Calendar Year (CY) 2020 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Proposed Rule: ESRD Quality Incentive Program (ESRD QIP) Proposals

August 20, 2019
2:00 PM ET

Presented by:

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Division of Value, Incentives & Quality Reporting,
Quality Measurement & Value Incentives,
Group Center for Clinical Standards & Quality,
Centers for Medicare & Medicaid Services
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention (HHS)</td>
</tr>
<tr>
<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid Services (HHS)</td>
</tr>
<tr>
<td>CY</td>
<td>Calendar Year</td>
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<tr>
<td>ESRD</td>
<td>End-Stage Renal Disease</td>
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<tr>
<td>ESRD QIP</td>
<td>End-Stage Renal Disease Quality Incentive Program</td>
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<td>FDA</td>
<td>Food &amp; Drug Administration (HHS)</td>
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<td>HHS</td>
<td>U.S. Department of Health &amp; Human Services</td>
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<td>MAP</td>
<td>Measures Application Partnership</td>
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<tr>
<td>MedRec</td>
<td>Medication Reconciliation for Patients Receiving Care at Dialysis Facilities</td>
</tr>
<tr>
<td>MIPPA</td>
<td>The Medicare Improvements for Patients and Providers Act of 2008</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>NHSN</td>
<td>National Healthcare Safety Network (CDC)</td>
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<tr>
<td>OGC</td>
<td>Office of General Counsel (CMS)</td>
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<tr>
<td>PAMA</td>
<td>The Protecting Access to Medicare Act of 2014</td>
</tr>
<tr>
<td>PPPW</td>
<td>Percentage of Prevalent Patients Waitlisted</td>
</tr>
<tr>
<td>PPS</td>
<td>Prospective Payment System</td>
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<tr>
<td>PSC</td>
<td>Performance Score Certificate</td>
</tr>
<tr>
<td>PSR</td>
<td>Performance Score Report</td>
</tr>
<tr>
<td>PY</td>
<td>Payment Year</td>
</tr>
<tr>
<td>STrR</td>
<td>Standardized Transfusion Ratio</td>
</tr>
<tr>
<td>SWR</td>
<td>First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients</td>
</tr>
<tr>
<td>TPS</td>
<td>Total Performance Score</td>
</tr>
<tr>
<td>UFR</td>
<td>Ultrafiltration</td>
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Today’s Objectives

At the conclusion of today’s call, the audience will:

A. Be familiar with statutory foundations and legislative drivers that guide ESRD QIP
B. Know the CMS Meaningful Measures Initiative and its alignment to ESRD QIP
C. Understand policies proposed in the CY 2020 ESRD PPS Proposed Rule
D. Gain insights into the rationale for proposed modifications and estimated impacts
E. Know how, and where, to view the proposed rule and to submit comments
F. Have access to additional resources about ESRD QIP
Today’s Call: CY 2020 ESRD PPS Proposed Rule

• This webinar is intended for CMS to provide information regarding requirements for the ESRD QIP that are contained within the CY 2020 ESRD PPS Proposed Rule released on July 29, 2019.

• Information is offered as an informal reference and does not constitute official CMS guidance. CMS encourages stakeholders, advocates, and others to refer to the Proposed Rule located in the Federal Register.
The Administrative Procedures Act

• Because CMS must comply with the Administrative Procedures Act, we are not able to provide additional information, clarification, or guidance related to the proposed rule.

• CMS encourages stakeholders, advocates, and others to submit comments or questions by using the formal comment period referenced in today’s call and described in the rule.
Introduction and ESRD QIP Overview
Statutory Foundations & Legislative Drivers
The ESRD QIP is described in Section 1881(h) of the Social Security Act, as added by Section 153(c) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)

- Program intent: Promote patient health by providing a financial incentive for renal dialysis facilities to deliver high-quality patient care

- Section 1881(h):
  - Authorizes payment reductions if a facility does not meet or exceed the minimum Total Performance Score (TPS) as set forth by CMS
  - Allows CMS to apply payment reductions of up to 2%

- The Protecting Access to Medicare Act of 2014 (PAMA) added section 1881(h)(2)(A)(iii) to the Social Security Act
  - Starting in 2016, 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
ESRD QIP Statutory Requirements: Overview

The Secretary of the Department of Health and Human Services (HHS) is required to create an ESRD QIP that will:

- Include measures addressing:
  - Anemia management, reflecting Food and Drug Administration (FDA) labeling
  - Dialysis adequacy
  - Patient satisfaction, as specified by the HHS Secretary
  - Iron management, bone mineral metabolism, and vascular access, as specified by the HHS Secretary

- Establish performance standards that apply to individual measures

- Specify the performance period for a given PY

- Develop a methodology for assessing total performance of each facility based on performance standards for measures during a performance period

- Apply an appropriate payment percentage reduction to facilities that do not meet or exceed established total performance scores

- Publicly report results through websites and facility posting of performance score certificates (PSC)
ESRD QIP Rule Development

1. CMS drafts proposals for ESRD QIP (applied on a PY basis)
2. HHS components and Office of Mgmt. & Budget (OMB) review proposals
3. CMS publishes proposed rule in the Federal Register
4. CMS drafts final rule addressing public comments, which passes through HHS and OMB internal clearance
5. Public afforded 60-day period to comment on proposed rule
6. CMS publishes final rule in the Federal Register
Meaningful Measures & the ESRD QIP
Meaningful Measures: Improving Outcomes, Reducing Burden

“At CMS the overall vision is to reinvent the Agency to put patients first. We want to partner with patients, providers, payers, and others to achieve this goal. We aim to be responsive to the needs of those we serve.”

- Administrator Seema Verma
Centers for Medicare and Medicaid Services
Application in ESRD QIP

MedRec

Patients Receiving Care at Dialysis Facilities, Medication Reconciliation
The measure assesses how well a facility has appropriately evaluated a patient’s medications – an important safety concern for the ESRD patient population, who typically take a large number of medications

Meaningful Measures Area
Making Care Safer by Reducing Harm Caused by Care Delivery

PPPW

Percentage of Prevalent Patients Waitlisted
This measure assesses the percentage of current patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist

Meaningful Measures Area
Promote Effective Communication and Coordination of Care

CMS Medicare Learning Network
CY 2020 Rulemaking
PY 2022 & PY 2023 Overview (Finalized in CY 2020 ESRD PPS)
Proposed Modifications & Rationale
Summary of Proposals & Estimated Impacts on PY 2022 & 2023
PY 2022 & PY 2023 Measure Set

A facility must be eligible to receive a score on at least one measure in any two domains to receive a Total Performance Score (TPS).

Clinical Care Domain
40% of TPS
- Kt/V Dialysis Adequacy (comprehensive)
- VAT Measure Topic:
  - Standardized Fistula Rate
  - Long-Term Catheter Rate
- Hypercalcemia
- Standardized Transfusion Ratio (STrR)
- Ultrafiltration Rate reporting measure

Care Coordination Domain
30% of TPS
- Standardized Readmission Ratio (SRR)
- Standardized Hospitalization Ratio (SHR)
- Clinical Depression Screening & Follow-Up
- Percentage of Prevalent Patients Waitlisted (PPPW)

Safety Domain
15% of TPS
- NHSN Bloodstream Infection (BSI)
- NHSN Dialysis Event reporting measure
- Medication Reconciliation

Patient & Family Engagement Domain
15% of TPS
- ICH CAHPS
Overview of Proposed ESRD QIP Modifications

1. Update scoring methodology for the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure
2. Convert STrR clinical measure (NQF #2979) into a reporting measure
3. Revise MedRec reporting measure’s scoring equation
4. Codify program requirements in regulation text
5. Continue data validation in PY 2022 and beyond
Proposal 1:

Update scoring methodology for the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure

<table>
<thead>
<tr>
<th>Percentage of Eligible Months* Reported</th>
<th>Points Awarded to Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% of eligible months</td>
<td>10 points</td>
</tr>
<tr>
<td>Less than 100% but no less than 50% of eligible months</td>
<td>2 points</td>
</tr>
<tr>
<td>Less than 50% of eligible months</td>
<td>0 points</td>
</tr>
</tbody>
</table>

Proposal

- Update the Eligibility Requirements for the PY 2022 ESRD QIP to allow facilities to receive a score even when they are ineligible to report for all 12 months
- Assess facilities based on number of months eligible to report
- Remove the requirement that new facilities have a CCN open date that is before the October 1st prior to the performance period

*“Eligible Months” = the months in which dialysis facilities are required to report dialysis event data to NHSN per the measure eligibility criteria. Includes facilities that offer in-center hemodialysis and facilities that treat at least 11 eligible in-center hemodialysis patients during the performance period
Proposal 1: Rationale

Update scoring methodology for the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure

Rationale

• Accumulated experience with the existing requirements, finalized in the CY 2017 ESRD PPS Final Rule, has led CMS to recognize a need for adjustment, which:
  • Recognizes effort from facilities ineligible to submit 12 months of data (new facilities or those granted an ECE)
  • Incentivizes reporting for facilities eligible to report data for fewer than 12 months
Proposal 2:
Convert the STrR clinical measure (NQF #2979) into a reporting measure

Proposal
- Convert STrR from a Clinical Measure to a Reporting Measure
- To receive 10 points: Facility must report the data required to determine the number of eligible patient-years at risk + have a minimum of 10 patient-years at risk
  - Multiple patients can be included within one patient year

Currently Finalized:
Clinical Measure

STrR Proposed Change

CY 2020/PY 2022:
Reporting Measure

Patient A
4 Months

Patient B
8 Months

= 1 Full Patient Year
Proposal 2: Rationale

Convert the STrR clinical measure (NQF #2979) into a reporting measure

Rationale

- Commenters to the CY 2019 ESRD PPS proposed rule raised concerns about the STrR clinical measure’s validity
- CMS is currently in the process of examining these concerns
- Fulfills the statutory requirement to include a measure of anemia management in the Program
- Ensure that facilities are not adversely affected during CMS’s continued examination of the measure
- Ensures that the Program’s scoring methodology results in fair STrR measure scores
Proposal 3:
Revise MedRec reporting measure’s scoring equation

Proposal

- Change MedRec scoring equation before the measure’s introduction in PY 2022 to use the term “Facility-Months” (instead of “Patient-Months”)

\[
\left(\frac{\text{# months successfully reporting data}}{\text{# eligible months}}\right) \times 12 - 2
\]
Proposal 3: Rationale

Revise MedRec reporting measure’s scoring equation

Rationale

• Facility-months is more appropriate because it would assess the proportion of months in a year that a facility reported the necessary data
• Calculating MedRec using facility-months is consistent with the scoring methodology used for all reporting measures that require monthly reporting
• Adjusts the measure’s scoring equation prior to the measure’s use in the Program
Proposal 4:
Codify Program Requirements

Proposal
• Codify automatic adoption of the baseline period and performance period for each payment year
• Codify data submission requirements for calculating measure scores
• Codify the Extraordinary Circumstances Exception (ECE) process, including a new option to provide facilities with flexibility
Proposal 4: Rationale

Codify Program Requirements

Rationale

• Previously finalized policies will be easier for the public to locate
• Data submission requirements will be easier to understand
• Guidance on ECE policies will be clearer and provide additional flexibility to facilities in affected areas
Proposal 5:

Continue Data Validation in PY 2022 and Beyond

Proposal

NHSN validation study
- Continue using PY 2022 methodology
- Adopt NHSN validation study as a permanent feature of the ESRD QIP.
Proposal 5: Rationale

Continue Data Validation in PY 2022 and Beyond

Rationale

• A sample size of 300 facilities ensures enough precision within the study
• Signals CMS’ commitment to accurate reporting of the topics covered by the adopted NHSN measures
Proposed Rule
PY 2023 OVERVIEW

Proposals
• Performance period: CY 2021
• Baseline period: CY 2019 and 2020
• Automatically adopt performance and baseline period for each year that is one year advanced from those specified for the previous payment
• Continue use of the PY 2022 measure weights and measure weight distribution policy in PY 2023 and future years

Rationale
• Provide clear guidance to the public on these policies for PY 2023 and future payment years
Payment Reductions

Provide estimated PY 2022 minimum total performance score (TPS) and payment reduction scale for PY 2022

PY 2022 minimum Total Performance Score (TPS) estimate

- Facility must meet or exceed a mTPS of 53 to avoid payment reduction

<table>
<thead>
<tr>
<th>Total performance score</th>
<th>Reduction (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100-53</td>
<td>0%</td>
</tr>
<tr>
<td>52-43</td>
<td>0.5%</td>
</tr>
<tr>
<td>42-33</td>
<td>1.0%</td>
</tr>
<tr>
<td>32-23</td>
<td>1.5%</td>
</tr>
<tr>
<td>22-0</td>
<td>2.0%</td>
</tr>
</tbody>
</table>

- Final mTPS and payment reduction ranges will be included in the Final Rule
# Anticipated Impact of Proposed Rule PY 2022 & PY 2023

<table>
<thead>
<tr>
<th>Projected Impact By Year</th>
<th>Number of Facilities</th>
<th>Number of Treatments 2017 (in millions)</th>
<th>Number of Facilities with QIP Score</th>
<th>Number of Facilities Expected to Receive a Payment Reduction</th>
<th>Payment Reduction (percent change in total ESRD payments)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PY 2022 &amp; PY 2023</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Facilities</td>
<td>7,099</td>
<td>45.1</td>
<td>6,876</td>
<td>1,506</td>
<td>-0.14%</td>
</tr>
<tr>
<td>Facility Type:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freestanding</td>
<td>6,681</td>
<td>43</td>
<td>6,510</td>
<td>1,407</td>
<td>-0.13%</td>
</tr>
<tr>
<td>Hospital-based</td>
<td>418</td>
<td>2.2</td>
<td>366</td>
<td>99</td>
<td>-0.22%</td>
</tr>
</tbody>
</table>

- **Projected Payment Reductions & History**

  - All Facilities:  
    - 7,099 facilities
    - 45.1 million treatments
    - 6,876 facilities with QIP score
    - 1,506 facilities expected to receive a payment reduction
    - Payment reduction: -0.14%

  - Freestanding:  
    - 6,681 facilities
    - 43 million treatments
    - 6,510 facilities with QIP score
    - 1,407 facilities expected to receive a payment reduction
    - Payment reduction: -0.13%

  - Hospital-based:  
    - 418 facilities
    - 2.2 million treatments
    - 366 facilities with QIP score
    - 99 facilities expected to receive a payment reduction
    - Payment reduction: -0.22%

- **Projected Payment Reductions for each PY**

<table>
<thead>
<tr>
<th>Payment Reduction</th>
<th>Number of Facilities</th>
<th>Percent of Facilities*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00%</td>
<td>5,370</td>
<td>78.10%</td>
</tr>
<tr>
<td>0.50%</td>
<td>1,116</td>
<td>16.23%</td>
</tr>
<tr>
<td>1.00%</td>
<td>325</td>
<td>4.73%</td>
</tr>
<tr>
<td>1.50%</td>
<td>56</td>
<td>0.81%</td>
</tr>
<tr>
<td>2.00%</td>
<td>9</td>
<td>0.13%</td>
</tr>
</tbody>
</table>

  *223 facilities not scored due to insufficient data
Participating in the Comment Period
How to Locate the Proposed Rule or Submit a Comment
Public Role in the Regulation Process

CMS implements the ESRD QIP through the federal regulation process, one of the basic tools of government used to implement public policy.

- CMS writes proposed rule
- CMS publishes proposed rule in the Federal Register
- Public comments on proposals
- CMS reviews public comments
- CMS publishes final rule in the Federal Register
  FINAL RULE BECOMES REGULATION

Your Comments Matter

The public comment period for the CY 2020 ESRD PPS Proposed rule is open until September 27, 2019.

regulations.gov
Commenting on the Proposed Rule
Commenting on the Proposed Rule (continued)
### Key ESRD QIP Dates to Remember

<table>
<thead>
<tr>
<th>Item</th>
<th>Timeframe/Notes</th>
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<tbody>
<tr>
<td><strong>PY 2019 Payment Reductions Applied</strong></td>
<td>January 1 – December 31, 2019</td>
</tr>
<tr>
<td><strong>PY 2020 Preview Period</strong></td>
<td>July 22-August 23, 2019 at 11:59pm PT (August 24 at 2:29am ET)</td>
</tr>
<tr>
<td><strong>PY 2021 Performance Period</strong></td>
<td>January 1 – December 31, 2019</td>
</tr>
<tr>
<td><strong>CY 2020 ESRD PPS</strong></td>
<td>Proposed rule published: display available on July 29, 2019</td>
</tr>
<tr>
<td></td>
<td>60-day comment period: starts July 29 and ends September 27, 2019</td>
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<tr>
<td></td>
<td>Final rule published: November 2019</td>
</tr>
<tr>
<td><strong>PY 2020 PSC Available for Download</strong></td>
<td>Mid-December 2019</td>
</tr>
<tr>
<td></td>
<td>• Post within 15 business days</td>
</tr>
<tr>
<td><strong>PY 2020 Payment Reductions</strong></td>
<td>January 1, 2020 through December 31, 2020</td>
</tr>
<tr>
<td>RESOURCE</td>
<td>URL</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Dialysis Facility Compare</td>
<td><a href="http://www.medicare.gov/dialysisfacilitycompare">www.medicare.gov/dialysisfacilitycompare</a></td>
</tr>
<tr>
<td>Regulations.gov</td>
<td><a href="https://www.regulations.gov/">https://www.regulations.gov/</a></td>
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Thank You

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