



FEDERAL REGISTER

Vol. 76

Wednesday

No. 3

January 5, 2011

Part II

Department of
Health and Human
Services

Center for Medicare & Medicaid Services

42 CFR Part 413
Medicare Program; End-Stage Renal
Disease Quality Incentive Program; Final
Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413

[CMS–3206–F]

RIN 0938–AP91

Medicare Program; End-Stage Renal Disease Quality Incentive Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will implement a quality incentive program (QIP) for Medicare outpatient end-stage renal disease (ESRD) dialysis providers and facilities with payment consequences beginning January 1, 2012, in accordance with section 1881(h) of the Act (added on July 15, 2008 by section 153(c) of the Medicare Improvements for Patients and Providers Act (MIPPA)). Under the ESRD QIP, ESRD payments made to dialysis providers and facilities under section 1881(b)(14) of the Social Security Act will be reduced by up to two percent if the providers/facilities fail to meet or exceed a total performance score with respect to performance standards established with respect to certain specified measures.

DATES: These regulations are effective on February 4, 2011.

FOR FURTHER INFORMATION CONTACT: Shannon Kerr, (410) 786–3039.

SUPPLEMENTARY INFORMATION:

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Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

- CIP Core Indicators Project
- CMS Centers for Medicare & Medicaid Services
- CPM Clinical performance measure
- CROWNWeb Consolidated Renal Operations in a Web-Enabled Network
- DFC Dialysis Facility Compare
- DFR Dialysis Facility Report
- ESA Erythropoiesis-stimulating agent
- ESRD End-stage renal disease
- FDA Food and Drug Administration
- Kt/V A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume
- LDO Large dialysis organization
- MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
- NQF National Quality Forum
- PPS Prospective payment system
- QIP Quality incentive program
- REMIS Renal management information system
- RFA Regulatory Flexibility Act
- SIMS Standard information management system
- SSA Social Security Administration
- the Act Social Security Act
- URR Urea reduction ratio

I. Background

A. Overview of Quality Monitoring Initiatives

For over 30 years, monitoring the quality of care provided to end-stage renal disease (ESRD) patients and provider/facility accountability have been important components of the Medicare ESRD payment system. In the proposed rule, we described the evolution of our ESRD quality monitoring initiatives by category: The ESRD Network Organization Program, the Clinical Performance Measures (CPM) Project, Dialysis Facility Compare (DFC), the ESRD Quality Initiative, the ESRD Conditions for Coverage, and CROWNWeb (75 FR 49216–49217). Most recently, we finalized three quality measures that we will use for the initial year of the QIP (see “End-Stage Renal Disease Prospective Payment System final rule (referred to in this final rule as the

“ESRD PPS final rule”), which appeared in the **Federal Register** on August 12, 2010 (75 FR 49030, 49182–49190). We also proposed to implement other components of the QIP in a notice of proposed rulemaking entitled “End-Stage Renal Disease Quality Incentive Program” proposed rule, which appeared in the **Federal Register** on August 12, 2010 (75 FR 49215–49232). We received and reviewed many helpful comments regarding the design of the QIP that contributed to the development of this ESRD QIP final rule.

We view the ESRD QIP, required by section 1881(h) of the Social Security Act (the Act), as the next step in the evolution of the ESRD quality program that began more than three decades ago. Our vision is to implement a robust, comprehensive ESRD QIP that builds on the foundation that has already been established.

B. Statutory Authority for the ESRD QIP

Congress required in section 153 of MIPPA that the Secretary implement an ESRD quality incentive program (QIP). Specifically, section 1881(h) of the Act, as added by section 153(c) of MIPPA, requires the Secretary to develop a QIP that will result in payment reductions to providers of dialysis services and dialysis facilities that do not meet or exceed an established total performance score with respect to performance standards established for certain specified measures. As provided under this section, the payment reductions, which will be up to two percent of payments otherwise made to providers and facilities under section 1881(b)(14) of the Act, will apply to payment for renal dialysis services furnished on or after January 1, 2012. The total performance score that providers and facilities must meet or exceed in order to receive their full payment in 2012 will be based on a specific performance period prior to this date. Under section 1881(h)(1)(C) of the Act, the payment reduction will only apply with respect to the year involved for a provider/facility and will not be taken into account when computing future payment rates for the impacted provider/facility.

For the ESRD QIP, section 1881(h) of the Act generally requires the Secretary to: (1) Select measures; (2) establish the performance standards that apply to the individual measures; (3) specify a performance period with respect to a year; (4) develop a methodology for assessing the total performance of each provider and facility based on the performance standards established with respect to the measures for a performance period; and (5) apply an

appropriate payment reduction to providers and facilities that do not meet or exceed the established total performance score.

C. Finalized Anemia Management and Hemodialysis Adequacy Measures

In accordance with section 1881(h)(2)(A)(i) of the Act, we finalized in the ESRD PPS final rule the following three measures for the initial year of the ESRD QIP:

- Percentage of Medicare patients with an average Hemoglobin Less Than 10.0g/dL;
- Percentage of Medicare patients with an average Hemoglobin Greater Than 12.0g/dL;
- Percentage of Medicare hemodialysis patients with an average Urea Reduction Ratio (URR) > 65 percent.

(75 FR 49182). However, we received some questions on the measures during the public comment period for this rule and are, therefore, providing clarifying information in this final rule.

As we stated in the ESRD PPS final rule, pediatric patients (those < 18 years of age) will not be included in the final calculation of the anemia management measures (75 FR 49185). However, we want to emphasize that providers/facilities do not need to submit any new data on the measures we are using for the first year of the QIP. This population will be excluded from the final calculation of the measure during the first year (75 FR 49185).

We also want to reiterate that the patient population for the anemia management measures will include hemodialysis and peritoneal dialysis patients who are receiving ESAs. To be eligible for inclusion in the patient population for these measures, the patient must have four or more eligible claims from the provider/facility within the performance period. Data from patients whose first ESRD maintenance dialysis started less than 90 days after diagnosis or who have hemoglobin values of less than 5g/dL or greater than 20g/dL will be excluded from the calculation (75 FR 49182). Also, patients not receiving ESAs are excluded from these measures (75 FR 49184).

We would like to clarify that as we stated in the ESRD PPS final rule, the hemodialysis adequacy measure will be calculated as the percentage of patients with a URR greater than or equal to 65 percent (75 FR 49190).

Additionally, providers/facilities do not need to submit any additional data with respect to the measures for the first year of the ESRD QIP. We will calculate the measures using claims data, which we will collect, as we do for DFC, in

accordance with the technical specifications outlined in the Dialysis Facility Reports, which can be accessed for reference at: <http://www.dialysisreports.org/Methodology.aspx>. For the hemodialysis adequacy measure, home hemodialysis patients and peritoneal dialysis patients, as well as pediatric patients, are excluded from the calculation (75 FR 49185).

We also note that the laboratory values we will use to calculate the three finalized measures are included on the Medicare ESRD claim form and, thus, are submitted by providers/facilities along with their claims. For guidance on how those values should be obtained and submitted, please see the Medicare Claims Processing Manual (Medicare Publication 100.04, Chapter 8—Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims, Section 50.3).

Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary, but shall not exceed three years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule finalizes provisions set forth in the Notice of Proposed Rulemaking, entitled “End-Stage Renal Disease Quality Incentive Program”, published on August 12, 2010 in the **Federal Register** (75 FR 49215 through 49232). In addition, this final rule has been published within the three-year time limit imposed by section 902 of the MMA. Therefore, we believe that this final rule is being published in accordance with the statutory requirements of section 902 to ensure the timely publication of final regulations.

II. Provisions of the Proposed Regulations

On August 12, 2010, we published in the **Federal Register** a proposed rule entitled “Medicare Program; End-Stage Renal Disease Quality Incentive Program” (75 FR 49215). In that proposed rule, we proposed that under

the ESRD QIP, ESRD payments for facilities/providers would be reduced by up to two percent if they failed to meet or exceed the total performance score for performance standards established with respect to certain quality measures. As stated above, the three quality measures we will use for payment consequence year 2012 are Hemoglobin Less Than 10.0g/dL, Hemoglobin More Than 12.0g/dL and Hemodialysis Adequacy \geq 65 percent (URR). As detailed below, we received numerous comments on the various portions of the proposed rule, which we analyze and respond to below. After consideration of these comments and responses, we are finalizing the ESRD QIP as proposed.

III. Analysis of and Responses to Public Comments

The proposed rule was published on August 12, 2010 (75 FR 49215 through 49232) in the **Federal Register** with a comment period that ended on September 24, 2010. We received approximately 71 public comments. Interested parties that submitted comments included dialysis facilities, the national organizations representing dialysis facilities, nephrologists, nurses, nutritionists, home health agencies, the major chain dialysis facilities, clinical laboratories, pharmaceutical manufacturers, hospitals and their representatives, individual dialysis patients, advocacy groups, and the Medicare Payment Advisory Commission (MedPAC). In this final rule, we provide a summary of each proposed provision, a summary of the public comments received, our responses, and any changes to the proposed ESRD QIP contained in this final rule.

A. Performance Standards for the ESRD QIP Measures

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the QIP for a performance period with respect to a year. Section 1881(h)(4)(B) of the Act provides that the performance standards shall include levels of achievement and improvement, as determined appropriate by the Secretary. However, for the first performance period, we proposed to use for the three selected measures the performance standard required by the special rule in section 1881(h)(4)(E) of the Act. Under this provision, the Secretary is required to “initially use”, as a performance standard, the lesser of a provider/facility-specific performance rate in the year selected by the Secretary under the second sentence of section

1881(b)(14)(A)(ii) of the Act, or a standard based on the national performance rates for such measures in a period determined by the Secretary. We did not propose to include in this initial performance standard levels of achievement or improvement because we do not believe that section 1881(h)(4)(E) of the Act requires that we include such levels. In addition, we interpret the term “initially” to apply only to the performance period applicable for payment consequence calendar year 2012. For subsequent performance periods, we will propose performance standards under section 1881(h)(4)(A) of the Act.

As stated above, to implement the special rule for the anemia management and hemodialysis adequacy measures, we proposed to use as the performance standard the lesser of the performance of a provider or facility on each measure during 2007 (the year selected by the Secretary under the second sentence of section 1881(b)(14)(A)(ii) of the Act, referred to as the base utilization year), or the national performance rates of all providers/facilities for each measure in 2008.

In setting the performance standard based on national performance rates, we proposed to adopt a standard that is equal to the national performance rates of all dialysis providers and facilities based on 2008 data as calculated and reported on the Dialysis Facility Compare (DFC) Web site. We proposed to use 2008 data because it is the most recent year for which data is publicly available prior to the beginning of the proposed performance period. Specifically, the national performance rates for the anemia management and hemodialysis adequacy measures were posted on DFC in November 2009, as follows:

- For the anemia management measure (referred to in this final rule as the “Hemoglobin Less Than 10g/dL Measure”)—the percentage of Medicare patients who have an average hemoglobin value less than 10.0g/dL: the national performance rate is two percent.
- For the anemia management measure (referred to in this final rule as the “Hemoglobin Greater Than 12g/dL Measure”)—the percentage of Medicare patients who have an average hemoglobin value greater than 12.0g/dL: the national performance rate is 26 percent.
- For the proposed hemodialysis adequacy measure (referred to in this final rule as “Hemodialysis Adequacy Measure”)—the percentage of Medicare patients who have an average URR level

greater than or equal to 65 percent: the national performance rate is 96 percent.

For purposes of implementing the special rule, we proposed that the performance standard for each of the three measures for the initial performance period with respect to payment consequence year 2012 would be the lesser of (1) the provider/facility-specific rate for each of these measures in 2007, or (2) the 2008 national performance rates for each of these measures.

We received several comments on our proposed selection of performance standards. Summaries of the comments received and our responses are set forth below.

Comment: Several commenters objected to setting the performance standards based on previous provider/facility performance in 2007 and 2008 because they believe that those years provide an inaccurate picture of the quality of care furnished to ESRD patients today. Specifically, these commenters noted that changes have been made since 2007 in anemia management clinical practice and suggested that CMS set the initial performance standards based on more current data, such as data from 2009.

Response: As stated above, under section 1881(h)(4)(E) of the Act, the Secretary is required to “initially use” as a performance standard the lesser of a provider/facility-specific performance rate in the year selected by the Secretary under the second sentence of section 1881(b)(14)(A)(ii) of the Act, or a standard based on the national performance rate for each measure in a period determined by the Secretary. In the ESRD PPS final rule we determined that 2007 was the year representing the lowest per-patient utilization of the renal dialysis services which comprise the ESRD payment bundle as required by section 1881(b)(14)(A)(ii) of the Act. (75 FR 49065). Therefore, in accordance with section 1881(h)(4)(E)(i), we must use the 2007 provider/facility performance rates.

In setting the performance standard based on national performance rates under section 1881(h)(4)(E)(ii), we sought to balance the importance of using the most recent available data with the desire to use data that was publicly available at the time we issued the proposed rule. At the time we issued the proposed rule, the most recent national performance rate data that was publicly available on DFC was from 2008.

We agree with the commenters that the initial performance standard should be based on the most contemporary data and as close to the performance period

as possible. However, we also believe that it is important for providers/facilities, beneficiaries and the public to know exactly what the performance standards are as soon as possible.

Comment: One commenter noted that the proposed initial performance standard based on the 2008 national performance rate of two percent for the Hemoglobin Less Than 10g/dL measure would be extremely difficult for providers/facilities to meet and would likely lead to overuse of ESAs. The commenter noted that the 2008 data reflects practices that were furnished prior to recent studies and FDA warnings regarding the danger of high hemoglobin levels, and that at the time, providers/facilities were unaware of the danger of high hemoglobin levels. Additionally, the commenter suggested setting the initial performance standards for the anemia management measures at 10 percent for Hemoglobin Less than 10g/dL and Hemoglobin Greater than 12g/dL.

Response: We disagree with the commenter’s suggestion that the anemia management measures performance standards should be set at 10 percent. We have made providers/facilities aware of the dangers of high hemoglobin levels related to use of ESAs since as early as 2005, when we changed our policy regarding ESAs and the monitoring of high hemoglobin levels (see CMS Manual System, Pub 100–04 Medicare Claims Processing, Transmittal 751 (November 10, 2005)). Since that time and with the release of the FDA guidelines in 2008, the historical data demonstrate that the number of patients with high hemoglobin levels has decreased and the number of patients with Hemoglobin Less than 10 g/dL has not increased. We believe that lowering the standard to 10 percent does not move quality forward.

We also believe that most providers/facilities are capable of meeting the initial 2 percent performance standard, and note that the 2008 national performance rates for the anemia management measures will only be used as the initial performance standard for those providers/facilities whose 2007 specific rates are lower than these national performance rates. For providers/facilities that had 2007 specific rates that were higher than the 2008 national performance rates their specific performance rates will be used as the initial performance standard. We also note that analysis of historical data for all three measures shows improvements in the average provider/facility performance of each measure, and therefore more facilities should receive maximum performance scores

for these measures in future years of the ESRD QIP.

Comment: One commenter requested that the initial performance standard for the hemodialysis adequacy measure be recalculated to reflect that home hemodialysis patients are excluded from the measure.

Response: As stated in the ESRD PPS final rule (75 FR 49186), home hemodialysis patients are not part of the measure population for the hemodialysis adequacy measure for purposes of the ESRD QIP. Therefore, home hemodialysis patients will not be included in the measure calculation.

After consideration of the public comments, we are finalizing the performance standards as proposed.

B. Performance Period for the ESRD QIP Measures

Section 1881(h)(4)(D) of the Act requires the Secretary to establish a performance period with respect to a year, and for that performance period to occur prior to the beginning of such year. Because we are required under section 1881(h)(1)(A) of the Act to implement the payment reduction beginning with renal dialysis services furnished on or after January 1, 2012, the first performance period would need to occur prior to that date.

We proposed to select all of CY 2010 as the initial performance period for the three finalized measures (42 FR 49218). We believe that this is the performance period that best balances the need to collect sufficient data, analyze the data, calculate the provider/facility-specific total performance scores, determine whether providers and facilities meet the performance standards, prepare the pricing files needed to implement applicable payment reductions beginning on January 1, 2012, and allow providers and facilities time to preview their performance scores and inquire about their scores prior to finalizing their scores and making performance data public (75 FR 49218). We requested public comments about the selection of CY 2010 as the initial performance period.

The comments we received on this proposal and our responses are set forth below.

Comment: Many commenters suggested that calendar year 2010 should not be selected as the performance period. Some commenters suggested that the QIP was created to ensure that patient outcomes are not negatively affected as an unintended consequence of the new prospective payment system for ESRD care, and for that reason, they believe that the initial performance period should be calendar

year (CY) 2011, when the new prospective payment system for ESRD care is effective, rather than CY 2010. Recognizing the time constraints that CMS is under with respect to the use of data from a performance period, one commenter suggested that CMS select the first half of 2011 as the performance period and conduct data processing during the final six months of 2011, if this final rule is published in 2010.

Response: Although an important goal of the ESRD QIP is to assess whether patient outcomes are negatively affected as a result of the new ESRD PPS, the primary purpose of the QIP is to incentivize providers/facilities to continuously improve their performance in the care of ESRD patients. In addition to the reasons we gave for selecting CY 2010 as the performance period in the proposed rule (42 FR 49218–19), we believe that selecting CY 2010 as the initial performance period will enable us to do two things: (1) Determine the first set of performance scores prior to the change in the ESRD payment system which, as indicated, may affect provider/facility practice especially as it relates to medication management, laboratory testing and other patient management practices that now come under the bundled payment; and (2) use this first set of performance scores to evaluate whether the new ESRD PPS has created positive or negative consequences. We also believe that using all of CY 2010 as the initial performance period will provide us with a more complete picture of provider and facility performance than we would get if we set a six month performance period, which will enable us to conduct a more robust evaluation of provider/facility performance. We also plan to implement a monitoring program in 2011 for the purpose of tracking the impact of the new ESRD PPS and observing any changes to access to and quality of care for beneficiaries.

Comment: Other commenters stated that using CY 2010 as the initial performance period would not serve as an incentive because dialysis providers and facilities would be judged on outcomes based on care provided to patients before the performance standards were established. Commenters also observed that data used for the QIP score will be over a year old by the time providers/facilities receive payments affected by that data.

Response: We agree that it is important to use up-to-date quality data for the ESRD QIP, which is why we are working on the feasibility of using such data in future years. Currently, claims are the most complete data source for

the selected measures, but we need a sufficient time period to collect and analyze the data before we can use it to make payment determinations. For this reason, we do not believe that we can select a performance period more recent than CY 2010 for the initial year of the ESRD QIP. As other data sources or accurate and reliable methodologies for faster analysis of claims data become available, we will seek to use those resources to reduce the gap between the performance period and payment implementation.

Comment: Several commenters objected to the proposed 2010 performance period, claiming that CMS should have established the performance standards (by issuing this final rule) by the end of 2009 if it wanted to set 2010 as the performance period. Specifically, commenters reference section 1881(h)(4)(C), which requires the Secretary to “establish the performance standards * * * prior to the beginning of the performance period for the year involved.”

Response: We acknowledge that section 1881(h)(4)(C) requires the Secretary to establish performance standards under subparagraph (A) prior to the beginning of the performance period for the year involved. However, we are establishing the performance standard that will affect ESRD payments in CY 2012 in accordance with section 1881(h)(4)(E), which does not impose the limitation suggested by the commenters. As we have stated, we believe that setting a CY 2010 performance period for the initial ESRD QIP will ensure that the performance scores are based on a robust set of data, and will allow us sufficient time to analyze that data, determine whether provider/facilities met the performance standards, implement the applicable payment reductions for CY 2012, and provide providers/facilities with an opportunity to preview their performance scores and submit related inquiries. For these reasons, we are finalizing calendar year 2010 as the performance period for the 2012 ESRD QIP.

After consideration of the public comments, we are finalizing the performance period as proposed.

C. Methodology for Calculating the Total Performance Score for the ESRD QIP Measures

Section 1881(h)(3)(A)(i) of the Act requires the Secretary to develop a methodology for assessing the total performance of each provider and facility based on the performance standards with respect to the measures selected for a performance period.

Section 1881(h)(3)(A)(iii) of the Act states that the scoring methodology must also include a process to weight the performance scores with respect to individual measures to reflect priorities for quality improvement, such as weighting scores to ensure that providers/facilities have strong incentives to meet or exceed anemia management and dialysis adequacy performance standards, as determined appropriate by the Secretary. In addition, section 1881(h)(3)(B) of the Act requires the Secretary to calculate separate performance scores for each measure. Finally, under section 1881(h)(3)(A)(ii) of the Act, for those providers and facilities that do not meet (or exceed) the total performance score, the Secretary is directed to ensure that the application of the scoring

methodology results in an appropriate distribution of payment reductions to providers and facilities, with those achieving the lowest total performance scores receiving the largest reductions.

We proposed to calculate the total performance of each provider and facility with respect to the measures adopted for the initial performance period by assigning 10 points to each of the three measures (75 FR 49219). If a provider or facility meets or exceeds the performance standard for one measure, then it would receive 10 points for that measure. We proposed to award points on a 0 to 10 point scale, because this scale is commonly used in a variety of settings and is easily understood by stakeholders. We also believe that the scale provides sufficient variation to show meaningful differences in

performance between providers/facilities.

We proposed that a provider or facility that does not meet or exceed the initial performance standard for a measure based on its CY 2010 data would receive fewer than 10 points for that measure, with the exact number of points corresponding to how far below the initial performance standard the provider/facility's actual performance falls (75 FR 49219). Specifically, we proposed to implement a scoring methodology that subtracts two points for every one percentage point the provider/facility performance falls below the initial performance standard. In the proposed rule, we discussed various examples of how this proposed methodology would work (75 FR 49219).

TABLE 1—PROPOSED SCORING METHODOLOGY FOR ANEMIA MANAGEMENT MEASURES USING NATIONAL PERFORMANCE RATES IN 2008 AS THE PERFORMANCE STANDARD FOR 2010 FACILITY-SPECIFIC COMPARISON

	Anemia management measures	
	Percentage of Medicare patients whose average hemoglobin levels are less than 10 g/dL	Percentage of Medicare patients whose average hemoglobin levels are greater than 12 g/dL
POINTS	Percentage	Percentage
10 points	2 percent or less	26 percent or less
8 points	3 percent	27 percent
6 points	4 percent	28 percent
4 points	5 percent	29 percent
2 points	6 percent	30 percent
0 point	7 percent or more	31 percent or more

Note that the bolded rows show the performance standard for the applicable measure.

TABLE 2—PROPOSED SCORING METHODOLOGY FOR ANEMIA MANAGEMENT MEASURES USING FACILITY-SPECIFIC RATES IN 2007 AS THE PERFORMANCE STANDARD AND 2010 FACILITY-SPECIFIC RATE FOR COMPARISON

	Anemia management measures	
	Percentage of Medicare patients whose average hemoglobin levels are less than 10 g/dL	Percentage of Medicare patients whose average hemoglobin levels are greater than 12 g/dL
POINTS	Percentage	Percentage
	4 percent (Example of a 2007 facility-specific score)	30 percent (Example of a 2007 facility-specific score)
10 points	4 percent or less	30 percent or less
8 points	5 percent	31 percent
6 points	6 percent	32 percent
4 points	7 percent	33 percent
2 points	8 percent	34 percent
0 points	9 percent or more	35 percent or more

TABLE 3—PROPOSED SCORING METHODOLOGY FOR HEMODIALYSIS ADEQUACY MEASURE USING NATIONAL PERFORMANCE RATES IN 2008 AS THE PERFORMANCE STANDARD FOR 2010 FACILITY-SPECIFIC COMPARISON

POINTS	Hemodialysis adequacy measure
	Percentage of Medicare patients whose average URR levels are greater than or equal to 65 percent
10 points	96 percent or more
8 points	95 percent
6 points	94 percent
4 points	93 percent
2 points	92 percent
0 points	91 percent or less

TABLE 4—PROPOSED SCORING METHODOLOGY FOR HEMODIALYSIS ADEQUACY MEASURE USING FACILITY-SPECIFIC RATES IN 2007 AS THE PERFORMANCE STANDARD AND 2010 FACILITY-SPECIFIC RATE FOR COMPARISON

POINTS	Hemodialysis adequacy measure
	Percentage of Medicare patients whose URR levels are greater than or equal to 65 percent
	92 Percent (Example of a 2007 facility-specific score)
10 points	92 percent or more
8 points	91 percent
6 points	90 percent
4 points	89 percent
2 points	88 percent
0 points	87 percent or less

We noted that our proposed methodology—subtracting two points for every one percentage point the provider or facility's performance falls below the performance standard—does not take into account the relative variability in performance associated with each measure. Despite the difference in variability in performance among the measures, we proposed to apply the straightforward methodology we described in the proposed rule (75 FR 49219) in a consistent manner across all three measures. We stated that in designing the scoring methodology for the first year, we wanted to adopt a clear-cut approach (subtracting two points for each percentage point providers and facilities fell below the performance standard) consistent with the conceptual model that we discussed

in the End-Stage Renal Disease Prospective Payment System Proposed Rule (CMS-1418-P)(74 FR 50010). We requested public comment on our proposal to apply the score reductions in this manner, as opposed to a methodology which takes into account the relative variations in performance that exists for each measure.

We recognize that this straightforward approach may not be appropriate in future years of the ESRD QIP as we adopt new measures for inclusion in the program which may have a wider variability in performance. Moreover, we may need to reevaluate this approach depending on how providers and facilities perform in future years on the current measures. As we have stated, we want to ensure the performance measures included in the QIP will result in meaningful quality improvement for patients at both the national and individual facility/provider level. Therefore, we requested comment on potential methodologies that would take into account variations in performance amongst all measures included in the QIP.

In calculating the total performance score, section 1881(h)(3)(A)(iii) of the Act requires the agency to weight the performance scores with respect to individual measures to reflect priorities for quality improvement. In developing the conceptual model, we originally considered that the initial scoring method would weight each of the three proposed measures equally. After further examination and based on public comments, we proposed to give greater weight to the Hemoglobin Less Than 10g/dL measure. Low hemoglobin levels below 10g/dL can lead to serious adverse health outcomes for ESRD patients such as increased hospitalizations, need for transfusions, and mortality. Assigning greater weight to the Hemoglobin Less Than 10g/dL measure ensures that providers/facilities are incentivized to continue to properly manage and treat anemia. We believe that this is important in light of concerns that have been raised that the new bundled ESRD payment system could improperly incentivize providers/facilities to under-treat patients with anemia by underutilizing ESAs.

Specifically, we proposed to weight the Hemoglobin Less Than 10g/dL measure as 50 percent of the total performance score (75 FR 49222). The remaining 50 percent of the total performance score would be divided equally between the Hemoglobin Greater Than 12g/dL measure (25 percent) and the Hemodialysis Adequacy Measure (25 percent) (75 FR 49222). When calculating the total

performance score for a provider/facility, we would first multiply the score achieved by that provider/facility on each measure (0–10 points) by that measure's assigned weight (either .50 or .25). Then we would add each of the three numbers together, resulting in a number (although not necessarily an integer) between 0–10. Lastly, this number would be multiplied by the number of measures (three) and rounded to the nearest integer (if necessary). In rounding, any fractional portion 0.5 or greater would be rounded up to the next integer, while fractional portions less than 0.5 are rounded down. Thus, a score of 27.4 would round to 27, while 27.6 would round to 28.

In the proposed rule, we discussed our rationale and provided examples of how the proposed scoring methodology would work for calculating the total performance score (75 FR 49222). As discussed in the proposed rule (75 FR 49219), we believe this proposed total performance score methodology is appropriate for the initial performance period in the new ESRD QIP, but recognize that it will be important to monitor the impact and potentially reevaluate this methodology as provider and facility performance changes, and as new measures are added in future years of the ESRD QIP. We requested public comment on the proposed scoring methodology for the ESRD QIP. We also solicited comment on potential weighting methodologies that could be incorporated into the QIP in future years as new measures are introduced.

The comments we received on this proposal and our responses are set forth below.

Comment: Many commenters supported our proposal to weight the three measures. A few commenters recommended that CMS re-evaluate the weights assigned to each performance measure. Several commenters suggested that the weight of the anemia management measure (Hemoglobin Less Than 10g/dL) was too high. Another commenter recommended a weighting schema of 35 percent (Low Hemoglobin), 30 percent (High Hemoglobin) and 35 percent (Dialysis Adequacy), while another suggested a weighting schema of 40 percent (Low Hemoglobin), 20 percent (High Hemoglobin) and 40 percent (Dialysis Adequacy), to highlight the significant impact inadequate dialysis can have on patient morbidity and mortality. Some commenters that supported the proposed weighting methodology for the initial year also asked CMS to revisit the issue in subsequent years, especially if additional measures are adopted for the

QIP or our quality improvement priorities change.

Response: The purpose of giving greater weight to the Hemoglobin Less Than 10g/dL Measure was twofold: (1) To provide a disincentive to providers/facilities to under-treat patients for anemia, particularly in light of the implementation of the new ESRD PPS; and (2) to reflect the clinical importance of this measure. Low hemoglobin levels that are not appropriately managed can lead to increased morbidity and mortality. In terms of giving greater weight to the Hemodialysis Adequacy (URR) Measure, we agree that inadequate dialysis contributes to what should otherwise be avoidable negative patient outcomes. As we have noted earlier in this final rule, we eventually intend to propose to replace the Hemodialysis Adequacy Measure with Kt/V, which is a more precise measure of dialysis adequacy. Further, unlike URR values, which are only reported for patients above the age of 18 years receiving in-center hemodialysis, Kt/V values can be reported for all ESRD beneficiaries. If we propose to replace the Hemodialysis Adequacy Measure with a measure that uses Kt/V values, we will re-evaluate our weighting methodology in light of the change. We also note that as the QIP evolves and as new measures are adopted in the program, we will reexamine the overall weighting methodology to ensure that it aligns with our quality improvement priorities. However, for the reasons discussed above, we believe that the proposed weighting methodology reflects our current quality goals.

Comment: One commenter suggested that CMS adopt a scoring system that will not unduly penalize providers/facilities for small deviations from the QIP performance standards.

Response: Based on our evaluation of historical data, we believe that the initial performance standards are achievable by most providers/facilities. We also considered whether providers/facilities would be unduly penalized for small deviations from the ESRD performance standards and used historical data to model various outcomes that could occur under the proposed scoring methodology. We concluded that because provider/facility performance will be initially evaluated based on the lower of the 2008 national performance rates or provider/facility specific performance in 2007, the proposed scoring methodology allows for flexibility in meeting ESRD QIP standards and will not result in undue penalties for providers/facilities. We appreciate the commenter's concern that providers/facilities not be unduly

penalized; however, we believe that the methodology carefully balances this concern with the need to adequately incentivize meaningful quality improvement. After consideration of the comments, we are finalizing the scoring methodology as proposed.

D. Payment Reductions Using the Total Performance Score

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of reductions in payments among providers and facilities achieving different levels of total performance scores; with providers and facilities achieving the lowest total performance scores receiving the largest reductions.

We proposed to implement a sliding scale of payment reductions for payment consequence year 2012, where the minimum total performance score that providers/facilities would need to achieve in order to avoid a payment reduction would be a score of 26 out of 30 points (75 FR 49224). Providers/facilities that score between 21–25 points would receive a 0.5 percent payment reduction; between 16–20 points a one percent payment reduction; between 11–15 points a 1.5 percent payment reduction; and between 0–10 points a two percent payment reduction (75 FR 49224).

In developing the proposed payment reduction scale, we carefully considered the size of the incentive to providers/facilities to provide high quality care and the range of total performance scores to which the payment reduction applies, recognizing that this would be the first year of a new program. Our goal is to avoid situations where small deficiencies in a provider/facility's performance results in a large payment reduction. We noted that we want to avoid imposing a large payment reduction on providers/facilities whose performance on one or more measures falls just slightly below the performance standard (75 FR 49224). At the same time, poorly performing providers/facilities should receive a more significant payment reduction. Our analysis suggests that using payment differentials of 0.5 percent for the total performance score ranges distinguishes between providers/facilities with fair to good performance and providers/facilities with poor performance. We will consider other differentials between payment levels for future years of the QIP, which we believe will further differentiate providers/facilities based on their performance. Additionally, section 1881(h)(1)(A) of the Act requires that the Secretary implement payment

reductions of up to two percent, and section 1881(h)(3)(A)(ii) requires that the application of the total performance score methodology result in an appropriate distribution of reductions in payment among providers/facilities. Consistent with these requirements, we believe that Medicare beneficiaries will be best served if the full two percent payment reduction is initially applied only to those providers/facilities whose performance falls well below the performance standards. We believe that applying a payment reduction of two percent to providers/facilities whose performance falls significantly below the performance standards, coupled with applying 0.5 payment differential reductions to providers/facilities based on lesser degrees of performance deficiencies, will incentivize all providers/facilities to improve the quality of their care in order to avoid or reduce the size of a payment reduction. We requested public comments about how the proposed payment reduction scale would incentivize providers/facilities to meet or exceed the performance standards for the first year of the QIP, and whether it is an appropriate standard to use in future years.

In general, ESRD facilities are paid monthly by Medicare for the ESRD services they furnish to a beneficiary even though payment is on a per-treatment basis. In finalizing the new bundled payment system starting on January 1, 2011, we elected to continue the practice of paying ESRD facilities monthly for services furnished to a beneficiary.

We proposed to apply any payment reduction under the QIP for payment consequence year 2012 to the monthly payment amount received by ESRD facilities and providers. The payment reduction would be applied after any other applicable adjustments to an ESRD facility's payment were made, including case-mix, wage index, outlier, *etc.* (This includes providers/facilities being paid a blended amount under the transition and those that had elected to be excluded from the transition and receive its payment amount based entirely on the payment amount under the ESRD PPS.)

Section 1833 of the Act governs payments of benefits for Part B services and the cost-sharing amounts for services that are considered medical and other health services. In general, many Part B services are subject to a payment structure that requires beneficiaries to be responsible for a 20 percent co-insurance after the deductible (while Medicare pays 80 percent). With respect to dialysis services furnished by ESRD

facilities, under section 1881(b)(2)(a) of the Act, payment amounts are 80 percent (and 20 percent by the individual).

Under the proposed approach for implementing the QIP payment reductions, the beneficiary co-insurance amount would be 20 percent of the total Medicare ESRD payment, after any payment reductions are applied. To the extent a payment reduction applies, we note that the beneficiary's co-insurance amount would be calculated after applying the proposed payment reduction and would thus lower the co-insurance amount.

We proposed to incorporate the statutory requirements of the QIP payment reduction set forth in proposed § 413.177.

The comments we received on this proposal and our responses are set forth below.

Comment: Several commenters recommended that CMS set the maximum first-year penalty (that is, payment reduction) in the QIP at one percent. The commenters characterized section 1881(h)(1)(A) of the Act as saying that “[p]ayment consequences of QIP should be up to two percent,” and believe that the Secretary has some latitude in setting the maximum payment reduction as an amount lower than two percent. Commenters noted that some provider/facilities have a case-mix (for example, nursing home patients, patients with complex conditions) that may make meeting the performance standards difficult. One of the commenters suggested that the lower penalty be used in the first year to allow for establishment of standards. A few commenters further suggested that payment reductions be implemented in increments of one quarter percent to support a one percent maximum reduction.

Response: We understand the importance of implementing the ESRD QIP in a manner that does not unfairly penalize providers/facilities, and we believe that the performance standards we are initially setting will be achievable by the majority of providers/facilities. However, we also believe that a full 2 percent payment reduction is appropriate for the lowest performers and that it will incentivize them to improve the quality of care they furnish to ESRD beneficiaries. We acknowledge the commenters' concern that some providers/facilities face increased challenges due to the population they serve (for example, nursing home patients, higher number of patients with complex conditions). Below, we discuss the monitoring plan we intend to implement for the ESRD QIP to monitor,

in part, the distribution of measure outcomes that show a possible pattern of concern.

Comment: Many commenters suggested that any funds withheld from provider/facility payments be used as additional incentive payments to other providers/facilities. Several commenters expressed strong concern that the quality incentive program would function only as a disincentive program and should not be used as a mechanism to achieve financial savings in the system. Specifically, some commenters requested any funds withheld from providers/facilities that failed to meet the national performance standards should be redistributed to providers/facilities that exceeded the national performance standards.

Response: We appreciate the commenters' concerns; however, we interpret section 1881(h)(1)(A) of the Act to require the Secretary to make payment reductions of up to 2 percent with respect to payments that would otherwise be made to providers/facilities if those providers/facilities do not meet the requirements of the ESRD QIP. The statute that establishes the QIP does not provide authority to issue bonus payments for performance above the standards selected for the QIP.

Comment: One commenter recommended that CMS apply the maximum penalty of a two percent payment reduction to any provider/facility whose performance on the Hemoglobin Less Than 10g/dL Measure falls six percent or more below the performance standard.

Response: We agree with the commenter about the higher relative importance of the Hemoglobin Less Than 10g/dL Measure and for that reason, we proposed to weight that measure more heavily in calculating the total performance score. However, we also believe that the maximum penalty should initially be applied only to those providers/facilities whose performance falls well below the performance standards for all three measures. We believe that instituting an automatic payment reduction along the lines suggested by the commenter would dilute the importance of the other measures. A score-based system provides an incentive for providers/facilities to track their progression over time while not neglecting outcomes on other measures. We would not want to apply such a reduction to provider/facilities that had achieved high scores on the other two measures, thereby removing any incentive for them to perform well on those measures in the future.

Comment: One commenter suggested that a two percent payment reduction is not a large enough deduction to ensure the quality and safety of dialysis patients.

Response: Section 1881(h)(1)(A) of the Act does not permit the Secretary to make payment reductions greater than two percent for ESRD providers/facilities. In determining the potential impact on facilities of all sizes, it was important to identify a maximum percentage level of payment reduction that provides an incentive, yet is not overly burdensome.

Comment: A few comments discussed the impact of lower beneficiary co-insurance amounts as a result of a payment reduction. One commenter expressed concern that higher co-insurance costs at high-performing ESRD facilities might serve as a disincentive for patients and that lower income patients may not be able to pay higher out-of-pocket costs, reducing patients' access to quality care. Another commenter agreed with CMS' proposal to calculate beneficiary co-insurance after applicable quality payment reductions are made, arguing that beneficiaries should not have to pay higher co-insurance for care delivered by facilities that perform below quality standards.

Response: Under section 1881(h)(1)(A), the Secretary is required to make reductions to the “payments otherwise made” to a provider/facility that furnishes ESRD services to an individual with ESRD. We interpret the phrase “payments otherwise made” to be the payments for ESRD services that would otherwise be made after applying all applicable adjustments, such as case-mix, wage index, and outlier. We note that there will be no increase in beneficiary co-insurance and that any changes to beneficiary co-insurance resulting from the QIP will likely be minimal. As such, we do not believe that resulting changes in co-insurance amounts will significantly affect beneficiary selection of providers/facilities.

After consideration of the public comments, we are finalizing the proposed methodology for implementing the QIP payment reductions as proposed. We are also finalizing our proposed addition of 42 CFR 413.77, which states that ESRD facilities that do not meet the requirements of the ESRD QIP will be subject to up to a 2 percent reduction in their payments otherwise made under section 1814(b)(14) of the Act.

E. Public Reporting Requirements

1. Introduction

Section 1881(h)(6)(A) of the Act requires the Secretary to establish procedures for making information regarding performance under the ESRD QIP available to the public, including information on the total performance score (as well as appropriate comparisons of providers and facilities to the national average with respect to such scores) and performance scores for individual measures achieved by each provider and facility. Section 1881(h)(6)(B) further requires that a provider or facility has an opportunity to review the information to be made public with respect to it prior to its publication.

In addition, section 1881(h)(6)(C) of the Act requires the Secretary to provide each provider and facility with a certificate containing its total performance score to post in patient areas within their facility. Finally, section 1881(h)(6)(D) of the Act requires the Secretary to post a list of providers/facilities and performance-score data on a CMS-maintained Web site.

2. Notifying Providers/Facilities of Their QIP Scores

Section 1881(h)(6)(B) of the Act requires CMS to establish procedures that include giving providers/facilities an opportunity to review the information that is to be made public with respect to the provider or facility prior to such data being made public.

CMS currently uses a secure, Web-based tool to share confidential, facility-specific, quality data with providers, facilities, and select others. Specifically, we provide annual Dialysis Facility Reports (DFRs) to dialysis providers/facilities, ESRD Network Organizations, and State Survey Agencies. The DFRs provide valuable facility-specific and comparative information on patient characteristics, treatment patterns, hospitalizations, mortality, and transplantation patterns. In addition, the DFRs contain actionable practice patterns such as dose of dialysis, vascular access, and anemia management. We expect providers and facilities to use the data included in the DFRs as part of their ongoing clinical quality improvement projects.

The information contained in the DFRs is sensitive and, as such, most of that information is made available through a secure Web site accessible only by that provider/facility and its ESRD Network Organization, State Survey Agency, and the applicable CMS Regional Office. However, select measures based on DFR data are made

available to the public through the Dialysis Facility Compare (DFC) Web site, which allows Medicare beneficiaries and others to publicly review and compare characteristics and quality information on dialysis providers and facilities in the United States. To allow dialysis providers/facilities a chance to “preview” these data before they are released publicly, we supply draft DFRs to providers/facilities in advance of every annual DFC update. Dialysis providers and facilities are generally given 30 days to review their facility-specific data and submit comments if the provider/facility has any questions or concerns regarding the report. A provider/facility’s comment is evaluated and researched. If a provider/facility makes us aware of an error in any DFR information, a recalculation of the quality measurement results for that provider/facility is conducted, and the revised results are displayed on the DFC Web site.

We proposed to use the above-described procedures, including the DFR framework, to allow dialysis providers/facilities to preview their quality data under the QIP before a payment reduction is applied and that data is reported publicly. Specifically, the quality data available for preview through the Web system will include a provider/facility’s performance score (both in total and by individual quality measure) as well as a comparison of how well the provider/facility’s performance scores compare to national averages for total performance and individual quality measure performance (75 FR 49225). We believe that adapting these existing procedures for purposes of the ESRD QIP will create minimum expense and burden for providers/facilities because they will not need to familiarize themselves with a new system or process for obtaining and commenting upon their preview reports. We also note that under these procedures, dialysis providers and facilities would have an opportunity to submit performance score inquiries and to ask questions of CMS data experts about how their performance scores were calculated on a facility-level basis. This performance score inquiry process would also give providers/facilities the opportunity to submit inquiries, including what they believe to be errors in their performance score calculations, prior to the public release of the performance scores. Every provider/facility that submits an inquiry will receive a response.

While we believe that the DFR process is the most logical solution for meeting the data preview requirements

at this time, we may decide to revise this approach in the future. Should we decide to make changes, or should we find a more administratively feasible or cost-effective solution, we proposed to use sub-regulatory processes to revise our approach for administering the QIP performance score preview process in a way that maintains our compliance with section 1881(h)(6)(B) of the Act. We also proposed to use sub-regulatory processes to determine issues such as the length of the preview period and the process we will use to address inquiries received from dialysis providers/facilities during the preview period.

We requested public comments on our proposal to use the DFR process and suggestions for other options that will allow dialysis providers/facilities to preview the information that is to be made public with respect to the provider or facility in advance of such information being made public.

The comments we received on this proposal and our responses are set forth below.

Comment: Although one commenter agreed with our proposal to use the existing DFR process to allow providers/facilities to preview their QIP data and make performance score inquiries, it suggested that CMS extend the review period from 30 days to 60 days.

Response: We believe the 30-day preview period is an adequate timeframe for providers/facilities to review their performance information and submit questions regarding their performance scores. Because the initial measures have been collected by ESRD providers/facilities since 2001, we believe that providers/facilities should be familiar with how they are calculated. We have also worked to make the calculation of the measures and the scoring methodology as transparent as possible to facilitate review by providers/facilities.

Comment: Another commenter recommended that there be a method to allow providers/facilities to post comments related to their scores.

Response: We appreciate the suggestion and will explore the possibility of allowing providers/facilities to post comments related to their scores on an appropriate venue (for example, a secure Web site).

Comment: One commenter suggested that there be a formal appeals process so that providers may appeal a payment determination if they believe it was made in error.

Response: As part of the preview process we discuss above, providers/facilities may submit inquiries related to what they believe to be one or more errors in their performance score

calculations, and we will respond to those inquiries. We note, however, that under section 1881(h)(5)(A), there is “no administrative or judicial review under section 1869, section 1878, or otherwise of * * * the determination of the amount of the payment reduction under paragraph (1).”

After consideration of the public comments, we are finalizing the proposed methodology for notifying providers/facilities of their QIP Scores as proposed.

3. Informing the Public Through Facility-Posted Certificates

Section 1881(h)(6)(C) of the Act requires the Secretary to provide certificates to dialysis providers and facilities about their total performance scores under the QIP. This section also requires each provider/facility that receives a QIP certificate to display it prominently in patient areas.

We proposed to meet this requirement by providing providers and facilities with an electronic file in a generally accessible format (for example, Microsoft Word and/or Adobe Acrobat). We proposed to disseminate these certificates to providers and facilities once per year after the preview period for the QIP performance scores has been completed. We would use a secure, Web-based system, similar to the system used to allow facilities to preview their QIP performance scores, to disseminate certificates. The secure Web-based system would allow CMS to transmit performance score certificates to providers/facilities in a secure manner. We stated that we would make every effort to synchronize the release of the certificates for provider/facility display with the release of performance score information on the Internet.

Under our proposal, each provider/facility would be required to display the certificate no later than 5 business days after CMS sends it. We stated that we expect that dialysis providers/facilities would have the capability to download and print their certificates from the secure Web site. We proposed that providers/facilities would be prohibited from altering the content of the certificates and that they must print the certificates on plain, blank, white or light-colored paper, no smaller than 8½ inches by 11 inches (a standard-sized document). In addition, providers/facilities may not reduce or otherwise change the font size on the certificate.

We proposed that each provider/facility must post at least one copy of the certificate prominently in a patient area of the dialysis provider/facility. Specifically, we proposed that providers/facilities must post the

certificate in a conspicuous place where they post other patient-directed materials so that it is in plain view for all patients (or their parents/guardians or representatives) to inspect. We stated that we would update the certificates annually with new performance information, and that providers/facilities would be required to post the updated certificate within 5 business days of the day that we transmit it. We stated that we expect that providers/facilities will take steps to prevent certificates from being altered, defaced, stolen, marred, or covered by other material. In the event that a certificate is stolen or destroyed while it is posted, providers/facilities would be responsible for replacing the stolen or destroyed certificate with a fresh copy by re-printing the certificate file they have received from CMS. The provider/facility would also be responsible for answering patient questions about the certificate in an understandable manner, taking into account that some patients might have limited English proficiency.

We proposed to include on the certificate of each provider/facility all of the information that we are also making available to the public under sections 1881(h)(6)(A) and 1881(h)(6)(D) with respect to the provider/facility. These data elements include:

- The total performance score achieved by the provider/facility under the QIP with respect to the year involved;
- Comparative data that shows how well the provider/facility’s total performance score compares to the national total performance rate;
- The performance score that the provider/facility achieved on each individual measure with respect to the year involved; and
- Comparative data that shows how well the provider/facility’s individual quality measure performance scores compare to the national performance rate for each quality measure. (75 FR 49226).

We considered several options for making the QIP performance score data available via certificate. Regarding the content of the certificates, we considered including not just information for the ESRD QIP-related quality measures, but additional quality measure information that CMS has at its disposal from the DFC Web site that is not related to the QIP, such as risk-adjusted survival information. Ultimately, we determined that an electronic method of disseminating certificates was the easiest way for CMS to deliver certificates directly to providers/facilities because it is the least burdensome and most cost

effective way of providing the certificates. We also determined that the information posted on the certificates should be restricted only to QIP information. We believe that limiting the information on the certificate to QIP-specific data will make the certificate easier for Medicare beneficiaries to read and understand.

We requested public comments on how to make the information contained on the certificate as user friendly and easy to understand as possible, and how to make the information available to Medicare beneficiaries who may be unable to read the certificates due to a physical disability or because of limited or no reading proficiency in the English language. We stated that we were particularly interested in comments on how we can educate Medicare beneficiaries and their families about the presence of certificates in dialysis providers/facilities and how the information can be used to engage in meaningful conversations with their dialysis caregivers and the clinical community about the quality of America’s kidney dialysis care.

Furthermore, we requested public comments on the proposal to use the DFR distribution process to provide the certificates to providers/facilities under section 1881(h)(6)(C) of the Act. Specifically, we requested comments on the feasibility and advisability of using the DFR system to provide the certificates to providers/facilities in a generally available format such as Microsoft Word or Adobe Acrobat.

The comments we received on this proposal and our responses are set forth below.

Comment: A few commenters offered recommendations about how to help patients interpret the certificates (including considerations for beneficiaries with limited English proficiency and low health literacy and/or numeracy) as well as provider/facility survey reports. One of the commenters recommended that the State survey reports and any complaint investigations by CMS or the ESRD Networks be posted in dialysis facilities along with the QIP certificates. Another commenter suggested that the certificates account for various levels of reading ability as well as cultural and language diversity. In addition, another commenter viewed the posting of the certificate as an opportunity to educate ESRD patients on quality and recommended including data on beneficiary-specific results (for example, hospitalizations, infections, UFR (Ultra-Filtration Rate) (ml/kg/hr), measures of bone health, Kt/V, and hemoglobin) in the context of the provider/facility’s

results (and in the context of state, Network area, national results), as well as CMS guidance on how to use the information. The commenter also offered that of the three finalized measures, only the Hemoglobin Less Than 10g/dL should be displayed.

Response: We appreciate the comments on how to make the QIP certificates useful and easy to understand for beneficiaries and other dialysis facility visitors. We will consider the suggestions from the commenters as we craft the certificates' visual display and language. Whenever possible, we will share draft designs with the public and seek a broad range of stakeholder input. We will consider including additional information on the certificates in future years. Also, we plan to include on the 2012 certificates quality data related to all three measures that we use to calculate the provider/facility's total performance score because we believe that this information is critical to inform beneficiaries and the public about the quality of care that the facility/provider is delivering, and that Medicare beneficiaries deserve. We believe that including on the certificates information related to all three measures, rather than just the Hemoglobin Less Than 10g/dL Measure, will provide a better picture of ESRD provider/facility care. Lastly, it is important to note that we have proposed to make enhancements to the DFC Web site so that it includes the same information that appears on the certificates, which we believe will provide more robust and meaningful information to beneficiaries. With access to more useful information, we hope that this will encourage more effective communication between patients and their providers.

Comment: One commenter recommended that performance scores be eliminated from the public certificate. The commenter stated that, "without appropriate individualized counseling as to the 'scores,' the document may lead to more confusion than what its intent originally was meant to accomplish." One of the commenters also noted that wherever CMS reports quality, consistency in its reporting is the most important decision CMS can make in public reporting. The commenter stated that patients need to be able to see the same quality information on the certificates that they see on the DFC Web site.

Response: Although we understand the commenter's concern, section 1881(h)(5)(C) of the Act requires that each certificate indicate the total performance score achieved by the provider/facility. We appreciate the

commenter's concern that the information be put into context for the reader. As previously mentioned, we are working to design the certificate so that it is a useful tool for beneficiaries. We are also working on a strategy for educating ESRD beneficiaries and their caregivers about what the certificates say and their implications for the quality of care ESRD beneficiaries can expect to receive from their provider/facility. We also will assure that information on the certificates matches what is contained on the DFC Web site.

After consideration of the public comments, we are finalizing the proposed methodology for informing the public through facility-posted certificates as proposed.

4. Informing the Public Through a Medicare Web Site

Section 1881(h)(6)(D) of the Act requires the Secretary to use a CMS-maintained Web site for the purpose of establishing a list of dialysis providers/facilities that furnish renal dialysis services to Medicare beneficiaries and indicates the total performance score and the performance score for individual measures achieved by the provider or facility.

We currently use the DFC Web site (a CMS-maintained Web site) to publish information about the availability of dialysis providers/facilities across the United States, as well as data about how well each of these providers/facilities has performed on existing dialysis-related quality of care measures. DFC is part of a larger suite of "Compare" tools, all of which are available online at <http://www.medicare.gov>. In addition to DFC, the suite of Compare sites include Nursing Home Compare, Home Health Compare, and Hospital Compare, as well as tools that allow users to compare prescription drug plans, health plans, and Medigap policies.

DFC links Medicare beneficiaries with detailed information about each of the over 5400 dialysis providers/facilities certified to participate in Medicare, and allows them to compare providers/facilities in a geographic region. Users can review information about the size of the provider/facility, the types of dialysis offered, the provider/facility's ownership, and whether the provider/facility offers evening treatment shifts. Beneficiaries can also compare dialysis providers/facilities based on three key quality measures—how well patients at a provider/facility have their anemia managed, and how well patients at a provider/facility have waste removed from their blood during dialysis, and whether the patients treated at a provider/facility generally live as long

as expected. DFC aims to help beneficiaries decide which dialysis provider/facility would best serve their care needs, as well as to encourage conversations among beneficiaries and their caregivers about the quality of care at dialysis providers/facilities, thus providing an additional incentive for dialysis providers/facilities to improve the quality of care they furnish. Lastly, DFC links beneficiaries to resources that support family members, as well as beneficiary advocacy groups.

We proposed to use DFC as the mechanism for meeting the Web-based public information requirement under section 1881(h)(6)(D) of the Act. We noted that the DFC is a consumer-focused tool, and the implementation of the QIP will not change this focus. We recognize that sharing information with the public about the QIP is not only a statutory requirement, it is also a function of open and transparent government. Ultimately, the intent of DFC is to provide beneficiaries with the information they need to be able to make proper care choices.

We believe that DFC already provides accurate and trusted information about the characteristics of all Medicare certified dialysis providers/facilities, as well as information about the quality of care furnished by these providers/facilities. Furthermore, CMS already has the information technology infrastructure in place to support DFC and its public reporting functions; therefore, adding new QIP-related data to the DFC Web site would not create additional significant expenditures or overly burden agency resources.

We proposed to update the DFC Web site once per year at a minimum with the following data elements for every provider/facility listed on DFC (that is, every Medicare-approved provider/facility):

- The total performance score achieved by each provider/facility under the QIP with respect to the year involved;
- Comparative data that shows how well the provider/facility's total performance score compares to the national total performance rate;
- Scores for each of the individual measures that comprise the overall QIP performance score for the provider/facility with respect to the year involved; and
- Comparative data that shows how well the provider/facility's individual quality measure performance scores compare to the national performance rate for each quality measure.

We note that this is the same information we proposed to include on the certificates that we will provide to

providers/facilities. We also note that for the 2012 payment year, we do not propose to include comparative information on DFC about how the provider's or the facility's performance has changed from year to year, since the 2012 total performance score calculation does not provide any differential scoring for improvement versus achievement. However, we will consider including this data on DFC in future program years.

We requested public comments about whether the total performance score and the individual measure performance scores should be integrated into the design of the DFC tool itself or whether we should alternatively implement section 1881(h)(6)(D) by making a file available to the public on the CMS Web site (at <http://www.cms.gov>). We are sensitive to the need to balance our interest in making QIP performance score information public with our need to provide beneficiaries with easy-to-understand, non-technical information about providers/facilities that they can use to make decisions about where to receive dialysis care.

We also requested public comment on the advisability of using DFC as our mechanism for making QIP information available over the Internet. We also requested comment on the presentation of QIP information on the Web site and the breadth of detail that we should make publicly available regarding QIP performance scores. Lastly, we requested comment on how DFC could be redesigned to make QIP information useful to Medicare beneficiaries as they compare the quality of care available at the nation's Medicare-approved dialysis providers/facilities.

The comments we received on this proposal and our responses are set forth below.

Comment: A few commenters recommended that the total performance score and the individual measure performance scores be integrated into the design of the DFC Web site.

Response: We appreciate the suggestion and are currently reviewing strategies for increasing the usefulness of DFC, especially for reporting information from the ESRD QIP. CMS is committed to providing beneficiaries and ESRD stakeholders with information that is accessible and useful.

After consideration of the public comments, we are finalizing the proposed methodology for informing the public through a Medicare Web site as proposed.

F. Applicability of the QIP

We received a number of comments asking if certain types of providers/facilities would be excluded from the first year of the QIP. These comments and our responses are set forth below.

Comment: Several commenters noted their concern that for providers/facilities that treat small numbers of patients, one or a few patients that achieve poor outcomes could dramatically affect the provider/facility's overall performance score. One of the commenters also recommended that CMS develop a statistically valid methodology for evaluating the performance of small dialysis providers/facilities.

Response: We agree with the commenter's concern regarding the potential impact on small providers/facilities, recognizing that one or two poor patient outcomes could greatly skew their performance scores for reasons unrelated to the quality of care they have furnished. Therefore, as we proposed, we are using for purposes of the CY 2012 QIP the specifications for the three finalized measures that are also used for DFC, each of which requires that a provider/facility have a minimum of 11 cases that meet the reporting criteria for the measure in order for us to calculate it. We believe that this minimum case threshold will help prevent the possibility that a small number of poor outcomes artificially, and for reasons unrelated to the quality of care, skews a small provider/facility's performance score. Also, eleven cases is a statistically valid threshold that will give us confidence that a provider/facility's total performance score is an accurate reflection of the quality of care it furnishes. As a result, this threshold will help preserve beneficiary access to care at much needed small providers/facilities in rural and/or under-served areas. We will also be closely monitoring to determine if the implementation of the QIP has any adverse impact on beneficiary access to care, including by looking at the rate of facility closures, and particularly small facility closures. We will also continue to examine how to best treat small providers/facilities and intend to address this issue in future years of the ESRD QIP.

Comment: Several commenters suggested that CMS exclude from the QIP provider/facilities that treat nursing home patients because the complex nature of the health problems faced by these patients will make it difficult for these facilities to achieve the performance standards.

Response: We understand that certain patients present a challenge in terms of their clinical management due to comorbidities and other factors that add to the complexity of care. However, we do not believe that providers/facilities that treat patients with complex health problems should be subject to a different standard than other providers/facilities.

Comment: One commenter asked if the ESRD QIP would affect home health agencies that provide dialysis supplies and medicine.

Response: We believe that the commenter's question is in reference to the provision of dialysis supplies and medicine under Method II. Effective January 1, 2011 Method II home dialysis will be eliminated. Medicare will no longer make payments directly to DMEPOS suppliers of home dialysis equipment and supplies. All Medicare payments for home dialysis services (including equipment and supplies) will be made to the dialysis provider/facility (75 FR 49056). Thus, the concern raised by the commenter will be moot by the time the QIP incentive payments are made.

Comment: Several commenters questioned how home dialysis providers will be evaluated under the QIP. Specifically, they asked how the absence of a relevant hemodialysis adequacy measure would affect the calculation of their total performance score and potential payment reductions.

Response: The commenters are correct that home hemodialysis patients (as well as peritoneal dialysis patients and pediatric patients) are excluded from the patient population for purposes of calculating the hemodialysis adequacy measure (URR) for payment consequence year 2012. As such, a very small provider/facility may not have a sufficient number of in-center dialysis patients to receive a score on the hemodialysis adequacy measure (URR), but could have enough patient data to be scored on the anemia management measures. For these providers/facilities that do not have enough data to assign a score on all three measures, we will not assign a total performance score for the CY 2012 ESRD QIP and will also not reduce their payment. As stated previously, we believe that requiring a minimum number of cases that meets the measure reporting criteria for the three finalized measures will help prevent the possibility that a small provider/facility's performance score could be greatly skewed for reasons unrelated to the quality of care it furnishes. We are also concerned about the impact of the QIP on small facilities, and particularly how that impact may

affect beneficiary access to these much needed facilities in rural or under-served areas. For these reasons, we will be closely monitoring to determine if the ESRD QIP has any adverse impact on beneficiary access to care, especially at small providers/facilities. We intend to examine alternative methodologies to address this situation for future years of the ESRD QIP.

Comment: Several commenters asked how new providers/facilities would be treated under the QIP. Some commenters asked what performance standards they would have to meet while others recommended that new providers/facilities, or those not in operation for 12 months, or those not in operation for 24 months, be exempt from any potential payment reductions.

Response: Under the special rule in section 1881(h)(4)(E), we will be setting the initial performance standard as the lesser of the provider's/facility's performance during 2007 or the 2008 national performance rates. If a provider/facility was not in existence in 2007, we will assign a score of zero for purposes of assessing which of the two standards applies to the provider/facility. The provider/facility's performance in 2010 will then be compared against that initial performance standard.

G. Additional Comments

Additional comments and our responses are set forth below.

Comment: One commenter asked that CMS utilize formal rulemaking procedures for future changes to the QIP, including changes to the measures, weighting, and scoring methodologies.

Response: We interpret the comment to be asking about the notice and comment rulemaking process (informal rulemaking versus where an agency is required by law to make a decision on the record after the opportunity for an agency hearing). We agree that the informal rulemaking process is the best approach for making changes to the ESRD QIP in the future and will use that approach whenever possible. We note that procedural guidance that does not impact measures, weighting, or scoring methodologies may be issued separate from the rulemaking process. We also note that section 1881(h) of the Act does not require us to establish the ESRD QIP rules via formal rulemaking procedures.

Comment: One commenter suggested that CMS solicit the participation of private insurance companies and Medicare Advantage Plans to develop a quality incentive program similar to the ESRD QIP.

Response: Medicare is currently conducting the Evaluation of the ESRD

Disease Management Demonstration to study the effectiveness of disease management for patients enrolled in Medicare Advantage plans. The demonstration will assess participating plans' clinical and financial impact to determine whether integrated disease management programs can minimize treatment complications and improve complications while reducing costs.

We are also exploring the feasibility of implementing a number of other programs that will attempt to align financial incentives with the quality of care delivered. These initiatives will touch on a wide variety of health care settings, including physician offices, inpatient rehabilitation facilities, inpatient psychiatric hospitals, long-term care hospitals, cancer hospitals, ambulatory surgery centers, hospice providers, and hospitals. Within the Medicare Advantage program, section 3201 of the Affordable Care Act requires CMS to provide for enhanced payments based on a Medicare Advantage plan's overall quality rating. CMS looks forward to working with payers, advocacy groups, patients, and other stakeholders in developing important initiatives aimed at transforming Medicare from a passive payer of claims to an active purchaser of quality health care.

Comment: Several commenters stressed the need to encourage greater use of home modalities. Another commenter suggested that CMS make all forms of dialysis equally profitable by equalizing profit margins across all forms of dialysis treatments and monitor recommended treatments to assess whether one treatment is being recommended over another because of the potential to receive a higher profit margin.

Response: Medicare currently pays one rate for all forms of dialysis. We agree with commenters that home dialysis is an important modality for ESRD patients that should be encouraged if clinically appropriate. Home modalities can enable patients to continue with employment and other activities that may be difficult with in-center dialysis. In an effort to promote patient-centered care, we want to ensure there are incentives to provide ESRD patients with options that fit their clinical needs and personal preferences.

We will be monitoring whether the implementation of both the ESRD PPS and the ESRD QIP leads to shifts in modality and, if so, whether those shifts affect the quality of care furnished to ESRD beneficiaries.

Comment: One commenter was concerned about the potential burden on small dialysis providers/facilities if

they have to manually record and maintain data for the ESRD QIP.

Response: The measures we have adopted for the initial year of the ESRD QIP are claims-based measures, and we can calculate them using information contained on Medicare FFS claims. To the extent we want to adopt QIP measures in the future for which providers/facilities would need to submit additional data, we will carefully consider any impacts that such data submission might have on providers/facilities.

Comment: One commenter suggested that CMS ensure that facilities/providers submit valid, reliable data and take steps to ensure that they don't misreport data.

Response: We agree that having reliable data is crucial in evaluating provider/facility performance for the QIP and intend to implement a formal validation process in the future. We also intend to monitor the ESRD QIP, including identifying whether certain patterns or trends warrant further investigation or response. We anticipate that these activities will help to ensure that providers/facilities are submitting complete and accurate data.

Comment: One commenter, a former dialysis patient, expressed support for the QIP.

Response: We appreciate the support the commenter expressed.

Comment: One commenter suggested that CMS involve more beneficiaries in committees and study groups.

Response: We appreciate the importance of beneficiary input. Beneficiaries are considered one of the most important stakeholder groups, and we plan to continue our outreach efforts to gather the feedback of beneficiaries and patient advocates when making decisions regarding the QIP.

IV. Future ESRD QIP Considerations

A. Monitoring and Evaluation

CMS plans to monitor and evaluate the new ESRD PPS and ESRD QIP as part of our ongoing effort to ensure that Medicare beneficiaries with ESRD receive high quality care. The monitoring will focus on whether, following implementation of the new PPS and the ESRD QIP, we observe changes in access to and quality of care, especially within vulnerable populations. We will be evaluating the effects of the new ESRD PPS and the QIP and focusing on areas such as:

- Access to care for beneficiaries, including categories or subgroups of beneficiaries;
- Changes in care practices that could adversely impact the quality of care for beneficiaries;

- Patterns of care suggesting particular effects of the new PPS—for example, whether there are increases/decreases in utilization of injectable ESRD drugs and the use of home modalities for certain groups of ESRD beneficiaries;

- Best practices of high-performing providers/facilities that might be adopted by other providers/facilities.

CMS currently collects detailed claims data on patients' hemoglobin levels and adequacy of dialysis, and also collects information on other facets of ESRD care, including treatments provided, drugs, hospitalizations, and deaths. In addition, we collect beneficiary enrollment data which provides important demographic and other information related to Medicare ESRD beneficiaries. These data and other data sources will provide the basis for early examination of overall trends in care delivery, access, and quality. We will also use the data to assess more fully the quality of care furnished to Medicare beneficiaries under the new PPS, and to help inform possible refinements to the PPS and QIP moving forward. We requested public comments about an approach to monitoring and evaluating the ESRD PPS and the ESRD QIP.

The comments we received on this monitoring approach and our responses are set forth below.

Comment: A number of commenters addressed the issue of monitoring and our plan to evaluate the impact of both the new ESRD PPS and the QIP on beneficiary access to, and the quality of, care. Many commenters expressed support for this plan and urged CMS to closely monitor whether the new ESRD PPS and QIP impact the quality of care furnished by ESRD providers/facilities to vulnerable populations and at-risk populations. Citing a March 2010 report issued by the Government

Accountability Office (GAO), one commenter recommended that CMS specifically monitor whether injectable drug usage increases or decreases after the new ESRD PPS and QIP go into effect. Other commenters raised the concern that the QIP could lead to increased "cherry picking" in the practice of patient referrals, increased involuntary discharges, and other barriers to dialysis care for difficult-to-treat patients or those patients who might negatively affect provider/facility performance metrics. One commenter recommended the universal implementation of CROWNWeb for monitoring the PPS and the QIP. Another commenter suggested that CMS establish a national database that tracks the number, demographics and reasons

why a provider/facility involuntarily discharged/released a patient. Another commenter requested that CMS set forth specific details on how it plans to monitor the effects of the QIP on beneficiaries, that CMS provide details on how it plans to engage the ESRD community to ensure that special needs are met, and that the agency provide an opportunity for public comment on the monitoring plan. One commenter recommended that facilities provide easier methods for patients to return satisfaction surveys. Finally, one commenter requested that the results of studies evaluating the QIP be made public.

Response: Beginning in 2009, we conducted a series of town hall meetings, listening sessions, and other outreach efforts to assess reaction to upcoming changes to the Medicare ESRD program. CMS had identified a need to monitor the impact of both the new ESRD PPS and the QIP, and through these interactions sought the feedback of the ESRD community, including facilities, providers, and patient advocates.

In its March 2010 report, entitled "End-Stage Renal Disease: CMS Should Monitor Access to and Quality of Dialysis Care Promptly after Implementation of New Bundled Payment System" (GAO-10-295), GAO recommended that CMS monitor whether beneficiary access to, and the quality of, dialysis care is diminished or degraded following implementation of the newly expanded ESRD bundled payment system, especially for certain groups of Medicare ESRD beneficiaries who may be more vulnerable. Specifically, the GAO report highlighted a concern that the new ESRD PPS might affect access to and quality of dialysis care for "certain groups of beneficiaries, such as those who receive above average doses of injectable ESRD drugs."

In response to these concerns and as part of fulfilling our mission to ensure effective, up-to-date healthcare coverage and quality care for beneficiaries, we will launch an ESRD services monitoring program to identify changes in beneficiary access to and quality of care following implementation of the ESRD PPS in January 2011 and the QIP in January 2012. The ESRD services monitoring program will enable CMS to identify whether there are access-to-care and quality concerns requiring further examination and response, as well as help to drive continuous improvement by identifying best practices and providing constructive feedback to ESRD facilities and providers. Findings from the monitoring program will also be used to design longer-term evaluation

studies assessing relationships between program policies and outcomes. While monitoring alone cannot determine the cause of observed changes, certain events identified through the monitoring program will be used to alert CMS of the need for further review and investigation.

In addition to conducting monitoring activities, CMS will be evaluating the impact of the new program on access to and quality of care for Medicare ESRD beneficiaries. Evaluation takes a long-term focus, examining relationships between ESRD PPS and/or QIP policies and patient outcomes for vulnerable subpopulations of ESRD beneficiaries over a study period.

In developing the ESRD services monitoring and evaluation program, we sought input from a broad array of stakeholders, including ESRD providers/facilities, the ESRD Network Organizations, and patient advocates. We also took into account the recommendations of a study that looked at whether particular segments of the ESRD population, including racial and ethnic minorities and other populations that we consider to be vulnerable or at-risk, could be disproportionately affected by the new ESRD PPS.

As part of the planned ESRD services monitoring and evaluation program, we will also examine a number of indicators and available data sources to ascertain whether any disruptions in access or quality occur following implementation of the QIP. We intend to track monitoring indicators of facility/provider practice, including patient loss rates, facility closures, and other areas of concern to determine if there are any changes that may need further study. We plan to utilize available data sources, including CROWNWeb, claims data, patient activity reports, provider forms, and other quantitative and qualitative data sources in the monitoring and evaluation program. As we continue to refine and develop the monitoring and evaluation program in 2011 and beyond, we will consider the commenters' suggestions.

As the ESRD services monitoring effort continues to expand and mature in 2012 and beyond, we expect to gain insight into how the ESRD PPS and QIP are affecting the quality of care furnished to individuals with ESRD, and with that insight in mind, we expect to design additional evaluation studies and make information available to the public, including the ESRD community and researchers.

B. Potential QIP Changes and Updates

As noted above, section 1881(h)(4)(B) of the Act provides that the performance standards established under section 1881(h)(4)(A) shall include levels of achievement and improvement, as determined appropriate by the Secretary. We anticipate that we will propose to adopt performance standards under section 1881(h)(4)(A) of the Act that include levels of achievement and improvement for the 2013 QIP.

In addition, we anticipate strengthening the performance standard for each measure in future years of the QIP, including potentially moving away from using the national performance rate as the performance standard and instead identifying absolute standards that reflect performance goals widely recognized by the ESRD medical community as demonstrating high quality care for ESRD patients. For instance, we may seek to raise the performance standard for each of the three measures finalized for the 2012 QIP above the proposed or finalized level (that is, Hemoglobin Less Than 10g/dL—two percent; Hemoglobin More Than 12g/dL—26 percent; and Hemodialysis Adequacy Measure—96 percent).

Additionally, for these initial three finalized measures, we intend to establish the national performance rates of each of these measures as “floors”, such that the performance standards will never be lower than those set for the previous year, even if provider/facility performance—and therefore the national performance rate—fails to improve, or even declines, over time. The performance standard to which facilities and providers will be held for these measures will not be lowered from one year to the next. This will better ensure that the quality of ESRD patient care will continue to improve over time. Establishing such floors for performance standards, however, will in no way prohibit the Secretary from establishing performance standards that are higher than the floors if the Secretary determines that higher performance standards are appropriate.

In establishing new measures for the QIP in future years, we intend that the concept of “floors” described above would be established for each new measure and applied to these new measures in order to better ensure improvement in the quality of care, once we have a historical perspective on how the measure performs. While we will consider the use of national performance rates, we also will take into consideration future performance standards that reflect performance goals

widely recognized by the ESRD medical community as demonstrating high quality care for ESRD patients, should such a consensus be reached.

As noted above, section 1881(h)(2)(A) of the Act also requires that the measures include, to the extent feasible, measures on patient satisfaction, as well as such other measures that the Secretary specifies, including iron management, bone mineral metabolism (that is, calcium and phosphorus), and vascular access. We are currently developing measures in each of the areas specified in section 1881(h)(2)(A) of the Act and are also moving forward with developing additional measures such as Kt/V, access infection rate, fluid weight management, and pediatric measures. As part of the process of developing these new measures, where necessary data are not currently being collected, we intend to require providers to submit data needed to establish a baseline for each of the measures under consideration, as listed above, as soon as is practicable. For QIP measures, we will use a collection process that has been determined appropriate by the Secretary to obtain this data. We anticipate proposing additional measures, such as those listed above under section 1881(h)(2)(A) of the Act, in future rulemaking for the QIP.

We requested public comments on how we might best incorporate both improvement and achievement standards as specified by the Act. We also requested comments on performance standards for future years of the QIP. We are committed to adopting additional quality measures for the QIP as soon as practicable. While we are evaluating measures for inclusion in future years of the QIP, we also requested public comment on setting performance standards for the first year a new measure is included in the QIP.

The comments we received on these issues and our responses are set forth below.

Comment: A few commenters encouraged CMS to measure improvement as well as achievement under the QIP. One of the commenters expressed disappointment that CMS has chosen not to address improvement in the first year of the QIP.

Response: We believe that levels of achievement and improvement are important components of the future QIP performance standards, and we anticipate proposing to adopt such levels for the 2013 QIP program year.

Comment: Several commenters expressed support for our concept of establishing “floors” for the performance standards, to ensure that a measure’s

performance standards will never be lowered in future years even if provider/facility performance fails to improve or even declines. Other commenters expressed concern that when measures change (for example, from URR to Kt/V), it would be necessary to establish new floors, and believe that CMS should remain open to changes based on scientific evidence and best practices.

Response: We appreciate the comments supportive of establishing performance standard floors for future years of the QIP, and will continue to examine the benefits of establishing them. We also share the commenters’ belief that we must be open to establishing new floors in the event that the scientific evidence or best practice changes with respect to a measure.

Comment: Many commenters offered suggestions regarding the inclusion of additional measures in future years of the QIP. Most commenters strongly advocated for the inclusion of new measures such as Kt/V, transplant referrals, access infection rates, fluid weight management, iron management, bone mineral metabolism, vascular access, patient satisfaction, and measures for pediatric and home hemodialysis patients as soon as possible.

Response: We plan to continuously work to improve the ESRD QIP, including adopting robust measures that provide valid assessments of the quality of care delivered to ESRD beneficiaries by providers and facilities. To that end, we are in the process of developing measures that can be applied to all modalities (that is, home and in-center) as well as the pediatric population. Measures that we are considering proposing to adopt include measures on mineral metabolism, vascular access infections, vascular access type, pediatric anemia (for example, iron targets), pediatric dialysis adequacy (Kt/V), and fluid management. Additionally, we are currently testing the feasibility of using claims data to calculate some of these measures. We are also considering establishing all or part of 2011 as the performance period for the 2013 QIP.

As the ESRD QIP continues to evolve, we realize the importance of assuring that the measures are reviewed and refined to confirm that they continue to align with currently accepted clinical practices. Further, we will review any needs for risk adjustment for measures that currently do not have this specification. As we consider the feasibility of adopting new measures for the QIP, we intend to seek the input of the ESRD community to ensure that the measures we seek to adopt are appropriate, scientifically acceptable,

and valuable to continuous quality improvement.

We are also focused on identifying QIP patient-centered measures such as patient satisfaction, access to nutrition services, referral to transplant, and training for those on home modalities. Patient perceptions of care and support services that contribute to dialysis outcomes are critical. Again, collaboration with beneficiaries as well as the renal community will be important for identifying key issues for measurement. CMS is dedicated to making the measure development and selection process as transparent and inclusive as possible so that it continuously advances the goals of the ESRD QIP to ensure that individuals with ESRD have access to quality care.

Lastly, as we work toward identifying and proposing to adopt new measures for the QIP, we understand the importance of collecting real-time data for more timely measurement of performance. We are working to expand the scope of the CROWNWeb project and intend to explore the feasibility of using the CROWNWeb system to collect QIP data.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are 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 (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency;
- The accuracy of our estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected;
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

In the proposed rule, we discussed a disclosure requirement (75 FR 49226). Section 1881(h)(6)(C) of the Act requires the Secretary to provide certificates to dialysis care providers and facilities about their total performance scores under the QIP. This section also

requires each provider and facility that receives a QIP certificate to display it prominently in patient areas.

To comply with this requirement, we proposed to issue QIP certificates to providers and facilities via a generally accessible electronic file format. We proposed that each provider and facility would prominently display the QIP certificate in patient areas. In addition, we proposed that each provider and facility will take the necessary measures to ensure the security of the certificate in the patient areas. Finally, we proposed that each provider/facility would have staff available to answer questions about the certificate in an understandable manner, taking into account that some patients might have limited English proficiency.

We finalized these requirements in this final rule.

We stated in the proposed rule that the burden associated with the aforementioned requirements is the time and effort necessary for providers and facilities to print the QIP certificates, display the certificate prominently in patient areas, ensure the safety of the certificate, and respond to patient inquiries in reference to the certificates. We estimated that 4,311 providers and facilities will receive QIP certificates and will be required to display them. We also estimated that it will take each provider or facility 10 minutes to print, prominently display and secure the QIP certificate, for a total estimated annual burden of 719 hours. We estimated that approximately one-third of ESRD patients will ask a question about the QIP certificate. We further estimated that it will take each provider/facility five minutes to answer each patient question about the QIP certificate, or 1.65 hours per provider or facility each year. We estimated that the total annual burden associated with this requirement would be 7,121 hours. We also estimated that the total annual burden for both displaying the QIP certificates and answering patient questions about the certificates would be 7,840 hours. While the total estimated annual burden associated with both of these requirements would be 7,840 hours, we stated that we did not believe that there would be a significant cost associated with these requirements because we would not be requiring providers/facilities to complete new forms. As discussed in the proposed rule (75 FR 49228), we estimated the total cost for all ESRD facilities to comply with the collection of information requirements would be less than \$200,000.

We did not receive any comments related to this information collection and are finalizing these burdens.

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule implements a QIP for Medicare ESRD dialysis providers and facilities with payment reductions beginning January 1, 2012. Under section 1881(h) of the Act, after selecting measures, establishing performance standards that apply to each of the measures, specifying a performance period, and developing a methodology for assessing the total performance of each provider and facility based on the specified performance standards, the Secretary is required to apply an appropriate reduction to ESRD providers and facilities that do not meet or exceed the established total performance score. We view the ESRD QIP required by section 1881(h) of the Act as the next step in the evolution of the ESRD quality program that began more than 30 years ago. Our vision is to implement a robust, comprehensive ESRD QIP that builds on the foundation that has already been established.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This final rule is not an economically significant rule because we estimate that the effects of the rule will fall well below the economic threshold of \$100 million (*see* analysis below). In addition, given this estimated impact, this final rule also is not a major rule under the Congressional Review Act. We requested comments on the economic analysis.

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small

entities. For purposes of the RFA, approximately 19 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's size standards, which consider small businesses those dialysis facilities having total Medicare revenues of \$34.5 million or less in any one year, and 19 percent of dialysis facilities are nonprofit organizations. For more information on SBA's size standards, see the Small Business Administration's Web site at http://sba.gov/idc/groups/public/documents/sba_homepage/

serv_sstd_tablepdf.pdf (Kidney Dialysis Centers are listed as 621492 with a size standard of \$34.5 million).

For purposes of the RFA, using DFC performance data based on Medicare claims from 2007 and 2008, we consider the 802 independent facilities and hospital-based facilities to be small entities. The ESRD facilities that are owned and operated by a Large Dialysis Organization (LDO) and/or regional chain, comprising approximately 3,509 facilities, would have total revenues in excess of \$34.5 million in any year

when the total revenues for all locations are combined for each business (individual LDO or regional chain). Table 5 below shows the estimated impact of the QIP on small entities for payment consequence year 2012. The distribution of ESRD providers/facilities by facility size (both among facilities considered to be small entities for purposes of this analysis and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities).

TABLE 5—IMPACT OF ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR CY 2012 INCLUDES ESTIMATED IMPACT ON SMALL ENTITIES FOR REGULATORY FLEXIBILITY ACT (RFA) ANALYSIS

Facility type	Number of facilities	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	4,311	1,106	-0.19
Type:			
Freestanding	3,916	977	-0.18
Hospital Based	167	47	-0.25
Unknown ¹	228	82	-0.30
Facility Size: ²			
Small entities	802	252	-0.27
Large entities	3,509	854	-0.17
Urban/Rural status:			
Urban	3,159	788	-0.19
Rural	924	236	-0.18
Unknown ³	228	82	-0.30
Geographic Region:			
Northeast	652	182	-0.22
South	2,048	521	-0.18
Midwest	871	237	-0.22
West	705	158	-0.16
Other ⁴	35	8	-0.23
Facility Size (number of treatments):			
Less than 3,000 treatments	261	77	-0.28
3,000–9,999 treatments	2,566	675	-0.20
Over 10,000 treatments	1,484	354	-0.18

¹ Based on DFC self-reported status.

² "Small entities" include hospital-based facilities and non-chain facilities based on DFC self-reported status.

³ Based on DFC self-reported status.

⁴ Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

Source: Analysis of DFC/Medicare claims data (2007–2008) for ESRD providers/facilities reporting data on all three measures.

We note that guidance issued by the Department of Health and Human Services interpreting the RFA considers effects to be economically significant if they reach a threshold of three to five percent or more of total revenue or total costs. Under the final rule, the maximum payment reduction applied to providers/facilities, regardless of its size, is 2.0 percent of aggregate Medicare payments for dialysis services. This falls below the 3.0 percent threshold for economic significance established by HHS. To further ascertain the impact on small entities for purposes of the RFA, we projected provider/facility performance based on DFC performance data from 2007 and 2008. For the 2012 ESRD QIP, of the 1,106 ESRD facilities expected to

receive a payment reduction, 252 small entities would be expected to receive a payment reduction (ranging from 0.5 percent up to 2.0 of total payments). The average payment reduction for the 252 small facilities receiving a payment reduction is approximately \$18,000 per facility. Using our projections of provider/facility performance, we next estimated the impact of expected payment reductions on small entities by comparing the total payment reduction for the 252 small entities expected to receive a payment reduction with aggregate ESRD payments to all small entities. For the entire group of 802 small entities, a minor decrease of 0.27 percent in aggregate ESRD payments is observed.

Therefore, we are not preparing an analysis for the RFA because the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

Comment: In reviewing Table 9 in the proposed rule (75 FR 49230) for the estimated impact of payment reductions, one commenter noted that 31 percent of small entities will be affected by this proposed rule as opposed to only 24 percent of large entities. The commenter further noted that this disproportionately affects smaller entities, which do not have the inherent volume discounts and diverse purchasing powers that large entities typically have. The payment reduction (percent changes in aggregate ESRD

payments), though considered minor, is estimated to be 0.10 percent higher for smaller entities.

Response: The technical specifications for each of the finalized measures require that a provider/facility has a minimum of 11 cases meeting the measure criteria in order to report it. We believe that these specifications will minimize the rule's economic burden on small entities. Second, we note that for purposes of RFA analysis in determining whether agencies must perform an initial or final regulatory flexibility analysis, agencies must determine whether the regulation is expected to have a significant economic impact on small entities. Though the rule may have a disproportionate, but not economically significant, impact on small entities, it is not relevant for purposes of the analysis. Third, we expect all facilities to provide quality care, particularly in the important areas of anemia management and dialysis adequacy, regardless of size. Finally, we intend to monitor and evaluate the impact of the ESRD QIP on access to and quality of care for ESRD beneficiaries, including indicators of facility financial health, to identify any disruptions or to make future improvements in the program.

Comment: Another commenter noted that CMS has provided an estimate of the number and geographic region of other facilities it projects will receive reductions based on other characteristics (such as small versus large and rural versus urban) but would like to understand the impact of the proposed payment reductions safety-net and other not-for-profit providers. The commenter also stated that it is important to estimate the influence of payment reductions by facility type (for example, large dialysis organizations (LDOs) versus independent facilities).

Response: As stated, we estimate 19 percent of ESRD facilities to be nonprofit for purposes of RFA analysis. These entities are included in the estimates of the impact of payment reductions on small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule has a significant impact on operations of a substantial number of small rural

hospitals because most dialysis facilities are freestanding. Overall, we estimate that the hospital-based dialysis facilities will experience an average 0.25 percent decrease in payments. As a result, this rule will not have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Finally, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year \$100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately \$135 million. We do not believe that this rule includes any mandates that would impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of \$135 million or more in 2010.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule and subsequent final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We do not believe this final rule will have a substantial direct effect on State or local governments, preempt State law, or otherwise have Federalism implications.

C. Anticipated Effects

This final rule is intended to mitigate possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries as a result of payment changes under the ESRD PPS by implementing a QIP that would reduce ESRD payments by up to two percent to dialysis providers/facilities that fail to meet or exceed a total performance score with respect to performance standards established by the Secretary with respect to certain specified measures. Any reductions in ESRD payment would begin on January 1, 2012 for services furnished on or after January 1, 2012.

The calculations used to determine the impact of this proposed rule reveal that approximately 27 percent, or 1,106, ESRD dialysis facilities would likely receive some kind of payment reduction for 2012. Again using DFC/Medicare claims data from 2007–2008, Table 6 shows the overall estimated distribution of payment reductions resulting from the 2012 ESRD QIP.

TABLE 6—ESTIMATED DISTRIBUTION OF CY 2012 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of ESRD facilities
No Payment Reduction	3,205
0.5% Payment Reduction	709
1.0% Payment Reduction	183
1.5% Payment Reduction	184
2.0% Payment Reduction	30

To estimate the total payment reductions in 2012 resulting from the proposed rule for each facility, we multiplied the number of patients treated at each facility receiving a reduction times an average of three treatments per week. We then multiplied this product by a base rate of \$229.63 per dialysis treatment (the finalized 2011 rate, before an adjuster is applied) to arrive at a total ESRD payment for each facility:

((Number of patients treated at each facility × three treatments per week) × base rate)

Finally, we applied the estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility:

(Total ESRD payment × estimated payment reduction percentage)

Totaling all of the payment reductions for each of the 1,106 facilities expected to receive a reduction leads to a total payment reduction of approximately \$17.3 million for payment consequence year 2012. Further, we estimate that the total costs associated with the collection of information requirements described in section IV of this final rule would be less than \$200,000 for all ESRD facilities. As a result, the estimated aggregate \$17.5 million impact for 2012 does not reach the \$100 million threshold for an economically significant rule.

D. Alternatives Considered

In developing this final rule, we considered a number of alternatives. We carefully considered the size of the incentive to providers and facilities to provide high-quality care. We also selected the measures adopted for the 2012 ESRD QIP because these measures are important indicators of patient outcomes and quality of care. Poor management of anemia and inadequate dialysis, for example, can lead to avoidable hospitalizations, decreased quality of life, and death. Thus, we believe the measures selected will allow CMS to continue focusing on improving the quality of care that Medicare

beneficiaries receive from ESRD dialysis providers and facilities.

We considered alternatives for identifying the performance standard, including the mean, median, and mode. However, we determined that the national average would be appropriate for the first payment year for the reasons listed below:

- CMS believes that the legislative intent was to set the performance standard at the “average,” as this is the performance standard that has been publicly reported on the Dialysis Facility Compare Web site (DFC) for the past ten years and was the standard in effect when the language was crafted;

- Recognizing, however, that there was some flexibility, CMS reviewed other possible standards and noted that there was little difference in the range of performance, with the exception of performance for Hemoglobin Greater Than 12g/dL (Hemoglobin < 10g/dL: 0 percent–3 percent; Hemoglobin > 12g/dL: 8 percent–38 percent; URR ≥ 65 percent: 94 percent–100 percent). As the bundled payment will likely reverse the incentive that may be leading to the wider range for this measure, the differences in the performance did not warrant moving from the use of a national performance rate for performance.

- CMS has seen great improvement in the rates for these measures over the past several years as reported in DFC, in part due to public reporting and continuous oversight and monitoring. The rate for Hemoglobin Less Than 10g/dL has improved and maintained improvement, while Hemoglobin Greater Than 12g/dL improved from 44 percent in 2007 to 26 percent in 2008 as demonstrated below. Should it become evident that the rates begin to move in the wrong direction due to the bundled payment, different performance standards can be proposed through future rulemaking. For example, if the national average for Hemoglobin Less

Than 10g/dL began to drop, CMS could propose to require a rate of two percent or less regardless of the national average.

- The national average was also selected because of the rapid implementation date for the first year and because the proposed rule was published more than halfway into the period of performance for the first payment year. Especially for this first year of the QIP, we did not believe introduction of a new performance standard after the period of performance has nearly ended was appropriate.

We also considered alternatives for applying payment reductions. Our main alternatives considered varying point reductions based on each one percentage point a facility or provider was below the performance standard. We did not propose alternatives that applied payment reductions that accounted for the variability seen within each measure, and as noted above, we asked for public comment on such alternatives.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

- For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

- 1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395(g), 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–113 (133 stat. 1501A–332).

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services and Organ Procurement Costs

- 2. Section 413.177 is added to subpart H to read as follows:

§ 413.177 Quality Incentive Program Payment.

(a) With respect to renal dialysis services as defined under § 413.171 of this part, in the case of an ESRD facility that does not meet the performance requirements described in section 1881(h)(1)(B) of the Act for the performance year, payments otherwise made to the provider or facility section 1881(b)(14) of the Act for renal dialysis services will be reduced by up to two percent, as determined appropriate by the Secretary.

(b) Any payment reduction will apply only to the payment year involved and will not be taken into account in computing the single payment amount under this subpart for services provided in a subsequent payment year.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 18, 2010.

Donald Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: December 15, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–33143 Filed 12–29–10; 11:15 am]

BILLING CODE 4120–01–P