

percent rule applies within the definition of outlier services and retain the 50 percent rule under the proposed ESRD PPS.

G. Medicare as a Secondary Payer

Medicare may be a secondary payer (MSP) when the primary payer is a group health plan for ESRD items and services furnished to Medicare beneficiaries during the 30-month Medicare coordination of benefit period. At this time, we are unable to identify the systems operations and billing procedures impact of this relationship under the current basic case-mix adjusted composite payment system, and we are exploring how it will be utilized and managed under the proposed ESRD prospective payment system. We believe that while there may need to be system changes in order to process MSP claims under the Proposed ESRD prospective payment system, there should be no impact on ESRD providers and on primary payers. We will issue through administrative issuance, any changes in the manner of reporting information, should that be required. We are soliciting public comment on the operational issues of MSP under the proposed ESRD payment system.

XV. Quality Incentives in the End-Stage Renal Disease

(ESRD) Program

A. Introduction

Section 1881(h) of the Social Security Act (the Act), as added by section 153(c) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), requires the Secretary to develop a quality incentive program (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 with respect to certain specified measures. As provided under section 1881(h) of the Act, the payment reductions, which will be up to 2.0 percent of the payments otherwise made to providers and facilities under section 1881(b)(14), will apply to renal dialysis services furnished on or after January 1, 2012, and the total performance score that providers and facilities must meet or exceed in order to receive their full payment will be based on a specific performance period prior to this date. The payment reductions will apply with respect to the year involved and will not be taken into account when computing future payment rates.

The CMS is committed to developing and implementing an ESRD QIP, and we intend to issue a subsequent proposed rule that makes detailed proposals regarding how we plan to implement section 1881(h) of the Act. However, in the interim, with one exception described below, we believe it

is important to describe the QIP conceptual model that CMS is considering proposing for purposes of the payment reduction that will apply with respect to renal dialysis services furnished on or after January 1, 2012. Therefore, we will present the model below so that the public has an opportunity to comment on it, and we will use the comments to inform our evaluative, analytic, and guidance efforts during the development of the QIP.

The one exception mentioned above is the measure set that will apply for purposes of the CY 2012 payment reduction. We are making specific proposals with respect to that measure set in this proposed rule so that the public will be informed as early as possible regarding the measures on which the performance standards will be based.

B. Background

Quality monitoring and provider accountability is important in the ESRD payment system and has been done 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 ensure that dialysis patients are provided appropriate care. The Networks' responsibilities include monitoring the quality and improvement of care received, providing technical assistance to patients who have ESRD and providers/facilities that treat ESRD patients, and addressing patient grievances. In 1994, CMS and the 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 included in the database included clinical measures thought to be indicative of key components of care surrounding dialysis.

2. Clinical Performance Measures (CPMs):

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

the ESRD CPM Project is to provide comparative data to ESRD facilities to assist them in assessing and improving the care furnished to ESRD patients. Sixteen CPMs were developed in 1998 to measure and report the quality of dialysis services furnished under Medicare in the areas of hemodialysis and peritoneal dialysis adequacy, anemia management, and vascular access management. The first data collection effort for the ESRD CPMs began in 1999. These CPMs are calculated using information contained in patients' records. CPMs are collected on a national random sample of adult in-center hemodialysis patients, all in-center hemodialysis patients less than 18 years of age, and a national random sample of peritoneal dialysis patients. Data are collected annually and submitted to CMS via a predominantly paper-based process. The CPMs are calculated and released in the Department of Health and Human Services' Annual Report on the ESRD CPM Project.

3. Dialysis Facility Compare (DFC):

Also in response to the Balanced Budget Act of 1997, we created Dialysis Facility Compare (DFC) as a new feature on www.medicare.gov that was modeled after Nursing Home

Compare. We 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 www.medicare.gov website to provide information to the public for comparing the quality of dialysis facilities and providers across the country, including specific information about services 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 key quality measures captured in this tool include facility-level measures of anemia control, adequacy of hemodialysis treatment and patient survival. Medicare claims data are used to calculate the anemia management and dialysis adequacy rates and administrative data (non-clinically based data such as demographic data, and data acquired from the Social Security Administration and obtained from the CMS forms 2728 and 2746) used to determine the patient survival rates. The anemia measure shows the raw number or the percentage of patients at a given facility/provider whose anemia (low red blood cell count) was not controlled. More specifically, the anemia

measure is the percentage of patients whose hematocrit levels are at 33 percent (33 percent out of 100 percent) or more (or hemoglobin levels of 11 g/dL or more). The dialysis adequacy measure shows the raw number or the percentage of in-center hemodialysis patients at a facility that get effective treatments during dialysis. More specifically, the measure is the percentage of patients with urea reduction ratio (URR) levels of 65 percent or more. The patient survival measure shows whether patients treated at a certain facility generally live longer, as long, or not as long as expected. These measures are updated annually on the DFC website, usually at the end of the year, using data from the previous year for the dialysis adequacy and anemia measures and data from the past four years for the patient survival measure.

In November 2008, the anemia management measure was updated using facility and claims data from 2007. Recent evidence about increased risk of certain adverse events associated with the use of erythropoiesis-stimulating agents (ESAs), which are used to treat anemia, raised concerns about patients who have hemoglobin levels 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/cder/drug/advisory/RHE200711.htm>) and to ensure that this information is provided to patients. The labeling guideline 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"

(<http://www.fda.gov/cder/drug/advisory/RHE200711.htm>). As a result of this guideline, 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). In addition, CMS has updated the way it reports patient survival rates on DFC to reflect whether patients treated at a provider/facility generally live longer than, as long, or not as long as expected.

4. ESRD Quality Initiative:

In 2004, the ESRD Quality Initiative was launched. The objective was to stimulate and support significant improvements in the quality of dialysis care. The initiative aimed 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 providers; assure compliance with conditions of coverage; and build strategic partnerships with patients, providers, professionals, and other stakeholders.

Components of this Quality Initiative included the DFC, the CPM Project, and the Fistula First Breakthrough Initiative.

5. ESRD Conditions for Coverage:

The ESRD Conditions for Coverage final rule published on April 15, 2008, and contains revised requirements that dialysis providers and facilities must meet in order to be certified under the Medicare program. As part of the revised requirements, dialysis providers and facilities are required to implement a quality assessment and performance improvement program. In addition, providers and facilities are required to submit the CPMs electronically on all their patients on an annual basis. The CPMs were updated and expanded in April 2008 through a National Quality Forum (NQF) endorsement process. 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. The anemia management measures for patients receiving erythropoiesis-stimulating agents (ESAs) and the urea reduction ratio

(URR) measure (in-center hemodialysis) are not NQF endorsed.

6. CROWNWeb:

CMS has developed a new web-based system, Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) for the purposes of collecting CPM data electronically from dialysis facilities. 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, CMS began implementing the CROWNWeb system with a number of providers/facilities and plans to expand reporting to additional providers/facilities as soon as practicable.

C. The ESRD Quality Incentive Program as Authorized by Section 1881(h) of the Act

Recognizing the need for additional quality monitoring in an ESRD payment system, 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 versus being focused on reporting outcome data.

Specifically, section 1881(h) of the Act, as added by section 153(c) of MIPPA, requires the Secretary to develop a QIP that will result in payment reductions to providers of services and dialysis facilities that do not meet or exceed a total performance score with respect to performance standards established with respect to 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), will apply to renal dialysis services furnished on or after January 1, 2012, and the total performance score that providers and facilities must meet or exceed in order to receive their full payment will be based on a specific performance period prior to this date. Under section 1881(h)(1)(C), the payment reduction will only apply with respect to the year involved and will not be taken into account when computing future payment rates.

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 develop a robust, comprehensive ESRD QIP that builds on the foundation that has already been established. As we move towards this larger goal, we understand the importance of giving providers and facilities time to prepare for the implementation of this new quality incentive program and to assess how the new program will affect them.

Therefore, we are outlining below a conceptual model that describes various components of an ESRD QIP that we are considering proposing in a future proposed rule. We want to make clear that this is only a model, with one exception. The exception, more fully described below, is that we are proposing to initially adopt for the QIP three measures, two of which assess anemia management and one which assesses hemodialysis adequacy, which can be calculated using Medicare claims data.

Our goal is to propose to implement other components of the QIP in future rulemaking. Our purpose in describing a model in this proposed rule is to notify the public regarding what we believe at this time to be essential components of the QIP in the hope of receiving detailed comments on those components. We also note that the model described below represents our thinking on what we are considering implementing only for payment consequence year 2012 because we anticipate that the program will evolve as we conduct additional analyses, gather experience, and respond to industry feedback.

1. Proposed Anemia Management and Dialysis Adequacy Measures

Section 1881(h)(2)(A)(i) of the Act requires that the measures specified for the QIP include measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management, and measures on dialysis adequacy. To implement this section, we are proposing that for the first QIP performance period, we will adopt the two anemia management measures and one hemodialysis adequacy measure that are currently used for DFC. Data needed to calculate these measures can be collected from Medicare claims submitted by ESRD providers and facilities on a patient-specific basis.

The anemia management measures used for DFC assess the percentage of patients at a facility whose anemia was not controlled at both the high and low ends of the FDA recommended hemoglobin levels. Specifically, these measures are: (1) the percentage of patients at a provider/facility whose hemoglobin levels were less than 10 g/dL, and (2) the percentage of patients at a provider/facility whose hemoglobin levels were greater than 12 g/dL.

Section 1881(h)(2)(A)(i) of the Act provides that the anemia management measures must reflect the labeling approved by the FDA for such management. The current FDA labeling guideline released November 8, 2007 for the administration of erythropoiesis-stimulating agents (ESAs) to patients with chronic kidney disease, including ESRD patients, 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."

We believe that the proposed anemia management measures reflect the approved FDA labeling for anemia management because they assess the number of patients whose hemoglobin levels are at the low and high end of the FDA label recommendation. In addition, we believe that it is more

appropriate to adopt two measures which together assess the high and low end of the FDA recommended hemoglobin level range, rather than a single measure that reflects the percentage of patients who have hemoglobin levels within the 10 through 12 g/dL range, because two measures will provide a richer picture of provider/facility performance. These data will also allow us to calculate the percentage of patients who have hemoglobin levels within the 10 through 12 range g/dL. Therefore, we propose to adopt these two anemia management measures for the QIP.

Anemia data has been reported on Dialysis Facility Compare (DFC) since January 2001. As we noted above, we updated the reporting of anemia data for DFC in November of 2008 to be consistent with the new FDA labeling guideline released in November 2007; however, the methodology for calculating the provider/facility, state, and national averages for anemia measures has not changed since the initial release of DFC. We are proposing to use the same methodology we use to calculate the anemia management measures for purposes of DFC to calculate them for purposes of the QIP because the methodology is consistent with how we have calculated that data since 2001. Under this methodology, we will calculate the measures using hemoglobin data for Medicare patients who have been

diagnosed with ESRD for at least 90 days and whose Medicare claims submitted by providers/facilities indicated the use of an ESA during that 90-day period. Data from patients whose first ESRD maintenance dialysis starts before day 90 or who have hemoglobin values of less than 5 or greater than 20 will be excluded from the measure calculation. In addition, there must be for the same patient at least 4 claims meeting this criteria for that data to be included in the data for a specific provider or facility. Technical details on the methodology we are proposing to use to calculate the anemia measures are available on the University of Michigan Kidney Epidemiology and Cost Center website at

<http://www.sph.umich.edu/kecc/assets/documents/facguide.pdf>.

The hemodialysis adequacy measure (urea reduction ratio [URR]) that we are proposing to adopt is also used for DFC and assesses the percentage of patients at a provider or facility that get their blood cleaned adequately (blood urea is removed during their in-center hemodialysis). Specifically, this measure assesses the percentage of hemodialysis patients at a provider or facility whose urea reduction ratio (URR) is 65 percent or greater, a standard based on the National Kidney Foundation's Kidney Disease Quality Initiative Clinical

Practice Guidelines (NKF-KDOQI). These guidelines are widely used and generally accepted throughout the ESRD community. More information on the calculation of the URR is available on the DFC website at www.medicare.gov. This measure has been endorsed by the National Quality Forum (NQF), an organization that endorses quality measures through a public consensus process, although we note that NQF endorsement of dialysis adequacy measures is not a requirement under section 1881(h)(2)(A)(i).

The methodology for calculating the provider/facility, state, and national averages for the in-center hemodialysis measure has been used since January 2001 with the initial release of DFC, and we are proposing to use the same methodology to calculate the measure for purposes of the QIP to be consistent with how that data has been calculated since 2001. Under this methodology, we will calculate URR data only for Medicare patients who have been diagnosed with ESRD and received maintenance dialysis for at least 183 days from the date that they received their first maintenance dialysis treatment, and whose Medicare claims submitted by providers/facilities included a value for the URR. In addition, there must be for the same patient at least 4 claims meeting the criteria above for that data to be included in the data for a specific provider or

facility. Technical details about the methodology we are proposing to use to calculate the hemodialysis adequacy measure are available on the University of Michigan Kidney Epidemiology and Cost Center website at <http://www.sph.umich.edu/kecc/assets/documents/facguide.pdf>.

We note that the data we need to calculate the proposed anemia management and hemodialysis adequacy measures described above can be collected through ESRD claims, which is the only complete provider and facility level data set available to CMS at this time. For this reason, we are proposing to adopt only the two anemia management measures and one dialysis adequacy measure described above. Although we recognize that section 1881(h)(2)(A)(i) states that the measures shall include "measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management and measures on dialysis adequacy," only one dialysis adequacy measure is collected nationally and available to determine provider and facility-specific values. For this reason, we are proposing at this time to adopt only one dialysis adequacy measure. We also note that section 1881(h)(2)(A)(iii) states that the measures shall include, to the extent feasible, other measures as the Secretary specifies including measures on iron

management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula). CMS is not proposing to adopt any measures in these categories at this time since we are not currently collecting data that would allow determination of provider and facility-specific performance with respect to these categories of measures. We are working to identify appropriate sources from which we can adequately capture data to support the future adoption of additional measures. Finally, it is not feasible to propose a patient satisfaction measure at this time because there is no validated data collection tool available to collect relevant and industry accepted patient satisfaction measure data. Therefore, it is not feasible to propose more than the aforementioned measures at this time because of the lack of complete and accurate data. Subsequent rulemaking will address other measures.

2. 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) provides that the performance standards shall include levels of achievement and improvement, as determined appropriate by the

Secretary. However, in our model, for the first performance period, we would establish a performance standard for the proposed anemia management and hemodialysis adequacy measures based on the special rule in Section 1881(h)(4)(E). This provision requires the Secretary to "initially" use as a performance standard for the anemia management and dialysis adequacy measures the lesser of a facility-specific performance rate in the year selected by the Secretary under the second sentence of section 1881(b)(14)(A)(ii), or a standard based on the national performance rate for such measures in a period determined by the Secretary. We would not include in this performance standard levels of achievement or improvement because we do not believe that section 1881(h)(4)(E) requires that we include such levels. In addition, we would interpret the term "initially" to apply only to the performance period applicable for payment consequence year 2012. For subsequent performance periods, we plan to propose performance standards under section 1881(h)(4)(A). Such standards will include levels of achievement and improvement, as required under section 1881(h)(4)(B).

As stated above, to implement the special rule for the proposed anemia management and hemodialysis adequacy measures, we would need to compare the performance of a

provider or facility on these measures during the year selected by the Secretary for purposes of calculating the ESRD bundle with the performance of the provider or facility using a performance standard based on the national performance rates for these measures in a period determined by the Secretary. For purposes of making this comparison in our model, the provider/facility-level performance year referenced in section 1881(h)(4)(E)(i) would be 2007, 2008, or 2009, depending on which of those years is selected by the Secretary for purposes of calculating the ESRD bundle. We would refer to this year as the "base utilization year." The provider/facility-specific rates for 2007 are currently posted on the DFC website.

In terms of establishing a performance standard based on national performance rates as required under section 1881(h)(4)(E)(ii), we are considering adopting a standard that is equal to the average performance of all dialysis providers and facilities based on 2008 data. These data for the anemia management and hemodialysis adequacy measures will be posted on DFC in November 2009.

Although the 2008 data are not yet available on DFC, the national averages currently posted on the DFC website for 2007 are

- For the proposed anemia management measure (Anemia Management Measure less than 10) -- the percentage of Medicare patients who have an average hemoglobin value less than 10.0 g/dL in a provider /facility: 2
Percent
- For the proposed anemia management measure (Anemia Management Measure more than 12) -- the percentage of Medicare patients who have an average hemoglobin value greater than 12.0 g/dL in a provider/facility: 44
Percent
- For the proposed hemodialysis adequacy measure (Hemodialysis Adequacy One) -- the percentage of Medicare patients in a provider/facility with URR levels above 65 percent: 95 *Percent*.

We expect that these averages will change for 2008.

This means that, for purposes of implementing the special rule in our model for the proposed anemia management and hemodialysis adequacy measures, the performance standard for the initial performance period would be the lesser of (1) the provider/facility-specific rate for the base utilization year, or (2) the national average results from 2008 claims data. If a provider or facility performed below the national average, then we would look at the provider/facility-specific rate for the

base utilization year to determine whether the provider/facility's performance during the initial performance period meets or exceeds the performance standard.

We note that the proposed hemodialysis adequacy measure would assess hemoglobin values only in hemodialysis patients who receive treatment at a provider or facility (and not in hemodialysis or peritoneal dialysis patients treated at home). In addition, the proposed hemodialysis adequacy measure would not assess hemoglobin values in pediatric dialysis patients. Therefore, we are seeking public input about this issue and ideas about whether and how we could assess dialysis adequacy for home dialysis (home hemodialysis and peritoneal dialysis) and pediatric dialysis.

3. 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) 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.

In selecting a performance period, we need to allow sufficient time to calculate the provider/facility-specific scores, determine whether providers and facilities meet the performance standards and prepare the pricing files needed to implement applicable payment reductions beginning on January 1, 2012. Among potential performance periods in our model would be all or portions of 2010. However, we are also considering other performance periods. We seek public comments about performance periods and will propose a specific performance period in future rulemaking.

4. 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) 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) requires the Secretary to calculate separate performance scores for each measure.

Finally, under section 1881(h)(3)(A)(ii), 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.

As discussed earlier, we are proposing to adopt for the initial performance period two anemia management measures and one hemodialysis adequacy measure that are currently used for DFC. In our model, for purposes of calculating the total performance of each provider and facility during the initial performance period, we are considering assigning 10 points to each of these measures. That is, if a provider or facility meets the performance standard for one measure, then it would receive 10 points for that measure, and if the provider or facility meets the performance standards for all three measures, it would receive a total performance score of 30 points.

In our model, we are considering, for scoring purposes, that a provider or facility that does not meet

the performance standard set for a measure would receive fewer than 10 points, with the exact number of points corresponding to how far from the set standard the provider/facility's performance falls. Specifically, we are considering implementing a scoring methodology that subtracts 2 points for each 2 percentage point increment range the provider or facility's performance falls from the set performance standard. For example, if we used as the performance standard during the initial performance period the national average of 44 percent (based on 2007 DFC data) for one of the proposed anemia management measures (percentage of patients whose hemoglobin levels are greater than 12 g/dL), and a particular provider/facility had 46 percent of patients with hemoglobin levels greater than 12 g/dL during that period, the provider/facility would receive 8 points for its performance on the measure because 46 percent is within the first 2 percentage point increment range from 44 percent (see Table 42 below). However, applying the special rule for the initial performance period, as required by section 1881(h)(4)(E), the provider/facility's performance of 46 percent would become the performance standard for scoring purposes, and the provider/facility would receive 10 points for this measure (see Table 43 below).

Under our model, providers and facilities that exceed the performance standards based on the national average for the period that the Secretary has determined and if their performance rate improved from the "base utilization year" then the provider or facility would receive additional points. Using the 2007 DFC data again to illustrate, if a provider/facility had 43 percent of patients with hemoglobin levels greater than 12 g/dL during the initial performance period, the provider/facility's performance would be better than the 2007 national average of 44 percent. In addition, if the provider/facility had a performance rate of 46 percent in the base utilization year then the provider/facility's performance of 43 percent for the initial performance period would also be better. Therefore, the provider/facility would receive 12 points, which is an additional 2 points or a "bonus" (maximum bonus in this conceptual model) above the 10 points that could be received for meeting the performance standard of a measure. We believe providers and facilities should only receive additional points if they achieve higher levels of performance, that is, their actual performance exceeds the performance standard for the national average for the period that the Secretary has determined and improves above the base utilization year.

As we noted above, the right side of Table 42 that represents the percentage of patients whose hemoglobin levels are greater than 12 g/dL, illustrates how this scoring methodology could work for a provider/facility for which, after applying the special rule, the performance standard for the proposed anemia management measures is the national performance rates for 2007. Likewise, Table 43 shows an example using a provider/facility-specific rate as the performance standard (after applying the special rule) for the proposed anemia management measures. In addition, Table 44 illustrates how the scoring methodology would work using the national performance rate for 2007 as the performance standard (after applying the special rule) for the proposed hemodialysis adequacy measure, and Table 45 shows an example of the scoring for the proposed hemodialysis adequacy measure using a facility-specific rate as the performance standard (after applying the special rule).

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

Table 42. Model Scoring Methodology for Proposed Anemia Management Measures using National Performance Rates in 2007 as the Performance Standards

| | Proposed Anemia Management Measures | | | | |
|------------------|--|----------------------------|--|---|----------------------------|
| | Percentage of patients whose hemoglobin levels are less than 10 g/dL | | | Percentage of patients whose hemoglobin levels are greater than 12 g/dL | |
| POINTS | Percentage | Distribution of Facilities | | Percentage | Distribution of Facilities |
| 12 points* | Below 2 percent | 2523 | | Below 44 percent | 2283 |
| 10 points | 2 percent | 657 | | 44 percent | 73 |
| 8 points | 3 to 4 percent | 884 | | 45 to 46 percent | 155 |
| 6 points | 5 to 6 percent | 358 | | 47 to 48 percent | 143 |
| 4 points | 7 to 8 percent | 149 | | 49 to 50 percent | 228 |
| 2 points | 9 to 10 percent | 54 | | 51 to 52 percent | 76 |
| 0 point | Over 11percent | 119 | | Over 53 percent | 1786 |

* Provider/Facility must be above both performance standards to receive the bonus points for the anemia management measures.

Table 43. Model Scoring Methodology for Proposed Anemia Management Measures using Facility-Specific Rates as the Performance Standards

| | Proposed Anemia Management Measures | |
|------------|--|---|
| | Percentage of patients whose hemoglobin levels are less than 10 g/dL | Percentage of patients whose hemoglobin levels are greater than 12 g/dL |
| POINTS | Percentage | Percentage |
| 12 points* | Below 3 percent | Below 46 percent |
| 10 | 3 percent | 46 percent |

| points | (Example of a facility-specific score) | (Example of a facility-specific score) |
|----------|--|--|
| 8 points | 4 to 5 percent | 47 to 48 percent |
| 6 points | 6 to 7 percent | 49 to 50 percent |
| 4 points | 8 to 9 percent | 51 to 52 percent |
| 2 points | 10 to 11 percent | 53 to 54 percent |
| 0 point | Over 12 percent | Over 55 percent |

* Provider/Facility must be above both performance standards to receive the bonus points for the anemia management measures.

Table 44. Model Scoring Methodology for Proposed Hemodialysis Adequacy Measure using National Performance Rates in 2007 as the Performance Standard

| POINTS | Proposed Hemodialysis Adequacy Measure | |
|------------------|---|----------------------------|
| | Percentage of patients whose URR levels are greater than 65 percent | Distribution of Facilities |
| 12 points** | Over 95 percent | 3,142 |
| 10 points | 95 percent | 296 |
| 8 points | 93 to 94 percent | 417 |
| 6 points | 91 to 92 percent | 245 |
| 4 points | 89 to 90 percent | 181 |
| 2 points | 87 to 88 percent | 102 |
| 0 point | Below 86 percent | 296 |

** Provider/Facility must be above both performance standards to receive the bonus points for the hemodialysis adequacy measure.

Table 45. Model Scoring Methodology for Proposed Hemodialysis Adequacy Measure using the Facility-Specific Rates as the Performance Standard

| POINTS | Proposed Hemodialysis Adequacy Measure |
|------------------|---|
| | Percentage of patients whose URR levels are greater than 65 percent |
| 12 Points** | Above 92 percent |
| 10 points | 92 Percent (Example of a facility-specific score) |
| 8 points | 90 to 91 percent |
| 6 points | 88 to 89 percent |
| 4 points | 86 to 87 percent |
| 2 points | 84 to 85 percent |
| 0 point | Below 83 percent |

**** Provider/Facility must be above both performance standards to receive the bonus points for the hemodialysis adequacy measure.**

Another example of how the scoring methodology might work follows below. The example assumes that Facility A achieves the following results during the initial performance period:

1. Anemia Management (less than 10 g/dL): Percentage of patients whose hemoglobin levels are less than 10 g/dL is 4 percent
2. Anemia Management (more than 12 g/dL): Percentage of patients whose hemoglobin levels are greater than 12 g/dL is 43 percent
3. Hemodialysis Adequacy: Percentage of patients whose URR levels are greater than 65 percent is 93 percent

The total performance score for Facility A would be 30 points. Facility A would receive bonus points for the anemia management (more than 12 g/dL) because the facility was above the national performance standard for the period determined by the Secretary, which in this example is 2007, and improved above the base utilization year, which is also 2007 in this example. However, the facility would not receive bonus points for the hemodialysis adequacy measure even though it improved from its base utilization year because it did not receive a percentage higher than the national average so the facility would receive a score of 10 points. Table 46 shows how the total performance score would be calculated for Facility A.

Table 46. Example of Total Performance Score Methodology Using Facility A

| Measure | Facility Performance Rate | Performance Standard Using Special Rule | Score |
|--|----------------------------------|---|------------------|
| Anemia Management: Percentage of patients whose hemoglobin levels are less than 10 g/dL | 4 percent | 3 Percent (Use Table 43) | 8 points |
| Anemia Management: Percentage of patients whose hemoglobin levels are greater than 12 g/dL | 43 percent | 44 Percent and 46 Percent (Use Table 42 and 43) | 12 points |
| Hemodialysis Adequacy: Percentage of patients whose URR levels are greater than 65 percent | 93 percent | 92 Percent (Use Table 45) | 10 points |
| TOTAL | | | 30 points |

We believe this total performance score methodology is appropriate for the initial performance period in the new

ESRD QIP because it is basic and straightforward, allowing providers and facilities to familiarize themselves with the new pay-for-performance quality system. We plan to propose a total performance scoring methodology using the applicable set of measures in future rulemaking. However, we are seeking input on this model of a total performance score methodology to be applied for payment consequence year 2012.

In our model, the initial scoring method weights each of the three proposed measures equally. As we stated above, we also plan to implement performance standards that include levels of achievement and improvement after the initial performance period. From a clinical perspective, we believe that providers and facilities may be concerned about whether they have as much opportunity to improve their performance on one of the proposed anemia management measures (hemoglobin levels less than 10 g/dL) as they might with the other two proposed measures. We are specifically soliciting comments on whether this is truly a concern among providers and facilities and, if so, whether we should consider assigning less weight to the measure based on that concern. We are also soliciting comments on how reassigning weights to measures in general (that is,

less to some, more to others) might affect providers and facilities in terms of the payment consequence.

5. Application of Payment Reductions Using the Total Performance Score

With respect to the providers/facilities that do not meet (or exceed) 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.

Under our model, for payment consequence year 2012, we are thinking about implementing a sliding scale of payment reductions, where the payment reduction for the lowest total performance score would be 2.0 percent.

Under our model, the minimum total performance score that providers and facilities would need to achieve in order to avoid a payment reduction would be 28 points. The range for the payment reductions is shown in Table 6:

Table 47. Model Range of Payment Reductions

| Total Performance Score | Percent of Payment Reduction |
|-------------------------|------------------------------|
| 28 to 30 Points | 0 Percent |

| | |
|-----------------|--------------|
| 24 to 26 Points | .25 Percent |
| 20 to 22 Points | .50 Percent |
| 16 to 18 Points | .75 Percent |
| 12 to 14 Points | 1.0 Percent |
| 8 to 10 Points | 1.25 Percent |
| 4 to 6 Points | 1.50 Percent |
| 2 Points | 1.75 Percent |
| 0 Points | 2.0 Percent |

Based on our example involving Facility A above, this facility would not receive a payment reduction in 2012 because it achieved a total performance score of 30 points.

We recognize that under our model, a provider or facility that scores poorly on one measure could nonetheless receive no reduction in payment because the provider or facility also exceeded the performance standard for one or both of the other two measures. We are concerned about this possibility and are considering proposing that, for any measure for which a provider or facility receives 4 points or less, the provider/facility receive a 0.25 percent payment reduction even if it receives a total performance score of 28 points. We are seeking comments on our modeled methodology for applying payment reductions in 2012.

6. Public Reporting of Measures

Section 1881(h)(6) requires the Secretary to establish procedures for making information regarding performance

under the QIP available to the public, including information on the total performance score and performance scores for individual measures achieved by each provider and facility. Providers and facilities are required to have an opportunity to review this information prior to it being made public. The Secretary is also directed in section 1881(h)(6)(D) to post a list of providers and facilities on the CMS website that indicates the total performance score and the performance scores for individual measures achieved by each provider and facility. In addition, under section 1881(h)(6)(C), the Secretary is required to provide certificates to providers and facilities that indicate the total performance score achieved by the provider or facility, and the provider or facility must prominently display the certificate in patient areas.

We plan to establish procedures for making information available to the public in a future rulemaking, but welcome comments on how to best implement these statutory requirements.

XVI. 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.