

CY 2022 ESRD PPS Proposed Rule

ESRD QIP Proposals

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Objectives



Attendees will be able to:

- Recognize statutory and legislative components for the End-Stage Renal Disease Quality Incentive Program (ESRD QIP).
- Understand the proposals in the CY 2022 ESRD Prospective Payment System (PPS) Proposed Rule for the ESRD QIP program.
- State the rationale for the finalized policies and their impact on the ESRD QIP Program.
- Access resources for the ESRD QIP.

Guidance



- During today's call, CMS will discuss the proposed updates for the ESRD QIP in the CY 2022 ESRD PPS Proposed Rule, released July 9, 2021.
- The information provided 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 <u>Federal Register</u>.



Legislative Drivers and 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).

- The program's intent is to promote patient health by providing a financial incentive for renal dialysis facilities to deliver high-quality patient care.
- Section 1881(h) authorizes payment reductions of up to 2 percent if a facility does not meet or exceed the minimum Total Performance Score (TPS).

The Protect Access to Medicare Act of 2014 (PAMA) added section 1881 (h)(2)(A)(iii).

 The 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.

Statutory Overview

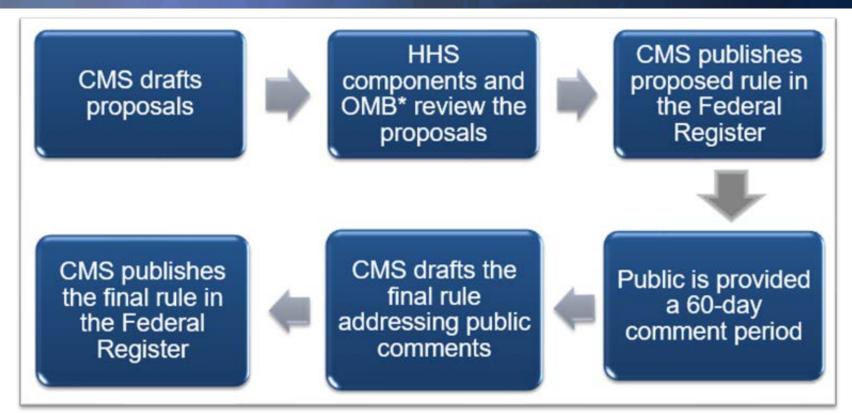


MIPPA requires the Health and Human Services (HHS) Secretary to create an ESRD QIP that will:

- Select measures that address the following:
 - Anemia
 - Dialysis adequacy
 - Patient satisfaction
 - Iron management, bone mineral metabolism, and vascular access
- Establish performance standards.
- Specify the performance period.
- Develop a methodology for calculating TPSs.
- Apply an appropriate payment percentage reduction.
 - Publicly report results.

Rule Development





^{*}Office of Management and Budget



Updates to Extraordinary Circumstance Exceptions (ECE) for the ESRD QIP

COVID-19 Relief Efforts



- On March 22, 2020, CMS announced relief for facilities participating in Medicare quality reporting and value-based purchasing programs.
- On March 27, 2020, there was supplemental guidance describing the scope and duration of the ECEs granted under each program.
 - Providers were relieved of their obligation to report data for Q4 CY 2019, Q1 CY 2020, and Q2 CY 2020.
 - CMS would score data if voluntarily reported.

Updates to ECE



- In September 2020, CMS adopted two updates to the ECE policy in the Interim Final Rule with Comment Period (IFC) to:
 - State that a facility has opted out of the COVID-19 ECE for Q4 2019 NHSN* data if the facility reported data by the deadline but did not notify CMS.
 - Remove the ability of facilities to opt-out of the ECE granted for Q1 2020 and Q2 2020 ESRD QIP data.
- We solicited public comment and will address them in the final rule.

^{*}Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network

Transition to EQRS



- On November 9, 2020, CMS launched the End Stage Renal Disease Quality Reporting System (EQRS) to consolidate the functionalities of multiple applications into one global application.
 - The migration eliminates the need for multiple user accounts, improves the overall user experience, reduces burden on providers.
- Several issues impacted the quality and accuracy of data, and we suspended all clinical data submissions via EQRS.
 - Data system issues were resolved on about July 12, 2021.

Blanket Extension

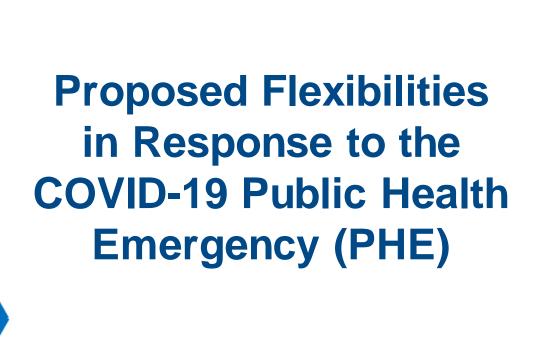


- CMS is announcing a blanket extension of the remaining CY 2020 clinical reporting deadlines.
 - Facilities will have until September 1, 2021, to submit ESRD QIP clinical data for September 2020, October 2020, November 2020, and December 2020.
- The extension aligns with the time estimated to resolve operational system issues and will give dialysis facilities nearly seven weeks to submit their data.
 - Further details were provided when EQRS issues were resolved, and facilities began submitting their data.

Rationale



- CMS cannot ensure the validity of the impacted data before submission.
 - Unresolved system issues could impact the accuracy and reliability of reported data, and CMS is concerned this will lead to unfair penalties.
- Facilities expressed concerns about their experience and their inability to verify the accuracy or completeness of their data.
- Observed and unresolved issues that may be identified following submission may impact the quality and accuracy of the data needed to calculate accurate scores for Payment Year (PY) 2022.



COVID-19 PHE



- In previous rules, CMS has identified the need for flexibility in quality programs to account for changing conditions.
 - This is to ensuring participants in quality programs are not affected negatively when performance suffers due to external factors.
- The COVID-19 pandemic continues to have significant effects on health care. CMS has the following concerns:
 - Decreased performance leading to payment penalties
 - Regional difference in COVID-19 prevalence during the performance period for PY 2022 directly affecting measure scores

Proposal



- Propose to adopt a measure suppression policy for the duration of the COVID-19 PHE to enable CMS to suppress the use of ESRD QIP measure data if it is determined that circumstances caused by the PHE significantly affected those measures and the resulting TPSs.
- Prose to adopt measure suppression factors to help determine whether to suppress measures for years that overlap with the COVID-19 PHE.
- There are four factors in this proposal.

Suppression Factors



<u>Factor 1</u>: Significant deviation in national performance on the measure during the COVID-19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.

<u>Factor 2:</u> Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID-19 PHE.

<u>Factor 3:</u> Rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

Suppression Factors (cont.)



<u>Factor 4:</u> Significant national shortages or rapid or unprecedented changes in the following:

- Healthcare personnel
- Medical supplies, equipment, or diagnostic tools or materials
- Patient case volumes or facility-level case mix

The intention is to provide short-term relief when it is determined that one or more of the Measure Suppression Factors warrants suppression.

Rationale



- Significant deviation in measured performance can be attributed to the COVID-19 PHE and indicates changes in clinical conditions.
- A measure may be focused on a clinical topic proximal to the disease or impacts of the PHE.
- Understanding of a disease may evolve quickly during an emergency.
- National or regional shortages or changes in staff, supplies, equipment and patient volumes may result in significant distortions to quality measurement.
- Suppression Factors will assist in evaluation of measures and is consistent across programs.

Proposals to Address the Impact of COVID-19 on ESRD QIP Measures for PY 2022

Proposal



Propose to suppress four measures for the PY 2022 ESRD QIP using proposed Measure Suppression Factors:

Measure	Proposed Factor
Standardized Hospitalization Ratio (SHR)	Factor 1 and Factor 4
Standardized Readmission Ratio (SRR)	Factor 1 and Factor 4
In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS)	Factor 1
Hemodialysis Vascular Access: Long-term Catheter Rate	Factor 1

Rationale



- Regional differences in COVID-19 rates may lead to distorted hospitalization rates effecting the reliability of national performance.
- There are concerns the PHE affects measure performance and the inability to score facilities fairly.
- The suppression for PY 2022 is being proposed rather than removal, as the measures are an important part of the ESRD QIP Program.

Proposal



Propose a special rule to modify the scoring methodology so no facility would receive a payment reduction for PY 2022

The rule would:

- Be codified in regulations to apply when CMS does not calculate or award a TPS to any ESRD facility.
- Calculate measure rates for all measures for that payment year.
 The rates would not use the rates to generate an achievement score, improvement score, domain score, or a TPS.
- Provide confidential reports on performance.
- Ensure the public reporting of PY 2022 data where feasible and appropriate.

Rationale



- All fourteen ESRD QIP measures for PY 2022 are impacted by system issues.
 - EQRS data are used to determine if the facility has treated enough patients to meet the minimum threshold.
- System issues could lead to distorted performance scores and unfair penalties.
- CMS wants to provide facilities with certainty regarding their PY 2022 payments.
 - Not reduce payments for facilities whose performance could not be accurately assessed

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Proposed Updates to Requirements Beginning with PY 2024

Proposal



Propose to update the Standardized Hospitalization Ratio (SHR) measure specifications to:

- Align with the National Quality Forum (NQF)-endorsed updates which would include:
 - Updates to the risk adjustment method, including a prevalent comorbidity adjustment, addition of Medicare Advantage (MA) patients and an MA indicator, updates to parameter updates to existing adjustment factors and re-evaluation of interactions, and an indicator for a patient time spent in the facility.
- Begin with PY 2024.

Rationale



- Updates would be consistent with evaluating opportunities to align program measures with NQF measure specifications
- Improvement in patient outcomes by measuring hospitalization ratios among dialysis facilities
- Would result in a more reliable and robust measure



Performance Standards and Payment Reduction

Performance Standards



The Performance Standards must:

- Include levels of achievement and improvement.
- Be established prior to the beginning of the performance period for the year involved.
 - CMS codified "achievement threshold," "benchmark," "improvement threshold, " and "performance standard" in its regulation.

Proposal



Propose to update the performance standards applicable to the clinical measures to calculate the performance standards for PY 2024 using CY 2019 data due to the impact of CY 2020 data that are excluded.

We will 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.

Rationale



Due to the proposed exclusion of CY 2020 data from the ESRD QIP for scoring purposes, it is appropriate to use CY 2019 data to set performance standards.

 It may be difficult to assess levels of achievement and improvement if the performance standards are based on a partial year of data.

Estimated Performance Standards for



76.77% 4.69%

99.42%

*0.00

*0.629

0

0.670

*33.90%

79.15%

72.66%

87.8%

*76.57%

78.3%

83.72%

PY 2024 ESRD QIP Clinical Measures					
	Measure	Achievement Threshold (15th percentile**)	Median (5 percentil		
Vascular	Standardized Fistula Rate	53.29%	64.36%		
Access Type (VAT)	Catheter Rate	18.35%	11.04%		

Kt/V K (dialyzer clearance of urea) *t

Standardized Readmission Ratio (SRR)

NHSN Bloodstream Infection (NHSN BSI)

Standardized Hospitalization Ratio (SHR)

Nephrologists' Communication and Caring

Providing Information to Patients

Overall Rating of Nephrologists

Overall Rating of Dialysis Center Staff

Overall Rating of the Dialysis Facility

Quality of Dialysis Center Care and Operations

Percentage of Prevalent Patient Waitlisted (PPPW)

are higher standards than the measures' PY 2024 numerical values.**Of National Performance.

Hypercalcemia

ICH CAHPS

(dialysis time)/V (patient's total body water)

97.61%

0.49

*0.998

0.516

0.967

*16.73%

67.90%

63.08%

81.09%

*62.22%

63.37%

69.04%

PY 2024 ESRD QIP Cli	nical Meası	ıres	CENTERS FOR MEDICARE & MEDICAID SERVI
Measure Measure	Achievement Threshold (15th percentile**)	Median (50th percentile**)	Benchmark (90th percentile

*These values are also the final performance standards for PY 2023. In accordance with CMS policy, we use those values for PY 2024 because they

94.33%

1.54

*1.268

1.193

*1.248

*8.12%

58.20%

54.64%

74.49%

*49.33%

50.02%

54.51%

Payment Reduction Scale



Under the current policy:

- A facility will not receive a payment reduction if it achieves a TPS that is at or above the minimum TPS (mTPS).
 - The mTPS in this proposed rule is based on data from the CY 2019 baseline period instead of the CY 2020 baseline.
- The payment reduction is implemented on a sliding scale using ranges the reflect payment reduction differentials of 0.5 percent for each ten points below the mTPS.

Data Used



Data Used to Estimate PY 2024 ESRD QIP Payment Reductions

Measure	Period used*	Performance period
ICH CAHPS Survey	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW	Jan 2018-Dec 2018	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
Standardized Fistula Ratio	Jan 2018-Dec 2018	Jan 2019-Dec 2019
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
Hypercalcemia	Jan 2018-Dec 2018	Jan 2019-Dec 2019

^{*}The period used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds.

Estimated Payment Reduction Scale CMS

Estimated Payment Reduction Scale for PY 2024 Based on CY 2019 Data*

TPS	Reduction
100-57	0%
56-47	0.5%
46-37	1.0%
36-27	1.5%
26-0	2.0%

^{*}If the proposed update to the performance standards is not finalized, the mTPS and payment reductions ranges will be updated in the final rule using CY 2020 data.

Estimated Distribution



Estimated Distribution of PY 2024 ESRD QIP Payment Reductions.

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,570	75.59%
0.5%	1,343	18.22%
1.0%	363	4.93%
1.5%	71	0.96%
2.0%	22	0.30%

^{*241} facilities were not scored due to insufficient data.

Domain Weights



Measure Domains and the TPS for PY 2025

Clinical Care Domain 40% of TPS

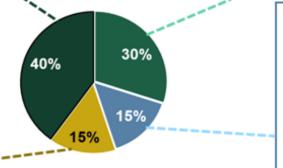
- Kt/V Dialysis Adequacy (comprehensive)
- VAT Measure Topic:
 - Standardized Fistula Rate
 - Long-Term Catheter Rate
- Hypercalcemia
- Standardized Transfusion Ratio (STrR)
- · Ultrafiltration Rate reporting measure

Patient & Family Engagement Domain 15% of TPS

ICH CAHPS

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

Performance Period



- CMS proposes to continue with the 12-month performance and baseline periods for PY 2025 and subsequent years as they provide reliable quality measure data.
- CMS would adopt CY 2023 as the performance period and CY 2021 as the baseline period for the PY 2025 ESRD QIP.

Performance Standards: Clinical Measures in PY 2025



- CMS does not have the necessary data to assign values for the clinical measures as we do not have CY 2021 data.
- Numerical values using CY 2021 data will be published in the CY 2023 ESRD PPS Final Rule.

Performance Standards: Reporting Measures in PY 2025



- CMS previously finalized the continued use of existing performance standards for the following:
 - Clinical Depression and Follow-Up reporting measure
 - Ultrafiltration Rate reporting measure
 - NHSN Dialysis Event reporting measure
 - MedRec reporting measure
- These performance standards will be used in PY 2025.



Requests for Information (RFIs) on Topics Relevant to ESRD QIP

Health Equity Gaps



As part of an ongoing effort across CMS to evaluate and reduce health disparities, feedback will be used to close health equity gaps in CMS programs and policies:

- Request for information (RFI) contains four parts:
 - Background
 - Current CMS disparity methods
 - Future potential stratification of quality measure results to include potential stratification results by dual eligibility, race and ethnicity, and improving demographic data collection, and potentially creating an ESRD Facility Equity Score
 - Solicitation of public comment



COVID-19 Vaccination Measures Request for Information

Seeking Comment



COVID-19 Vaccination Coverage Among Healthcare Personnel Measure

 The measure would assess the proportion of the workforce that has been vaccinated against COVID-19.

COVID-19 Vaccination Coverage for Patients in End-Stage Renal Disease (ESRD) Facilities Measure

 The measure would assess the proportion of a facility's patient population that has been vaccinated against COVID-19.

Rationale



- Addresses the "Promoting Effective Prevention and Treatment of Chronic Disease" through the Meaningful Measures Area of "Preventive Care."
- CMS believes facilities should track vaccination among their personnel and patients to assess and reduce risk of transmission.
- Publication of HCP vaccination rates will be helpful to patients when choosing facilities to seek treatment.

Review of Measures



- These two measures were included on the Measures Under Consideration (MUC) list in December 2020 for use in various programs.
- The Measure Applications Partnership (MAP) workgroup:
 - Recognized the measures would bring value by providing transparency about intervention in HCP and patients.
 - Stated that collecting COVID-19 information and providing feedback to facilities will allow facilities to benchmark coverage rates.
 - Noted that reducing rates of COVID-19 may reduce transmission among a highly susceptible patient population and reduce instances in staff shortages due to illness.
- The MAP offered conditional support contingent upon specifications being further refined.

Seeking Comment



CMS is seeking comment on:

- COVID-19 Vaccination Measures: COVID-19 Vaccination Coverage for Patients in ESRD Facilities and COVID-19 Vaccination Coverage Among Healthcare Personnel measures for inclusion in the ESRD QIP measure set in the next rulemaking cycle.
 - Vaccination measure data are currently being collected via the CDC's NHSN
 - CMS is evaluating options for publicly reporting the information on official CMS datasets that compare the quality of care provided in Medicare-certified dialysis facilities nationwide.

Advancing to Digital
Quality Measurement and
the Use of Fast Healthcare
Interoperability Resources
(FHIR)

Background Information



- It is CMS' aim to move fully to digital quality measurement by 2025 and acknowledge providers may be at different stages of readiness.
- The use of electronic health records (EHRs) remains burdensome and does not incorporate data sources such as patient-reported outcomes (PROs) and patient-generated health data (PGHD).
- Advances in interoperability of health information technology has increased electronically accessible health information.
- CMS worked collaboratively and identified FHIR as the standard to support Application Programming Interface (API) policies.
- Data standardization and interoperability enabled by API will support the transition to full digital quality measurement by 2025.

The Definition of Digital Quality Measures (dQMs)



- CMS seeks input on future elaboration that would define a dQM as software that processes digital data to produce a measure score(s).
- The intention of dQMs is to improve care and reduce cost.
- Data sources for dQMs may include:
 - Administrative systems
 - Electronically submitted clinical assessment data
 - Case management systems
 - EHRs
 - Instruments (medical devices, wearable devices)
 - Health Information exchanges, registries and other sources

Modernizing Quality Measurement



- To enable the transformation, CMS is considering modernizing quality measurement in four ways:
 - Leverage and advance standards and obtain all EHR data required via FHIR-based APIs
 - Redesign quality measures to be self-contained tools
 - Better support data aggregation
 - Work to align measure requirements across programs

Future Plans



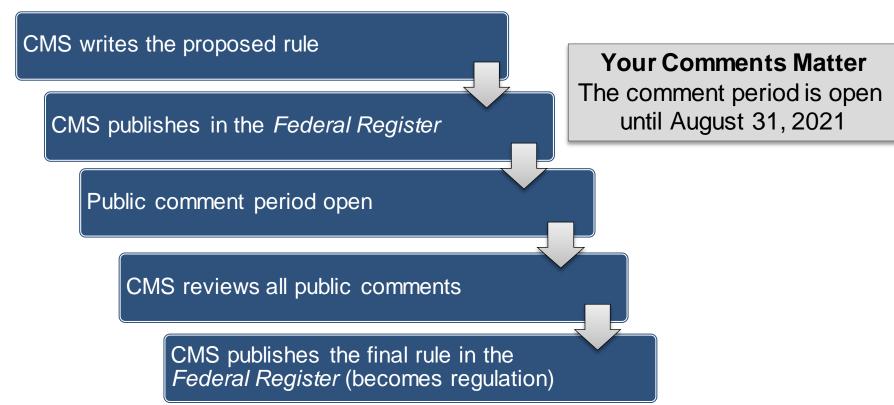
- CMS plans to continue working to coordinate and inform of any potential transition to dQMs by 2025.
- CMS will not be responding to specific comments submitted in response to this RFI in the CY 2022 ESRD PPS final rule. We will actively consider all input as we develop future regulatory proposals or future sub-regulatory policy guidance
- Any program-specific updates related to quality measurement and reporting will be addressed through separate and future rulemaking.



Commenting

Public Role in Rulemaking





Submitting Comments



- Comments must be received by August 31, 2021.
- CMS encourages submission of electronic comments to <u>regulations.gov.</u>
 - Comments may also be submitted by regular mail, express mail, or overnight mail to the designated addresses provided.
- Responses to comments will be in the final rule.

Finding the Proposed Rule



- 1. Begin at www.FederalRegister.gov
- 2. Enter CMS-1749-P in the [Find] box.
- Select the [magnifying glass] button.



Open the Rule



4. Click on the title in blue.

DOCUMENTS RELEVANT NEWEST OLDEST Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model by the Centers for Medicare & Medicaid Services on 07/09/2021. 31, 2021. ADDRESSES: In commenting, please refer to file code CMS-1749-P. Because of staff and resource limitations, we cannot accept comments ... Medicaid Services, Department of Health and Human Services, Attention: CMS-1749-P, P.O. Box 8010, Baltimore, MD 21244-8010. Please allow sufficient...

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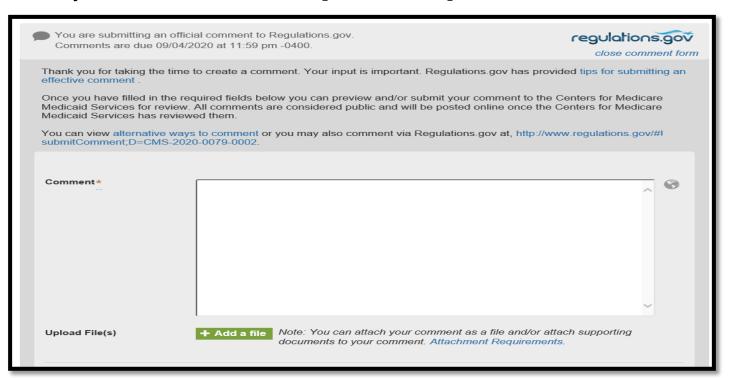
5. To submit a comment, select the [Submit A Formal Comment] button.



Enter Your Comment



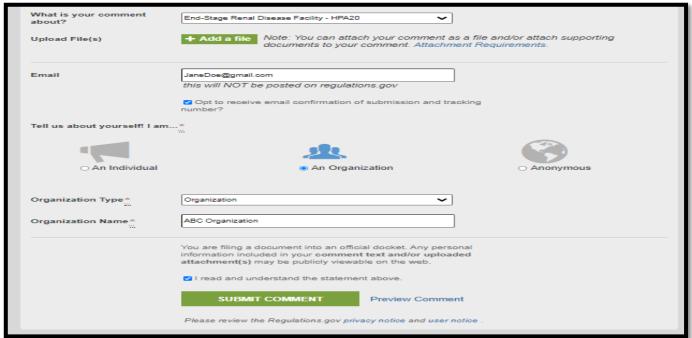
6. Enter your comment in the [Comment] field.



Submit Your Comment



- 7. Enter your information
- 8. Select the [I read and understand the statement above] box.
- 9. Select the [Submit Comment] button.



Resources



Resource	Location
Program (General)	ESRD QIP Section on CMS.gov ESRD QIP Section on QualityNet
ESRD QIP Measures	Technical Specifications on CMS.gov ESRD QIP Measures on CMS.gov ICH CAHPS on CMS.gov ESRD QIP Measures on QualityNet
Public Reporting	Dialysis Facility Compare
Stakeholder Partners	Partners in ESRD Care
Proposed Rule	ESRD QIP Proposed Rule

To reach us for comment:

Contact us via the <u>ServiceNow Q&A Tool</u> or <u>ESRDQIP@CMS.HHS.gov</u>.

Acronyms



ADI	Analization Decomposition lateria	BALLO.	Management Under Consideration
API	Application Programming Interface	MUC	Measures Under Consideration
BSI	Bloodstream Infection	NHSN	National Healthcare Safety Network
CDC	Centers for Disease Control and Prevention	NQF	National Quality Forum
CMS	Centers for Medicare & Medicaid Services	OMB	Office of Management and Budget
CMS	Centers for Medicare & Medicaid Services	PAMA	Protecting Access to Medicare Act of 2014
CY	Calendar Year	PGHI	Patient-generated Health Data
DVIQR	Division of Value, Incentives, and Quality Reporting	PHE	Public Health Emergency
dQM	Digital Quality Measure	PPPW	Percentage of Prevalent Patient Waitlisted
ECE	Extraordinary Circumstances Exception	PPS	Prospective Payment System
ESRD QIP	End-Stage Renal Disease Quality Incentive Program	PRO	Patient-reported outcome
EHR	Electronic Health Record	PY	Payment Year
EQRS	End Stage Renal Disease Quality Reporting System	Q	Quarter
FHIR	Fast Healthcare Interoperability Resources	RFI	Request for Information
HCP	Healthcare Personnel	SHR	Standardized Hospitalization Ratio
HHS	Health and Human Services	SRR	Standardized Readmission Ratio
ICH	In-Center Hemodialysis Consumer Assessment	STrR	Standardized Transfusion Ratio
CAHPS	of Healthcare Providers and Systems	SIIK	
IFC	Interim Final Rule with Comment Period	TPS	Total Performance Score
MAP	Measure Applications Partnership	VAT	Vascular Access Type
MIPPA	Medicare Improvements for Patients and Providers Act		
mTPS	Minimum Total Performance Score		

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