHSN Validation study and the CROWNWeb data validation study.

In the Calendar Year 2019 ESRD PPS Final Rule, we adopted the CROWNWeb data validation study as a permanent feature of the program.

Under that policy, we will continue validating CROWNWeb data in payment year 2023 and subsequent payment years, and we will deduct 10 points from a facility's Total Performance Score if it is selected for validation but does not submit the requested records.

We also adopted a methodology for the PY 2022 NHSN validation study, which targets facilities for NHSN validation by identifying facilities that are at risk for under-reporting.

In the CY 2019 ESRD PPS Final Rule, we 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. In this proposed rule, we are proposing to change the number of records a facility is required to submit for the NHSN validation study to a total of 20 records across any two quarters.

We believe the reduction in patient records still provides an adequate sample size for the validation study and reduces overall facility burden, as well as to allow flexibility if a facility has fewer than 20 applicable patients in a quarter. For example, a facility may only be able to submit five records in one quarter and 15 records in the second quarter, as long as the total across the two quarters is 20 records. We also look forward to comments on this proposal.

To summarize, for Payment Year 2023,we are proposing updates to 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; clarification of the reporting requirements for the NHSN Bloodstream Infection measure; as well as the NHSN validation study; and, lastly, a change to the number of records a selected facility is required to submit for NHSN validation.

Under the Paperwork Reduction Act of 1995, CMS is required to provide 60-day notice in the *Federal Register* and solicit public comment before a

collection of information requirement is submitted to the Office of Management and Budget for review and approval.

This proposed rule does not impose any new information collection requirements in the regulation text. However, wage estimates, as well as the estimated burden associated with the data validation requirements, and CROWNWeb reporting requirements have been updated. We are soliciting public comment on each of these estimates.

Let's move on to discuss the estimated payment reduction for the Payment Year 2023 for this program.

We continue to believe that twelve-month performance and baseline periods for the ESRD QIP are appropriate. In the CY 2020 ESRD PPS Final Rule, we finalized the performance and baseline periods for Payment Year 2023. We also finalized our proposal to adopt automatically a performance and baseline period for each year that is one year advanced from those specified for the previous payment year. For example, under this policy, we would automatically adopt CY 2022 as the performance period and CY 2020 as the baseline period for the PY 2024 ESRD QIP. In this proposed rule, we are not proposing any changes to this policy.

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 refer readers to the CY 2012 ESRD PPS Final Rule for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We recently codified definitions for the terms "achievement threshold," "benchmark," "improvement threshold," and "performance standard" in our regulations.

Under our current policy, we assign the Patient & Family Engagement Measure domain a weight of 15 percent of TPS, the Care Coordination Measure domain a weight of 30 percent, the Clinical Care Measure

domain a weight of 40 percent, and the Safety Measure domain a weight of 15 percent of Total Performance Score for the PY 2023 ESRD QIP.

In the Calendar Year 2019 ESRD PPS Final Rule, we finalized a policy to assign weights to individual measures and a policy to redistribute the weight of unscored measures in the PY 2022 ESRD QIP.

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

Our current policy was previously codified and states that a facility would 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 that we establish for the payment year.

We have defined the minimum Total Performance Score 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. Our current policy is also to implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of point five (0.5) percent for each ten points that the facility's TPS falls below the minimum TPS.

For PY 2023, we estimate 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 TPS estimated in this proposed rule is based on data from calendar year 2018 instead of the PY 2023 baseline period because calendar year 2019 data are not yet available.

The table here for Payment Year 2023 is based on the most recently available data for the estimated values of the 50th percentile of national performance for clinical measure. CMS intends to update the minimum

Total Performance Score for Payment Year 2023, as well as the payment reduction ranges for that payment year in the Calendar Year 2021 ESRD PPS Final Rule.

The general methodology that we are using to determine a facility's TPS is described in our regulations. The table here demonstrates the overall estimated distribution of payment reduction resulting from the PY 2023.

Any reductions in the ESRD PPS payments as a result of a facility's performance under the Payment Year 2023 ESRD QIP would apply to the ESRD PPS payments made to the facility for services furnished in CY 2023, as codified in our regulations.

For the Payment Year 2023 ESRD QIP, we estimate that, of the 7,386 dialysis facilities enrolled in Medicare, approximately 23.2 percent, or 1,657 of the facilities that have sufficient data to calculate a TPS, would receive a payment reduction for Payment Year 2023. We are presenting an estimate for the payment year 2023 ESRD QIP to update the estimated impact that was provided in the Calendar Year 2020 ESRD PPS Final Rule. Due to the proposal to update the scoring methodology for the Ultrafiltration Rate reporting measure, the total estimated payment reductions have decreased.

The total payment reductions for all the 1,657 facilities expected to receive a payment reduction is approximately $15,586,000. Facilities that do not receive a Total Performance Score do not receive a payment reduction. To estimate whether a facility would receive a payment reduction, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Payment reduction estimates are calculated using the most recent data available.

This table displays the measures and data used to estimate PY 2023 and PY 2024 payment reductions.

For all measures except SHR and SRR, clinical measures with less than 11 patients for a facility were not included in that facility's TPS. For SHR and STrR, 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. 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 outlined in this proposed rule. Facility reporting measure scores were estimated using available data from calendar year 2017 and 2018. Facilities were required to have at least one measure in at least two domains to receive a Total Performance Score.

On this slide, you will see trends and estimated payment reductions across seven payment years of ESRD QIP. The average annual payment reduction across seven years is approximately $20 million, with our lowest estimated payment reduction of $11.5 million in payment year 2018 and the highest estimated payment reduction of $32 million in payment year 2021.

As I have said throughout the presentation, CMS reads and considers every comment. We encourage you to submit comment on our proposals. 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 prosed rule. This document is posted publicly in the *Federal Register*. The comment period then opens. As you can see here, our comment period is open until September 4, 2020.

As I have stated before, CMS reviews all comments. The comments and 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 September 4, 2020. In commenting, please refer to file code CMS-1732-P. Because of staff and resource limitations, CMS cannot accept comments by fax transmission.

CMS does encourage submission of comment by electronic means to http://www.regulations.gov. Follow the Submit a Comment instructions. You may also submit comments via regular mail, by express mail, or overnight mail. There are separate addresses for these two types of mails. So, please 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 be at the *Federal Register* home page. To access the Calendar Year 2021 ESRD PPS Proposed Rule, you will enter CMS-1732-P, as seen here on the slide, and then click the magnifying glass.

This will take you to the initial publication page. You will click on the title of the rule in blue, as indicated here by the arrow.

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. You may also choose the PDF icon on the right.

To submit a comment, you will click on the Summit a Formal Comment icon in green towards the top of the page. You will be directed to Regulations.gov 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 to do so. You will scroll down that page and enter your information. Please make sure you click on the "I read and understand the statement above." box. Then, you will simply click the Summit Comment button. Please comment. CMS looks forward to hearing from you about the proposals discussed here today.

That concludes our discussion on the CY 2021 ESRD PPS Proposed Rule as it relates to the ESRD QIP.

Finally, here are a few important updates that we'd like for you to keep in mind this year. Given the overlap of the rule-making process and the scoring process, it's easy to see that a lot of activity, impacting multiple payment years, happens at the same time. To recap: The payment year 2020 payment reductions are currently being applied. We are also currently in our payment year 2021 preview period, with an end-date of August the 31st, 2020, at 11:59 p.m. Pacific Time. We are also currently

in our payment year 2022 performance period which spans from January 1 to December 31 of 2020.

As we've been talking about today, we are currently in our calendar year 2021 rule making cycle, which affects payment year 2023 and payment year 2024.

Here are a list of hyperlink resources for information that was referenced in our discussion. This includes technical specifications, the proposed rule text, statutes, and methods for providing your comments and feedback.

On behalf of CMS, I would like to thank you for your time. Again we encourage you to submit any questions or comments using the methods mentioned throughout this presentation.

Thank you. Have a great day.