DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413

[CMS–3206–P]

RIN 0938–AP91

Medicare Program; End-Stage Renal Disease Quality Incentive Program

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

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes to 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)). The proposed ESRD QIP would reduce ESRD payments by up to 2.0 percent for dialysis providers and facilities that fail to meet or exceed a total performance score for performance standards established with respect to certain specified measures.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. eastern standard time (EST) on September 24, 2010.

ADDRESSES: In commenting, please refer to file code CMS–3206–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–3206–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–3206–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. This document does not propose any paperwork requirements in the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Lynn Riley, (410) 786–1286.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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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. Evolution of Quality Monitoring Initiative

Monitoring the quality of care provided to ESRD patients and provider/facility accountability are important components of the Medicare ESRD payment system and have been priorities for over 30 years. We will describe the evolution of our ESRD quality monitoring initiatives by category below.

1. ESRD Network Organization Program

In the End-Stage Renal Disease Amendments of 1978 (Pub. L. 95–292), Congress required the formation of ESRD Network Organizations to further support the ESRD program. CMS currently contracts with 18 ESRD Networks throughout the United States to perform oversight activities and to assist dialysis providers and facilities in providing appropriate care for their dialysis patients. The Networks' responsibilities include monitoring the quality of care provided to ESRD patients, providing technical assistance to patients who have ESRD and to providers/facilities that treat ESRD patients to assist them in improving care, addressing patient complaints and/or grievances, and emergency preparedness. In 1994, CMS and the ESRD Networks, with input from the renal community, established the ESRD Core Indicators Project (CIP). The ESRD CIP was CMS's first nationwide population-based study designed to assess and identify opportunities to improve the care of patients with ESRD. This project established the first consistent clinical ESRD database. Information in this database included clinical measures thought to be indicative of key components of care provided to individuals who required dialysis. The initial Core Indicators focused on adult hemodialysis patients who received care in dialysis facilities. The Core Indicators included measures related to anemia management, adequacy of hemodialysis, nutritional status and blood pressure control. On March 1, 1999, the ESRD CIP was merged with the ESRD Clinical Performance Measures (CPM) Project (described below).

2. Clinical Performance Measures (CPM) Project

Section 4558(b) of the Balanced Budget Act of 1997 required CMS to develop and implement, by January 1, 2000, a method to measure and report the quality of renal dialysis services furnished under the Medicare program. To implement this legislation, CMS developed the ESRD Clinical Performance Measures (CPM) Project based on the National Kidney Foundation's Dialysis Outcome Quality Initiative (NKF–DOQI) Clinical Practice Guidelines. The purpose of collecting and reporting the ESRD CPMs was to enable us to provide comparative data to ESRD providers/facilities to assist them in assessing and improving the care furnished to ESRD patients.

3. Dialysis Facility Compare (DFC)

Also in response to the Balanced Budget Act of 1997, CMS created Dialysis Facility Compare (DFC) as a new feature on *http://www.medicare.gov* that was modeled after Nursing Home Compare and continues to be used by CMS today. CMS worked with a contractor and a consumer workgroup to identify dialysis facility-specific measures that could be provided to the public for consumer choice and information purposes. This tool was launched in January 2001 on the *http://www.medicare.gov/Dialysis* Web site to provide information to the public for comparing the quality of dialysis facilities across the country, including specific information about services available and the quality of care furnished by a specific dialysis facility/provider. DFC captures administrative and quality related data submitted by dialysis facilities and providers.

The quality measures initially reported on DFC were measures of anemia control, adequacy of hemodialysis treatment and patient survival. Medicare claims data were used to calculate the anemia management and hemodialysis adequacy rates, and administrative data (non-clinically based data such as demographic data, and data acquired from the Social Security Administration (SSA) and obtained from the CMS forms 2728 and 2746) were used to determine patient survival rates. The anemia measure assessed the percentage of Medicare patients receiving an erythropoiesis-stimulating agent (ESA) at a given provider/facility whose anemia (low red blood cell count) was not controlled. More specifically, the anemia measure when DFC was launched in January 2001 assessed the percentage of Medicare patients whose hematocrit levels were at 33 percent (33 percent out of 100 percent) or more (or hemoglobin levels of 11 g/dL or more). Since that time, evidence about increased risk of certain adverse events associated with the use of ESAs, which are used to treat anemia, raised concerns about patients who have hemoglobin levels that are too high, as well as patients whose hemoglobin levels are too low. The Food and Drug Administration (FDA) responded by requiring manufacturers to develop a Medication Guide (*http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm054716.htm*) and to ensure that this information is provided to patients. The labeling guideline for ESAs states "The dosing recommendations for anemic patients with chronic renal failure have been revised to recommend maintaining hemoglobin levels within 10 g/dL to 12 g/dL". As a result of this guideline, in November 2008 DFC was revised to include two anemia measures: one measure shows the percentage of patients whose hemoglobin levels are considered too low (that is, below 10 g/dL), and a second measure shows the percentage of patients whose hemoglobin levels are too high (that is, above 12 g/dL). The dialysis adequacy measure assesses the percentage of in-center hemodialysis Medicare patients treated by the facility who had enough wastes removed from their blood during dialysis. More specifically, the measure is the percentage of Medicare patients with urea reduction ratio (URR) levels of 65 percent or more. The patient survival measure indicates general facility survival as better than expected, as expected, or worse than expected. These measures are updated annually on the DFC Web site, usually at the end of the year, using Medicare claims data from the previous year for the hemodialysis adequacy and anemia measures and Medicare administrative data from the past 4 years for the patient survival measure.

4. ESRD Quality Initiative

In 2004, the ESRD Quality Initiative was launched and continues today. The objective is to stimulate and support significant improvements in the quality of dialysis care. The initiative aims to refine and standardize dialysis care measures, ESRD data definitions, and data transmission to support the needs of the ESRD program; empower patients and consumers by providing access to facility service and quality information; provide quality improvement support to dialysis facilities and providers; assure compliance with conditions of coverage; and build strategic partnerships with

patients, providers/facilities, professionals, and other stakeholders. Components of this Quality Initiative include the DFC, and the CPM Project.

5. ESRD Conditions for Coverage

On April 15, 2008, we published in the **Federal Register**, the updated ESRD Conditions for Coverage final rule, which contains revised requirements that dialysis providers and facilities must meet in order to be approved by Medicare and receive payment (73 FR 20370 April 15, 2008). As part of the revised requirements, dialysis providers and facilities are each required to implement their own quality assessment and performance improvement program. In addition, providers and facilities are required to submit electronically the CPMs developed under the ESRD CPM Project for all Medicare patients on an annual basis. The CPMs were updated and expanded in April 2008. The current CPMs include 26 measures in the areas of anemia management; hemodialysis adequacy; peritoneal dialysis adequacy; mineral metabolism; vascular access; patient education/perception of care/quality of life; and patient survival.

6. CROWNWeb

CMS has developed a new web-based system, Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) for the purposes of electronically collecting information about patients, facilities, providers, and clinical data to support the CPM Project. CROWNWeb supports the mineral metabolism, anemia management, hemodialysis adequacy, peritoneal dialysis adequacy, survival, and type of vascular access CPMs. Use of the CROWNWeb system will increase the efficiency of data collection for both CMS and providers/facilities, improve data quality, and provide a more stable and accessible platform for continual improvements in functionality. In February 2009, for Phase one, we began implementing the CROWNWeb system with a number of providers/facilities testing the system and expanded reporting to additional providers/facilities in July 2009 for Phase two.

During these initial phases, nearly 200 dialysis providers/facilities (representing a cross section of small independent facilities and large dialysis organizations (LDOs)) were selected to enter data into CROWNWeb. These providers/facilities worked closely with CMS, their respective ESRD Networks, and CROWNWeb development and support contractors to understand the requirements of CROWNWeb, and to refine the internal business processes and procedures used to submit data effectively and efficiently into the system.

The successful launch of both Phase One and Phase Two and helpful feedback provided by users has enabled CMS to work on additional upgrades to CROWNWeb that address both the technical and usability elements of the system. We continue to further refine the system as an additional tool for quality improvement.

7. QIP Conceptual Model

On September 29, 2009, we published in the **Federal Register** (74 FR 49922), the ESRD Prospective Payment System (PPS) proposed rule, describing how the Agency proposes to implement the new ESRD PPS in 2011. As part of that proposed rule, we outlined a conceptual model of the initial ESRD QIP design and solicited public comments. We received and reviewed many helpful comments regarding the design of the QIP that contributed to the development of this proposed rule.

B. Statutory Authority for the ESRD QIP

Congress required in section 153 of MIPPA that the Secretary implement an ESRD quality incentive program (QIP). We believe that the QIP is the next step in the evolution of the ESRD quality program because it measures provider/facility performance rather than simply reporting outcomes data.

Specifically, section 1881(h) of the Social Security Act (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 services and dialysis facilities that do not meet or exceed a 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 2.0 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 initially 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 quality incentive program, 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 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.

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.

C. Selection of the ESRD QIP Measures

As required by section 1881(h)(2)(A)(i) of the Act, we finalized the measures for the initial year of the QIP to include two-anemia management measures that reflect the labeling approved by the Food and Drug Administration (FDA) for the administration of erythropoesis stimulating agents (ESAs), and one-hemodialysis adequacy measure in the Medicare End-Stage Renal Disease Prospective Payment System Final Rule (CMS–1418–F) published on August 12, 2010. The following are the three finalized measures for the initial year of the ESRD QIP:

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

Data for these measures are collected from ESRD claims submitted to CMS for payment purposes. We have publicly reported anemia and adequacy of hemodialysis data on DFC since January 2001. The quality measure selection is limited to these three measures for the first year of the QIP because they are measures for which we already have complete data available to us. We are working to develop additional quality measures that we can adopt for the ESRD QIP in subsequent years.

The ESRD QIP is the first Medicare program that links any provider or facility payments to performance based on outcomes as assessed through specific quality measures. The three measures that we adopted for the initial year of the ESRD QIP are important indicators of patient outcomes because poor management of anemia and inadequate dialysis can lead to

avoidable hospitalizations, decreased quality of life, and death. These measures are at the core of medical management of ESRD patients.

As noted previously, data for these three measures are collected through ESRD claims submitted to CMS. The process used to ensure accuracy of claims coding and measure calculation has been used and refined since our implementation of the DFC. A full description of the methodologies used for the calculation of the measures can be reviewed at: *http://www.dialysisreports.org/pdf/esrd/public/DFRGuide.pdf* under the "Facility Modality, Hemoglobin, and Urea Reduction Ratio" section.

As we have previously stated, we are committed to adding additional quality measures as soon as complete data sources become available to us. For example, we are considering the possibility of adopting measures such as Kt/V, vascular access rates, bone and mineral metabolism, and access infection rates to the ESRD QIP for future years. CMS is committed to further development of quality measures for future years of the QIP in order to better assess the quality of care provided by ESRD facilities.

II. Provisions of the Proposed Rule

A. Overview of the Proposed ESRD QIP

This proposed rule proposes to implement a quality incentive program for Medicare ESRD dialysis providers and facilities with payment reductions beginning January 1, 2012, in accordance with the statutory provisions set forth in section 1881(h) of the Act. This proposed rule was developed based on the conceptual model set forth in the September 29, 2009 proposed rule (74 FR 49922) and on comments received on this model. In general, we propose to calculate individual total performance scores ranging from 0–30 points for providers and facilities based on the three finalized measures. We propose to weigh the total performance score for each provider/facility such that the percentage of Medicare patients with an average Hemoglobin <10 g/dL measure makes up 50 percent of the score, and the other hemoglobin measure and the hemodialysis adequacy measure will each be 25 percent of the score. Providers/facilities that do not meet or exceed a certain total performance score would receive a payment reduction ranging from 0.5 percent to 2.0 percent. We also propose below how we plan to implement the public reporting requirements in section 1881(h)(6) of the Act.

B. 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 propose to establish a performance standard for the two anemia management and one hemodialysis adequacy measures based on the special rule in section 1881(h)(4)(E) of the Act. This provision requires the Secretary to "initially" use as a performance standard for the anemia management and hemodialysis adequacy measures 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 such measures in a period determined by the Secretary. We are not proposing 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 plan to propose performance standards under section 1881(h)(4)(A) of the Act. Such standards will include levels of achievement and improvement, as required under section 1881(h)(4)(B) of the Act, and are discussed below in section III.B QIP Changes and Updates.

As stated above, to implement the special rule for the anemia management and hemodialysis adequacy measures, we propose to select 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 terms of establishing a performance standard based on national performance rates, we propose 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 Web site. We propose 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 (discussed below). Specifically, the rates for the anemia management and hemodialysis adequacy measures were posted on DFC in November 2009, and are as follows:

- For the anemia management measure (referred to in this proposed rule as "Hemoglobin Less Than 10 g/dL")—the national performance percentage of Medicare patients who have an average hemoglobin value less than 10.0 g/dL: The national performance rate is 2 percent.
- For the anemia management measure (referred to in this NPRM as "Hemoglobin More Than 12 g/dL")—the national performance percentage of Medicare patients who have an average hemoglobin value greater than 12.0 g/dL: The national performance rate is 26 percent.
- For the proposed hemodialysis adequacy measure (referred to in this NPRM as "Hemodialysis Adequacy Measure")—the percentage of Medicare patients who have an average URR level above 65 percent: The national performance rate is 96 percent.

This means that, for the purpose of implementing the special rule for the anemia management and hemodialysis adequacy measures, we propose that the performance standard for each of the three measures for the initial performance period with respect to 2012 payment would be the lesser of (1) the provider/facility-specific rate for each of these measures in 2007, or (2) the 2008 national average rates for each of these measures.

C. 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 propose to select all of CY 2010 as the initial performance period for the three finalized measures. We believe that this is the performance period that best balances the need to collect sufficient data, analyze the data, allows us sufficient time to 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 (discussed in section II.D. of this proposed rule). We emphasize that providers/facilities are already required to submit all the necessary data needed to calculate the measures as part of their Medicare claims, so this proposal will not create any new requirements. We seek public comments about the selection of CY 2010 as the initial performance period.

D. 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 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 reductions in payments to providers and facilities, with providers and facilities achieving the lowest total performance scores receiving the largest reductions.

We propose to calculate the total performance of each provider and facility with respect to the measures we have adopted for the initial performance period by assigning 10 points to each of the three measures. That is, if a provider or facility meets or exceeds the performance standard for one measure, then it would receive 10 points for that measure. We propose to award points on a 0 to 10 point scale because this scale is commonly used in a variety of settings and we believe it can be easily understood by stakeholders. We also believe that the scale provides sufficient variation to show meaningful differences in performance between providers/facilities.

We propose that a provider or facility that does not meet or exceed the initial performance standard for a measure based on its 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. Specifically, we propose to implement a scoring methodology that subtracts 2 points for every 1 percentage point the provider or facility's performance falls below the initial performance standard. For example, if under the special rule, the initial performance standard for a particular provider or facility for the Hemoglobin More Than 12 g/dL is set under section 1881(h)(4)(E)(ii) as the 2008 national average rate (26 percent), then if that provider/facility had 28 percent of Medicare patients with hemoglobin levels greater than 12 g/dL during 2010 (the initial performance period), the provider/facility would receive 6 points for its performance on the measure because 28 percent is 2 percentage points below the performance standard (see Table 1, which also illustrates how the scoring would work if the Hemoglobin Less Than 10 g/dL was set under section 1881(h)(4)(E)(ii) as the 2008 national average rate (2 percent)). However, if the initial performance standard for the provider/facility is set under section 1881(h)(4)(E)(i) as the provider or facility's actual performance during 2007 (for purposes of this example, 30 percent), the provider/facility would receive 10 points for this measure so long as its performance during 2010 (the initial performance period) was not worse than 30 percent (see Table 2, which also illustrates how the scoring would work if the Hemoglobin Less Than 10 g/dL was set under section 1881(h)(4)(E)(i) as the facility's actual performance during 2007 (for purposes of the example, 4 percent)). Tables 3 and 4 illustrate how scores would be assigned for the Hemodialysis Adequacy Measure.

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Table 1. Proposed Scoring Methodology for Anemia Management Measures using National Average 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 Average 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 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 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 note that our proposed methodology—that is, subtracting 2 points for every 1 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. For example, based on 2008 data, a 1 percentage point difference under the Hemoglobin Less Than 10 g/dL measure would affect a greater proportion of facilities and providers than a 1 percentage point difference under the Hemoglobin More Than 12 g/dL measure. The table below highlights the variability in performance associated with each measure. (We note that lower scores on the anemia measures reflect better performance.)

Table 5: Variation among finalized ESRD QIP measures in 2008

	Nat'l Average	Median	Mode	Low Range	High Range	1 SD	2 SD	3 SD	25th percentile	50th percentile	75th percentile
Hgb<10	2%	2%	0%	0%	31%	95%	99%	100%	0%	2%	3%
Hgb>12	26%	25%	13%	0%	93%	72%	97%	100%	15%	25%	38%
URR>65	96%	97%	100%	0%	100%	96%	99%	100%	94%	97%	100%

Despite this difference in variability in performance among the measures, we are proposing to apply the straightforward methodology we have described above in a manner that is consistent across all three measures adopted in this rule. In designing the scoring methodology for the first year, CMS wanted to adopt a clear-cut approach (that is, subtracting two points for each percentage point providers and facilities fell below their performance standard) consistent with the conceptual model published in the End-Stage Renal Disease Prospective Payment System Final Rule (CMS–1418–F) on August 12, 2010 in the **Federal Register**. We seek public comment on our proposal to apply the score reductions in this manner, as opposed to a methodology which takes into account the relative variation in performance that exists for each measure.

We recognize that this straightforward approach may not be appropriate in future years of the QIP as we adopt new measures for inclusion in the program that may have a wider variability in performance. Moreover, we may need to reevaluate this approach for the three measures adopted in this rule, depending on how providers and facilities perform in future years on these measures. If this approach is finalized, we will continue to evaluate the applicability and appropriateness of such an approach in future years of the QIP. As we have stated, we want to ensure that 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 seek comment on potential methodologies that would take into account variation in performance amongst all measures included in the QIP. For example, under one possible methodology, a provider or facility's performance could be awarded 10 points for achieving a higher level of performance (for example, the 90th percentile). The remaining points could then be assigned according to a linear distribution, where a provider/facility might receive 0 points for a lower level of performance (for example, 1 standard deviation below the mean).

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, such as weighting scores to ensure that providers/facilities have strong incentives to meet or exceed the performance standards. In the development of our conceptual model, we initially considered that the initial scoring method would weight each of the three proposed measures equally. After further examination and based on the public comments received, we propose to give greater weight to the Hemoglobin Less Than 10 g/dL measure. Low hemoglobin levels below 10 g/dL can lead to serious adverse health outcomes for ESRD patients such as increased hospitalizations, need for transfusions, and mortality. Giving more weight to the Hemoglobin Less Than 10 g/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 undertreat patients with anemia by underutilizing ESAs.

Specifically, we propose to weight the Hemoglobin Less Than 10 g/dL measure as 50 percent of the total performance score. The remaining 50 percent of the total performance score would be divided equally between the Hemoglobin More Than 12 g/dL measure and the Hemodialysis Adequacy Measure. 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 (.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.

An example of how the proposed scoring methodology would work follows below. The example assumes that the performance standard for Facility A during the initial performance period is based on the 2008 national average rates under section 1881(h)(4)(E)(ii) of the Act (which are set forth above) (because Facility A's base utilization year results were higher than the 2008 national average) and that Facility A achieves the following results in 2010:

1. Hemoglobin Less Than 10 g/dL: 2 percent.

2. Hemoglobin More Than 12 g/dL: 26 percent.

3. Hemodialysis Adequacy: 93 percent.

The total performance score for Facility A would be 26 points. Facility A would receive 10 points for achieving the 2008 national average rate for the Hemoglobin Less Than 10 g/dL measure (*see* Table 1); 10 points for achieving the 2008 national average rate for the Hemoglobin More Than 12 g/dL measure (*see* Table 1); and 4 points for performing 3 percentage points below the 2008 national average rate for the Hemodialysis Adequacy Measure in 2010. Next, we would multiply each individual measure's score by its assigned weight: $10 \times .5 = 5$; $10 \times .25 = 2.5$; $4 \times .25 = 1$. Then, all three scores would be added together and multiplied by three: $(5 + 2.5 + 1) \times 3 = 25.5$. Finally, we would round Facility A's score to the nearest whole number, resulting in a total performance score of 26 points (see Table 6 below).

Table 6. Proposed Methodology for Calculating the Total Performance Score; Example showing National Performance Rate as the Performance Standard

Measure	2008 National Average Rates	2010 Performance	Score	Weight	Weighted Score
Hemoglobin Less Than 10g/dL	2%	2%	10	0.5	5.0
Hemoglobin More Than 12g/dL	26%	26%	10	0.25	2.5
Hemodialysis Adequacy Measure	96%	93%	4	0.25	1.0
				Subtotal	8.5
				x 3	25.5
	Total Performance Score				**26**

It is important to note that this example assumes that Facility A's facility specific performance in 2007 (the base utilization year) on each of the three measures was better than or equal to the national performance average in 2008. If however, Facility A's performance in 2007 on the Hemodialysis Adequacy Measure had been 92 percent, then its performance standard for that measure would have been set according to section 1881(h)(4)(E)(i), therefore setting a lower performance standard for Facility A (*see* Table 4). In that case, Facility A's score of 93 percent during the performance period would have earned it a score of 10 points, resulting in a total performance score of 30 points (*see* Table 7 below).

Table 7. Proposed Methodology for Calculating the Total Performance Score; Example showing Facility-Specific Performance during 2007 as a Performance Standard

Measure	2007 Performance (Facility-Specific)	2008 National Average Rates	2010 Performance	Score	Weight	Weighted Score
Hemoglobin Less Than 10g/dL	1%	2%	2%	10	0.5	5.0
Hemoglobin More Than 12g/dL	25%	26%	26%	10	0.25	2.5
Hemodialysis Adequacy Measure	92%	96%	93%	10	0.25	2.5
					Subtotal	10.0
					x 3	30.0
	Total Performance Score					**30**

As we stated above, we believe that this proposed weighting methodology will ensure that providers/facilities have the incentive to adequately maintain patients' hemoglobin levels, particularly considering concerns about appropriate ESA use that could arise when the new bundled ESRD payment system is implemented. We believe this proposed weighting methodology is appropriate for the initial year of the QIP. However, consistent with our desire to improve the quality of care provided to ESRD patients, we solicit comments on potential weighting methodologies that could be incorporated to the QIP in future years as new measures are introduced.

As previously discussed, 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 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 seek public comments about the proposed scoring methodology for the ESRD QIP.

E. 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 propose 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 26 points. Providers/facilities that score between 21–25 points would receive a 0.5 percent payment reduction, between 16–20 points a 1.0 percent payment reduction, between 11–15 points a 1.5 percent payment reduction, and between 0–10 points the full 2.0 percent payment reduction (*see* Table 8). Applying this payment reduction scale to the example of Facility A above, Facility A's total performance score of 26 would result in it receiving no payment reduction.

Table 8. Proposed Payment Reduction Scale

Total Performance Score	Percent of Payment Reduction
26 to 30 Points	0.0 Percent
21 to 25 Points	0.5 Percent
16 to 20 Points	1.0 Percent
11 to 15 Points	1.5 Percent
0 to 10 Points	2.0 Percent

In developing the proposed payment reduction scale, we carefully considered the size of the incentive to providers/facilities to provide high quality care and range of total performance scores to which the payment incentive 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. For example, 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. At the same time, we want poorly performing providers/facilities to receive a more significant payment reduction. Our analysis suggests that use of payment differentials of 0.5 percent for the total performance score ranges we are proposing differentiates between providers/facilities with fair to good performance and providers/facilities with poor performance. We will consider smaller 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 2.0 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 2.0 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 2.0 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 and avoid a payment reduction the following year. We seek public comments about how the proposed payment reduction scale will 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 in the End-Stage Renal Disease Prospective Payment System Final Rule (CMS–1418–F) published on August 12, 2010.

In keeping with this practice, we propose 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, including case-mix, wage index, outlier, etc, were made. (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 (and Medicare pays 80 percent). With respect

to dialysis services furnished by ESRD facilities to individuals with ESRD, 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 seek public comment on the impact of this effect.

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

F. 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 DFRs is sensitive and as such, most of that information is made available through a secure Web site only to 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 DFC Web site, which allows Medicare beneficiaries and others to 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 provided 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 in the DFC Web site.

We propose to use the above-described procedures, including the DFRs framework, to allow dialysis providers/facilities to preview their quality data under the QIP before they are 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. 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. Any 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 requirement 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 propose 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 propose 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 seek 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.

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 propose 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 propose 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. CMS will 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 expect that dialysis providers/facilities would have the capability to download and print their certificates from the secure Web site. We propose 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.

Once printed, we propose 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 propose 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 will update the certificates annually with new performance information, and providers/facilities must post the updated certificate within 5 business days of the day that we transmit it. 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 propose 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 are:

- 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 score average;
- 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 score average for each quality measure.

We considered several options for making QIP performance score data available via certificates. 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 seek 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 are 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 seek 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 seek 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.

4. Informing the Public Through Medicare's 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 that 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, CMS hosts 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 4,700 dialysis providers/facilities approved by 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.

Because DFC is a current component of the Medicare suite of Compare tools, we propose to use DFC as the mechanism for meeting the Web-based

public information requirement under section 1881(h)(6)(D) of the Act. 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-approved 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 propose 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 score average;
- 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 score average for each quality measure.

We note that this is the same information that we are proposing to include on the certificates that we will provide to providers/facilities. We seek 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.hhs.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 seek public comment on the advisability of using DFC as our mechanism for making QIP information available over the Internet. We also seek 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 seek 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.

III. Future QIP Considerations

A. Program Monitoring and Evaluation

CMS plans to monitor and evaluate the new ESRD Prospective Payment System (PPS) and 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 QIP, we observe changes in access to and quality of care, especially within the vulnerable populations. We will be evaluating the effects of the new PPS and the QIP in areas such as:

- Access to care for beneficiaries including categories or subgroups of beneficiaries.
- Changes in care practices that could adversely impact on 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 provide 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 also will 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 welcome public comments about an approach to monitoring and evaluating the PPS and the QIP.

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 10 g/dL—2 percent; Hemoglobin More Than 12 g/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 reduced 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 quality of care, once we have a historical perspective on how the

measure performs. While we will consider use of national performance rates, we also will take into consideration future performance measures 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 (i.e. for calcium and phosphorus), and vascular access. CMS is currently developing measures in each of the areas specified in section 1881(h)(2)(A) of the Act and is also 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 most measures, CMS will use a collection process that has been determined appropriate by the Secretary to obtain this data. For collection of calcium and phosphorus levels, however, we intend to collect information on facility and provider ESRD claims as soon as practicable. Additional detail on submission of the calcium and phosphorus levels will be provided as soon as it is available. 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 seek public comments on how we might best incorporate both improvement and achievement standards as specified by the Act. We also seek comments on performance standards for future years of the QIP. We are committed to adopting additional quality measures for the QIP as soon is practicable. While we are evaluating measures for inclusion in future years of the QIP, we also seek public comment on setting performance standards for the first year a new measure is included in the QIP.

IV. 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

Section VIII.C. of the preamble of this proposed rule discusses a disclosure requirement. As stated earlier in the preamble, 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, CMS will be issuing QIP certificates to providers and facilities via a generally accessible electronic file format. We propose that each provider and facility would prominently display the QIP certificate in patient areas. In addition, we propose that each provider and facility will take the necessary measures to ensure the security of the certificate in the patient areas. Finally, we propose 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.

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 estimate that 4,311 providers and facilities will receive QIP certificates and will be required to display them. We also estimate 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 estimate that approximately one-third of ESRD patients will ask a question about the QIP certificate. We further estimate that it will take each provider/facility 5 minutes to answer each patient question about the QIP certificate, or 1.65 hours per provider or facility each year. The total estimated annual burden associated with this requirement is 7,121 hours. The total estimated annual burden for both displaying the QIP certificates and answering patient questions about the certificates is 7,839 hours. While the total estimated annual burden associated with both of these requirements as discussed is 7,839 hours, we do not believe that there will be a significant cost associated with these requirements because we are not requiring facilities to complete new forms. As discussed in Section VI. of the preamble of this proposed rule, we estimate that the total cost for all ESRD facilities to comply with the collection of information requirements would be less than $200,000.

If you wish to comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention:* CMS Desk Officer, [CMS–3206–P].

Fax: (202) 395–6974; or

E-mail: *OIRA_submission@omb.eop.gov.*

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review, 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 (March 22, 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). As explained in the analysis that follows, we have determined that this proposed rule is not economically significant since it does not have effects of $100 million or more. Furthermore, it is not considered a major rule under the Congressional Review Act.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers or facilities are small entities, either by nature of their nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. Based on our review of 2007–2008 DFC quality performance data, we estimate that approximately 19 percent of ESRD facilities are small entities according to the Small Business Administration's (SBA) size standard of those dialysis facilities having total revenues of $34.5 million or less in any one year, and that 19 percent of dialysis facilities are nonprofit organizations. For more information on SBA's size standards, see the SBA Web site at *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf.* (Kidney Dialysis Centers are listed as North American Industry Classification System (NAICS) Code 621492 with a size standard of $34.5 million.)

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 9 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).

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Table 9. Impact of Proposed 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 (# 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.

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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 3 to 5 percent or more of total revenue or total costs.

Under the proposed 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 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). We expect payment reductions received would average approximately $18,000 per facility, regardless of facility size. 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 initial analysis for the RFA because the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of 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. This analysis must conform to the provisions of section 603 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 for Medicare payment regulations and has fewer than 100 beds. We do not believe this proposed rule has a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. Therefore, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately $135 million. This rule will not have a consequential effect on State, local, or tribal governments in the aggregate, or by the private sector of $135 million.

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. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

B. Anticipated Effects

This proposed 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 quality incentive program (QIP) that would reduce ESRD payments by up to 2 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. The methodology that we are proposing to determine a provider/facility's performance score is described in section VI (Methodology for Calculating the Total Performance Score for the ESRD QIP Measures). Any reductions in ESRD payment would begin on January 1, 2012 for services furnished on or after January 1, 2012.

The End-Stage Renal Disease Prospective Payment System Final Rule (CMS–1418–F) published on August 12, 2010 estimates payments to ESRD facilities in 2012 to be $8.5 billion. 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 10 shows the overall estimated distribution of payment reductions resulting from the 2012 QIP.

Table 10. 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 (before an adjustor is applied) to arrive at a total ESRD payment for each facility:

((Number of patients treated at each facility × 3 treatments per week) × base rate)

Finally, we applied the estimated payment reduction percentage expected under the 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 the preamble of this proposed 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.

C. Alternatives Considered

As stated above, this proposed rule proposes to implement 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. In developing the proposed QIP, 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 More Than 12 (Hgb <10–0%–3%; Hgb >12–8%–38%; URR 94%–100%). As the bundled payment will likely reverse the incentive that may be leading to the wider range for the Hgb>12, the differences in the performance did not warrant moving from the use of a national average for performance.
- CMS has seen great improvement in the rates for these measures over the past several years in part due to public reporting and continuous oversight and monitoring. The rate for Hemoglobin Less Than 10 has improved and maintained improvement, while Hemoglobin More Than 12 improved from 44% in 2007 to 26% 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 10 began to drop, CMS could propose to require a rate of 2% 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 period of performance for the first payment year has already begun. We anticipate the final rule will be published near the end of the performance period. Therefore, introduction of a new performance standard after the period of performance has nearly ended was not appropriate.

We also considered alternatives for applying payment reductions. Our main alternatives considered varying point reductions based on each 1 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 ask 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 propose to amend 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), 1395I(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 a provider of services or a renal dialysis 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 under this subpart for renal dialysis services will be reduced by up to 2.0 percent, as determined appropriate by the Secretary.

(b) Any payment reduction will apply only to services provided in 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: March 18, 2010.

Marilyn Tavenner,

Acting Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

Approved: July 19, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–18465 Filed 7–26–10; 4:15 pm]

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