

Centers for Medicare & Medicaid Services
Special Open Door Forum:
End Stage Renal Disease Prospective Payment System Proposed Rule Overview
Thursday October 15, 2009
3:30PM – 5:00PM EDT
Conference Call Only

The Centers for Medicare & Medicaid Services (CMS) will hold a Special Open Door Forum (ODF) to discuss the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) proposed rule that went on display at the Federal Register on September 15, 2009. The primary audiences for this Special ODF are ESRD facilities and provider, supplier, laboratory and beneficiary groups.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) was enacted on July 15, 2008. Section 153(b) of MIPPA amended section 1881(b) of the Social Security Act to require the implementation of an end-stage renal disease (ESRD) bundled payment system effective January 1, 2011 (herein referred to as the “ESRD PPS”).

In the September 29, 2009 Federal Register (74 FR 49922), we published a proposed rule outlining the proposed ESRD PPS. This ESRD PPS proposed rule would implement a case-mix adjusted bundled prospective payment system (PPS) for Medicare outpatient ESRD facilities beginning January 1, 2011, in compliance with section 153(b) of MIPPA. The proposed ESRD PPS would replace the current basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services.

During this ODF, CMS staff will highlight the key features of the proposed ESRD PPS including the:

- composition of the bundle and basis for the proposed unit of payment;
- data sources used in developing the system;
- proposed patient-level and facility-level case mix adjusters;
- proposed outlier policy; and
- proposed market basket.

CMS will also discuss implementation issues associated with the proposed system, highlight key findings reflected in the impact analysis, provide a brief overview of the quality incentive program that CMS discusses as a conceptual model with the proposal of three quality measures for 2012, and summarize issues that have been identified for further analysis within the final rule.

Afterwards, there will be an opportunity for the public to ask questions.

Discussion materials for this Special ODF will be available to download at <http://www.cms.hhs.gov/ESRDPayment/> by October 14, 2009.

We look forward to your participation.

Special Open Door Forum Participation Instructions:

Dial: 1-800-837-1935

Reference Conference ID#: 26811397

Note: TTY Communications Relay Services are available for the Hearing Impaired.

For TTY services dial 7-1-1 or 1-800-855-2880. A Relay Communications Assistant will help.

An audio recording and transcript of this Special Open Door Forum will be posted to the Special Open Door Forum website:

http://www.cms.hhs.gov/OpenDoorForums/05_ODF_SpecialODF.asp and will be accessible for downloading beginning October 25, 2009 and will be available for 30 days.

For automatic emails of Open Door Forum schedule updates (E-Mailing list subscriptions) and to view Frequently Asked Questions please visit our website at

<http://www.cms.hhs.gov/opendoorforums/> .

Thank you for your interest in CMS Open Door Forums.

Audio file for this transcript: <http://media.cms.hhs.gov/audio/ESRDPPS101509.mp3>

Centers for Medicare & Medicaid Services
Special Open Door Forum:
End Stage Renal Disease Prospective Payment System Proposed Rule Overview
Moderator: Natalie Highsmith
October 15, 2009
3:30 pm ET

Operator: Good afternoon. My name is Krista and I'll be your conference facilitator today. At this time we would like to welcome everyone to the Centers for Medicare and Medicaid Services Special Open Door Forum on End-Stage Renal Disease Prospective Payment Systems Proposed Rule.

All lines have been placed on mute to prevent any background noise. After the speaker's remarks will be a question and answer session. If you'd like to ask a question during this time, simply press star then the number 1 on your telephone keypad.

If you would like to withdraw your question, please press the pound key.
Thank you. Miss Highsmith, you may begin your conference.

Natalie Highsmith: Thank you, Krista and good day to everyone and thank you for joining us on this Special Open Door Forum. Today on this Special Open Door Forum, CMS staff will discuss the End-Stage Renal Disease Prospective Payment System proposed rule.

The proposed rule is currently on display at the Federal Register and it was on display September 15.

Today's staff will highlight the following: composition of the bundle and basis for the proposed unit of payment, data sources used in developing the system, proposed patient level and facility level case adjusters, proposed outlier policy and proposed market basket.

Discussion materials for today's Open Door are listed on www.cms.hhs.gov/esrdpayment. I will now turn the call over to Ms. Janet Samen who is the Director of the Division of Chronic Care Management. Janet?

Operator: Excuse me. I have Regional Office Chicago has joined.

Natalie Highsmith: Thank you. Janet.

Janet Samen: Yes, thank you. Thanks for joining us this afternoon. We really appreciate the opportunity to present the key features of the proposed system and look forward to receiving your input on the proposal.

This proposed rule would implement the requirement in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) that CMS adopted to become effective January 1, 2011.

We believe the system will improve care in several key ways -- first by targeting increased payments to facilities with more costly patients thus improving access to care, by promoting efficiency while increasing ESRD facility flexibility in providing ESRD services, by eliminating incentives to overuse separately billable drugs and by establishing performance standards for dialysis facilities.

On Slide 2 is the agenda. I wanted to point out that on the slides, if you're following along on the slides, that there are Federal Register citations in the slide deck will help you in tracking the discussion to the regulation. The citations are located in the lower, right-hand corner of the slides.

Natalie already provided the agenda, so I won't go through that because there is certainly a lot to cover. The goal for this system was to propose a model with the maximum explanatory power.

With the valuable support in analyzing Medicare data that we receive from our contractor, the University of Michigan's Kidney Epidemiology and Cost Center, which we refer to as UM-KECC, we believe we've accomplished this goal.

I'd like to take a moment to thank Professor Richard Hirth and Dr. Marc Turenne and their colleagues at the University of Michigan for their contributions and support during this whole process.

In addition to the key features of this system, I'll also highlight key findings reflected in the impact analysis, provide a brief overview of existing policies and the implications under the PPS and touch on some key implementation issues that we've identified. And finally to summarize issues that we've identified for further analysis for the final rule.

And then, finally Jean Moody-Williams, our colleague in CMS's Office of Clinical Standards and Quality will provide an overview of the quality incentive piece that was included in the proposed rule.

And then hopefully we'll have time at the end to take some questions and comments.

Next slide. Following the origination of Medicare's ESRD benefit in 1972, the composite payment system became effective in 1983. The composite payment system included the cost of furnishing outpatient maintenance dialysis including routine drugs, labs and supplies.

However, new items and services emerged after implementation of the composite payment system that have been paid separately outside of the composite rates, most notably EPO and other injectable drugs.

Governmental entities including MedPAC and GAO have expressed concerns about the use of separately billable services and that many of these services were being overused.

And as a result, legislation was enacted in recent years to improve the accuracy of ESRD payment and eliminate incentives to overuse separately billable services.

We conducted studies examining the bundling of additional services into the composite payment system and the results of these studies were summarized in reports to Congress that were issued in 2003 and 2008.

Currently, we have three basic case mix adjusters, which were implemented April 2005, which put us closer towards one of the keys goals of the proposed ESRD PPS, that is, increasing the accuracy of payments by reflecting unique resource needs of individual patients.

The three basic case mix adjusters are age, body surface area and low body mass.

In Slide 4 I'll discuss the proposed payment bundle. The first step in developing the proposed bundle was to define ESRD related services. MIPAA specified these services as composite rate services, ESAs and oral forms of these agents, which have yet to emerge on the market, used in treating ESRD.

Other drugs and biologicals that are used to treat ESRD and any oral forms of these drugs for which payment was made separately under Medicare, and lab

tests and other items and services beyond those that were already included in the composite rate, used in the treatment of ESRD.

The composite rate services apply to patients treated in an ESRD facility as well as those receiving dialysis at home. Composite rate services include maintenance dialysis treatments and all ESRD related drugs, labs tests, equipment supplies and staff time.

The costs of self-dialysis training services for home patients is currently paid separately, that is in addition to the composite payment rate. We have included these training costs in the development of the proposed base rate.

We did not propose to include physician services in the ESRD PPS system. Payment for physicians would continue as it does today.

The remaining items listed on the slide are considered separately billable under Medicare part B or in the case of self-administered, oral drugs, currently paid under Medicare part D.

Only those services that are directly related to ESRD have been included in the bundle.

Oral Part D drugs that we proposed to include do not include drugs that are used in treating co-morbid conditions that are common amongst ESRD patients. Many ESRD benes suffer from diabetes and hypertension, for example, however the medications used in treating those conditions are not proposed to be included.

On Slide 5, oh, sorry. For the unit of payment, we have proposed that we would continue to make payment on a per treatment basis. While we considered a month unit of payment, we believe that the proposed per

treatment approach is the most administratively feasible, especially during the transition period.

Now, the next slide, Slide 5 is, we're going to discuss data sources that we used for the case mix analysis.

We were able to use the Medicare cost reports to collect cost information for composite rate services. Outpatient institutional claims and carrier claims collect information for utilization of separately billable services and Part D claims for utilization of ESRD drugs currently covered under Part D.

These data, with the exception of the Part D claims, were compiled and used to develop the case mix model, which is based on data sets that link claims and cost report records for calendar years 2004 through 2006.

We used data from those years because they represented the latest, most complete data available for the preparation of the proposed rule.

To calculate total payments for ESRD related drugs currently covered under Part D, we used calendar year 2007 Part D claims submitted by prescription drug plans for ESRD beneficiaries.

Next slide. For this proposed rule, we also used several data sources for evaluating patient and facility characteristics in the case mix analysis. Patient demographic information was obtained from REMIS, EDB and SIMS. These data sources include information reported on the medical evidence report form known as the 2728, which is completed at the onset of renal replacement therapy.

We obtained facility level characteristics from SIMS, cost reports, and OSCAR.

Slide 7. The base rate represents average Medicare payments for composite rate and separately billable services. Specifically proposed to include payments for the following renal dialysis services based on 2007 claims data in developing the base rate.

First composite rate services, durable medical equipment and supplies and dialysis support services furnished to method 2 home dialysis patients (these are patients that deal directly with the DME supplier to obtain their needed supplies, dialysis training services for home patients) Part B drugs and biologicals, laboratory tests billed by dialysis facilities or ordered by physicians receiving monthly capitation payments for treating ESRD patients, supplies and other services, for example, syringes used to administer IV drugs during dialysis, and current Part D drugs from a handful of classes that were determined to be used to treat ESRD.

Next slide. An update factor was applied to each component of the base rate to bring us up to 2011. This resulted in the projected 2011 unadjusted per treatment-based rate of \$261.58.

The wage index and all applicable patient and facility level adjustments were applied to this amount to determine the estimated payment amount for each treatment and ESRD facility.

We apply a wage index floor of 0.60 for the current system, but proposed to eliminate that floor for the proposed ESRD PPS.

Next, a standardization factor of 0.7827 to account for the positive effect of the case mix adjustments was then applied to the unadjusted base rate, bringing it down to \$204.74.

We then reduced that amount by 1% to account for the outlier policy. And finally the 2% neutrality adjustment required under MIPPA was applied, resulting in the proposed 2011 base rate of \$198.64.

In summary, \$198.64 reflects a base rate that would make total spending in calendar year 2011 98% of what would have been paid had there not been a new PPS.

The market basket adjustment minus 1%, which I'll discuss shortly, would update this base rate beginning in calendar year 2012.

Next slide. The transition budget neutrality adjustment is described in two parts. The purpose of the first part is to make payments the same as if there were no transition.

This would be computed separately for each year of the transition. The 3% budget neutrality reduction during the first year of the transition in 2011 would apply to all payments, that is payments made under the current system and under the PPS.

As for the second part of the transition budget neutrality adjustment, we've included a discussion about Part D drugs. Specifically when the PPS system is implemented in 2011, payments may no longer be made for ESRD related part D drugs outside of the PPS.

Thus, during the transition for the current payment system of the blended payment, there is no mechanism to pay for these drugs. To account for this, we have proposed a \$14 per treatment allowance applicable to the current payment system portion of the blend during the transition.

Consistent with MIPAA, this allowance facilitates our ability to make a single payment under Medicare for renal dialysis services furnished by ESRD facilities.

We believe that our proposal to apply the transition budget neutrality adjustment factor to all payments to evenly distribute the effect of the adjustment would help to ensure that facility incentives would op out of the transition would not be affected.

Next slide. Section 153(b) of MIPAA requires that effective 2012 that the bundled payment amount be annually increased by an ESRD bundled market basket increase factor minus 1%.

The statue also requires that the market basket increase factor should reflect the changes over time and the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

Although the term market basket technically describes the mix of goods and services used to provide care, this term is also commonly used to denote Medicare's various PPS input price indexes, for example those associated with updating payments to IPPS, skilled nursing facilities and other Medicare providers.

These market baskets have historically been integrated into the Medicare program and are intended to measure the price changes of the input such as labor materials and so on associated with the services furnished by Medicare providers.

In accordance with the statutes, we've developed an all-inclusive ESRD bundled rate known as the ESRDB input price index.

The ESRDB contains a set of mutually inclusive and exhaustive input price cost categories, their respective weights or shares of the total and associated price proxies. For example, the ESRDB contains a prescription drug input cost category with a cost weight of 30.7%. And it identifies that the producer price index for prescription drugs was assigned this category's price proxy.

The ESRDB would also be used to update the composite portion of the ESRD payments during the transition from calendar year 2011 through calendar year 2013.

Next slide. The resources required to furnish routine dialysis vary by patient. For example, it may require a higher and thus more costly dose of medication that is based on body weight for a larger patient to have the same affect than would be required for a smaller patient.

Another example is a severely disabled, frail individual who may require more staff time than a healthier one. As a result, facilities that treat a greater than average proportion of resource intensive patients could be economically disadvantaged if their payment rate is based on average resources and may in turn result in disincentives to treat or provide requisite care for costly patients.

Our analysis in the proposed rule builds on the current case mix payment system that adjusts for age, body surface area and low body mass index. Thus, the base rate would be adjusted using patient specific case mix adjustment factors developed from two equations, one for composite rate and one for separately billable services.

These adjusters were developed using standard techniques of multiple regression to yield case mix adjusted payment per treatment that includes age, body surface area, low BMI, sex, 11 co-morbidity categories and the onset of renal dialysis.

Next slide. Let's start with patient age. As we found when we developed the current payment system, when comparing costs for each age group to a reference group, the regression indicated that the Medicare allowable payments rise as patient age increases.

Age groupings were determined based on the stability of the data and the similarity of the adjustments for the ages within each group. Although ages 60 - 69 is the reference group under the current payment system, the group 45-59 is the reference for this proposed rule because it was identified as the lowest cost group.

Due to the small number of pediatric patients we proposed to use a separate regression analysis, which I'll discuss in a moment.

Next, patient sex. Unlike with the analysis used to develop the current payment system, where we found male patients more costly, the analysis for this proposed rule found that female ESRD patients were more than 13% more costly per treatment than male patients even when body size measures are included.

We believe that this is primarily due to the addition of the separately billable services in the analysis.

Body size. For this proposed rule we analyzed both of the measures individually, both body surface area and body mass index, and found that they continued to be strong predictors of cost variation for ESRD patients.

Under the proposed rule, the payment adjustment factor for body surface area is a 3.4% change increase or decrease in cost for every 0.1 meter squared change in BSA from the national average of 1.87.

As in the current payment system, we continue to use the measure of low BMI as less than 18.5 kilogram per metered squared in the proposed rule because it is consistent with the CDC and NIH's definition for malnutrition. The adjustment factor in the proposed rule is 2%.

Next slide. The regression analysis using data that reflected the amount of separately billable payments relative to the number of months the patient has been on dialysis, showed that there are higher costs in the first four months of dialysis.

We believe the higher costs are attributable to the need to stabilize the patient's condition, administrative and labor costs associated with patients being new to dialysis and the initial cost incurred for training patients and their caregivers to perform home dialysis.

We propose to define onset of dialysis beginning with the start date reported on the 2728, through the first four months of dialysis. However only the period of time during that first four months of dialysis that occurs while the patient is under the Medicare ESRD benefit would be eligible for the adjustment.

In developing the current basic case mix composite payment system, we considered a large number of specific co-morbidities. However the data on claims was limited at that time and we encouraged ESRD facilities to report co-morbidities for use in future analysis.

For the proposed rule there were still very few ESRD claims that contain co-morbidity codes. As a result, the co-morbidities we tested used a combination of the conditions reported on the 2728 and on claims in various setting such as

skilled nursing facilities, physician offices, suppliers, hospice and home health.

We defined co-morbidities as specific, concurrent patient conditions that are secondary to the principal ESRD diagnosis. The mere presence or history of the condition that has no affect on costs would not be eligible for the adjustment.

Our analysis for the proposed rule found that 11 co-morbidity categories had statistically significant relationships to per treatment costs and would be eligible for a co-morbidity adjustment.

The co-morbidity categories are listed on the slides and we provided a list of relevant ICD codes used in the analysis in these proposed rules. As you can see the list includes some time limited adjustments and others that would be paid if the patient had ever had the condition.

Next slide. In accordance with MIPAA, we considered race and ethnicity as one of the patient characteristics in development of the proposed rule, but did not propose to incorporate them.

Using regression analysis, we relied on two separate data sources to assess the extent to which race and ethnicity would account for cost factors that are otherwise unexplained in the models.

The first source was from REMIS, which includes data, obtained from the 2728. The second is from the enrollment database, which is populated with data obtained form the Social Security Administration, which includes ethnicity as a racial category as well as data from the Railroad Retirement Board.

We determined that due to concerns with the quality of data on race and ethnicity in REMUS and EDB, we did not believe that the data was of sufficient quality upon which to base payment adjustments for a number of reasons.

First, there have been two versions of the 2728 during the analysis period, each with different categorizations for race and ethnicity. This leads to a need to default a significant number of these individuals into the Other category to reconcile differences between the two versions. Second, the 2728 is routinely completed by the ESRD facility physicians. Third, the EDB does not contain race and ethnicity on behalf of the railroad industry for those entering the railroad system prior to 1964. Fourth, race and ethnicity classification of some segments of the population is either unavailable or defaulted into the Unknown category within the EDB.

Fifth, the Enumeration at Birth process in place since 1989 allows parents to obtain a social security number on behalf of their newborns without filing an SSA application which captures race and ethnicity data, so unless there's a subsequent need to file a new SSA application, we are unaware of a mechanism by which this information ever finds its way into the SSA system.

And finally, race and ethnic categories are not well defined. And it is not possible to identify absence at genetic testing. We plan to explore opportunities for improving data on race and ethnicity in accordance with the requirements in section 185 of MIPPA. That section requires evaluating approaches for Medicare data collection that would allow for evaluation of data on disparities in healthcare services and performance based on race, ethnicity and gender.

With respect to modality, because composite rate costs and separately billable payments are lower for a Peritoneal Dialysis or PD, the use of modality as a payment variable would result in lower payments for an adult PD patient.

Since we want to encourage home dialysis and we believe that the lower payment for PD would discourage the increased use of PD, we are proposing a PPS which does not make separate payment rates based on modality.

However, in the case mix adjustments proposed for pediatric patients, we do distinguish between HD and PD as a payment variable.

Next slide. In the next slide we'll talk about the pediatric analysis. We attempted when implementing the current payment system to develop case mix adjusters for outpatient ESRD patients under the age of 18, however we found that for the approximately 600 patients for whom we had data in 2000 through 2002, the results were highly variable and statistically unstable and therefore inappropriate for the development of case mix adjusters.

MIPAA provided that beginning October 1, 2002, ESRD facilities in which at least 50% of patients are under 18 are considered pediatric facilities and are eligible for a pediatric exception to its composite rate.

However, due to the costliness of providing dialysis to the pediatric population, we believed that we should develop a temporary methodology for ESRD facilities that provided pediatric dialysis regardless if the facility met the pediatric facility definition.

This methodology resulted in an adjustment factor based on the average amount of the atypical service exceptions granted for 20 ESRD facilities that sought and received an exception compared to the average unadjusted composite payment rate for the same 20 facilities.

This comparison results in a 62% adjustment factor automatically applied to the composite per treatment payment rate for all pediatric patients.

For the proposed rule, the small sample size also limited the potential payment adjusters for separately billable services in the proposed models. Unlike the adult model with multipliers for co-morbidities, age, body size and other variables, the pediatric model includes only age, the presence of co-morbidities regardless of the type, and dialysis modality.

Because of the small number of pediatric patients, we limited the number of age groups to two, less than age 13 and ages 13 to 17 where the data had a natural break related to body size and greater use of resources.

The result of our analysis was a proposed payment model which reflects eight possible case mix adjusters determined by the pediatric patient's classification using the two age groups, two dialysis modality groups, that is, hemo or PD, and two groups based on the absence or presence of co-morbidities.

Next slide. With respect to the wage index, we propose to continue to use the same method and source of wage index values as we do in the current payment system, which is based on hospital wage data.

For calculation purposes, we currently use OMBs, CBSA-based geographic area designations to define urban and rural areas and corresponding wage index values. The ESRD wage index values are calculated without regard to geographic reclassifications and utilize pre-floor hospital data that are unadjusted for occupational mix.

Then a wage index budget neutrality factor is applied so that changes in the wage index do not increase or decrease aggregate ESRD payments.

While we are choosing to use the same method and source of wage data that we currently do, there are some slight changes that we'd like to make for the PPS.

Under the current payment system, we apply a floor as a substitute wage index for areas with very low wage index values. However since calendar year 2005, we have been gradually reducing the floor in an effort that patient access in areas that have low wage index values would not be compromised.

During the transition, which I'll discuss in a moment, we intend to continue to gradually reduce the ESRD wage index floor for the portion of the payment that is based on the current payment system.

Lastly, we propose to use the labor share from the proposed ESRDB market basket, which is 38.16 instead of the existing labor share from the ESRD market basket, which is 53.711.

The labor-related share for the proposed PPS is lower because there are no labor costs associated with the separately billable portion of the proposed ESRD bundled market basket.

Nest slide. MIPAA required us to define what a low-volume facility is and required us to develop a payment adjustment that reflects the extent to which costs incurred by low-volume facilities exceed the cost incurred by other facilities in furnishing those services and that the payment adjustment not be less than 10% during the transition.

Next slide. We use data from the Medicare cost reports SIMS and OSCAR for calendar year 2004 through '06 and performed the analysis that allowed us to

determine what ESRD facility level characteristics best demonstrate a low-volume facility.

The variables we considered to be major contributors to cost were facility size in terms of treatments, facility ownership type and location, specifically urban versus rural.

Next slide. Based on the results of the analysis, we determined that a low-volume facility is an ESRD facility that furnished less than 3000 treatments in each of the three years preceding the payment year and has not opened, closed or received a new provider number due to a change in ownership during the three years preceding the payment year.

We found that the threshold of 3000 treatments struck a balance between establishing an increment in payment that reflects the substantially higher treatment costs incurred by low-volume facilities, but still apply to a large enough number of facilities to have an impact.

We believe that those facilities that furnish less than 3000 treatments over three years demonstrate consistency in furnishing a low volume of treatment.

We chose to exclude facilities that opened, closed or received a new provider because again we want to capture those facilities that have routinely furnished a small number of treatments per year.

In order to identify which existing ESRD facilities meet the low volume criteria, we proposed that they would attest to their FI that they qualify. Under this approach the FI or MAC would verify the ESRD facility's attestation using the facility's final settled cost report.

However, we're concerned that the low volume adjustment could be an incentive to the establishment of small ESRD facilities in close geographic proximity to other facilities, leading to unnecessary efficiencies in order to obtain the low volume adjustment.

Therefore, we proposed additional criteria. For purposes of determining the number of treatments considered furnished by a facility, we would take the treatments provided by that facility and combine them with the number of treatments furnished by other ESRD facilities that are both under common ownership and within 25 miles or less from the facility in question.

Although we propose to limit the application of the low volume adjustment to ESRD facilities with common ownership, we propose to grandfather in the ones that have been in existence and certified for Medicare participation on or before December 31, 2010 from the treatment determination requirement and the geographic proximity restriction.

Based on the analysis, we determined that the resulting proposed low volume payment adjustment would be a 20.2% increase. However, we did discuss in the proposed rule, other options that we are considering such as the 10% adjustment, as described in the statute, and a 15% adjustment.

Next slide. There are issues that have developed subsequent to the proposed rule getting published that we are currently evaluating. One issue is that there are Medicare certified ESRD facilities that solely furnish support services and training for patients that receive PD or home hemodialysis that may be eligible for the adjustment.

We will need to consider if these types of facilities would be paid the low volume adjustment.

Because of our concerns, we believe it's necessary to monitor changes in the ESRD industry's behaviors and emerging trends nationwide. In working along with the regional offices, we would be able to monitor survey and certification activities and impose additional safeguards that may be necessary in the interest of program integrity.

Next slide. There are two other facility level adjustments that we considered. The first was regarding facilities located in Alaska and Hawaii. We considered providing a cost of living adjustment for those facilities, however we did an analysis to see if a COLA was needed.

We found that the proposed ESRD PPS would adequately reimburse those facilities and therefore did not propose this adjustment.

The second was regarding rural status and we found that the rural ESRD facilities as a group would be adequately reimbursed under the proposed PPS and again for this reason we did not propose a rural adjustment.

But it's important to note that during the analysis for the low volume adjustment, we found that out of all the facilities that meet the low volume criteria, approximately 40% were located in rural areas.

Next slide. Next I'm going to talk about the proposed outlier policy. The outlier adjustment is one of the required adjustments of MIPPA. It's intended to protect the ESRD facilities from significant financial losses that could result from unusually high cost patients.

Outlier eligibility would be determined at the patient level and any outlier payments would be added to the per treatment payment amount. We propose to define outlier services as the current separately billable items and services under Part B and the current separately billable renal dialysis service drugs

under Part D currently covered under Part D, but proposed for inclusion in the PPS.

Next slide. Under the proposed policy, we would compare the facility's predicted payment amount for outlier services to its imputed payment amount for those same services to determine eligibility for outlier payments.

An individual patient's predicted payment amount would be based on his or her outlier services case mix adjusters multiplied by an adjusted average outlier services payment amount.

Part D payment amounts have not yet been incorporated into the case mix regressions models. The current adjusters, which are simply the separately billable, case mix adjusters are understated for this reason. However, we intend to build Part D payments in to the regression model for purposes of establishing the outlier services case mix adjusters in the final rule.

An individual patient's imputed payment amount would be based on a tally of the individual outlier services listed on the monthly claim and priced in CMS systems divided by the corresponding number of treatments furnished in that month.

Items and services that are currently billed separately under Part B would continue to be priced as they are today. We have not yet determined an appropriate pricing mechanism for the renal dialysis service drugs that are currently paid under Part D. However, the proposed rule lays out a few possibilities such as relying on pricing mechanisms reported by the industry or CMS or on ESRD facility costs.

A facility would be eligible for outlier payments when the imputed payment amount exceeds the outlier threshold plus the predicted payment amount.

Next slide. A facility's high cost above the sum of the individual's predicted payment amount plus the fixed dollar loss amount would generate an outlier payment.

Specifically Medicare would pay a percentage of this amount. The percentage proposed at 80% is referred to as the loss sharing percentage. We propose an outlier percentage of 1% of total aggregate payments.

We believe that this percentage strikes a balance between protecting ESRD facilities from significant losses due to high cost patients, but it also provides an appropriate level of payment for months that do not qualify for outlier payment.

Next slide. We'll get into the impact analysis. The purpose of the impact analysis is to show how ESRD facilities are affected by the proposed PPS. To understand the impact of changes affecting payments to different categories of ESRD facilities, we compared estimated payments in calendar year 11 under the proposed PPS to estimated payments under the current payment system.

In order to estimate payments in calendar year of 2011, we estimated which facilities would elect to be paid 100% PPS in 2011 by opting out of the transition. We did this by estimating two payment amounts for each facility.

First, what they would be paid in the first year of the transition using a blend of 25% of payments under the proposed PPS and 75% under the current composite payment system or opted for the transition and what each facility would be paid in the first year of the transition if they were paid entirely under the PPS, therefore opting out of the transition.

We assume that the facility would elect whichever would give them the highest payment. Based on these assumptions, we estimated that 36% of ESRD facilities would choose to opt out of the transition.

In the impact table we also showed the hypothetical effect if all facilities opted to be paid 100% PPS in 2011.

In the next slide we'll talk about existing ESRD policies and other issues. We reviewed many other existing ESRD policies to determine whether they should still apply under the proposed PPS.

The first is exceptions under the case mix adjusted payment system. We propose to eliminate on or after January 1 2014, the cost and training exceptions currently in effect.

No further exception windows would be opened effective for services furnished after January 1, 2011. In the event though that an ESRD facility elects to receive full payment under the ESRD PPS, January 1, 2011, any existing exceptions would no longer be recognized.

We believe that we've addressed the higher cost related to case mix through the patient characteristics adjustments and the outlier payment policy.

With respect to ESA claims monitoring policy, we're currently evaluating the extent to which we would continue this policy under the PPS. And how we might apply the ESA claims monitoring policy to establish eligibility for outlier payments.

With respect to the 50-cent deduction to fund the ESRD networks, we propose to continue that approach under the PPS as described in the Medicare Claims Processing Manual.

And then with respect to bad debts, under the PPS bad debt would continue to be made for the unpaid Medicare deductibles and co-insurance amounts for only those items and services associated with the basic case mix adjusted composite rate.

In other words, the goal is to prevent bad debt payment for services paid under fee schedules or PPSs which is consistent with bad debt policy overall.

Next slide. MIPAA explicitly provides for limitations on administrative or judicial review on the determination of payment, establishment of the unit of payment, identification of renal dialysis service included in the bundle, the adjustments, application of the transition and the establishment of the market basket.

With respect to the 50% rule utilized in laboratory payments, currently as specified in the claims processing manual, if 50% or more of the covered laboratory tests within the AMCC test panel are included under the composite rate payment for a particular date of service then all submitted tests are included within the composite payment and no separate payment is made to the other lab.

If less than 50% of the covered lab tests under the AMCC are composite rate tests, then all AMCC tests are separately payable.

We are considering excluding AMCC tests subject to the 50% rule from the definition of outlier services thus negating the need to apply this rule under the PPS. We are continuing to evaluate the impact of this approach.

And then finally, with respect to Medicare secondary payer policies, we are exploring how MSP systems operations and billing procedures would be utilized and managed under the PPS.

We believe that while there may be systems changes to process claims, we should see no significant impact on ESRD providers and on primary payers.

We would issue any changes to this process through administrative issuances.

In the next several slides, we'll get into transition and implementation issues.

MIPPA required us to provide a four-year transition period during which payments would be based on a blend of the payment rates under the current payment system and on the new PPS.

In addition, MIPPA permitted facilities to make a one-time election prior to January 1, 2011, to be excluded from the transition. We're also required to make an adjustment during the transition to ensure that payments made during this time frame are budget neutral, which I discussed earlier.

To implement the transition period, we propose to blend payments made under the current and new systems in increments over a four year period.

The blends starts with 75% of the current system's payments and 25% of the PPS beginning January 1, 2011 and continuing until January 1, 2014 when payment would be based 100% on the PPS.

As I mentioned, MIPPA permitted facilities to make a one-time election to be excluded from the transition. The facilities would not be able to rescind their election once it's made. We propose that facilities notify CMS of their

election choice in a manner established with the respective FI or MAC no later than November 1, 2010.

We further propose that those facilities that fail to submit an election by then, that payment for those facilities would be based on the blended payment amount and any elections submitted after that time would not be accepted.

We do not believe that new ESRD facilities would require a transition period in order to make adjustments to their operating procedures and therefore new facilities that begin to provide renal dialysis services and home services to Medicare beneficiaries after January 1, 2011, would be paid based entirely on the PPS.

Next slide. Because ESRD facilities would receive an all-inclusive payment during the transition, other entities such as Method 2 DME suppliers, laboratories and Part D plans would no longer be paid by Medicare for these beneficiaries beginning January 1, 2011.

To the extent that these entities finish items or services to ESRD patients they would need to seek payments from the patient's ESRD facility.

Those items and services that are currently paid separately under Part B or Part D would be priced to reflect how they are currently paid, for example, using the fee schedule or ASP amount.

Next slide. The basic case mix adjusted composite payment system portion of the blend would be comprised of the composite payment rate, which is adjusted by the basic case mix adjustment and the wage index, the drug add on amount, payment for items and services that are currently separately paid under Part B by Medicare to entities other than the ESRD facilities, and the ESRD market basket.

In addition to those components, as part of the transition budget neutrality adjustment we discussed earlier, we're also proposing to include a \$14 adjustment, which accounts for ESRD related drugs and biologicals that are currently paid under Medicare Part D.

Next slide. The ESRD PPS portion of the blend includes the base rate and all applicable patient level and facility level adjustments that I described earlier.

We're also proposing the outlier payments would be paid in addition to the adjusted per treatment payment amount.

With respect to beneficiary co-insurance, in general, beneficiaries are subject to a 20% co-insurance on most Part B services and for ESRD would work this way as well. Therefore we propose that a 20% beneficiary co-insurance would be applicable to the ESRD PPS base rate and include all the adjustments and outlier payments or the blended payment amount for those facilities that transition.

Nest slide. Implementation of the PPS would require changes in the way we process claims. Some of the changes would entail consolidated billing rules and edits to avoid payment to facilities other than the ESRD facility.

Since the ESRD PPS payment model represents an all-inclusive payment for all dialysis items and services, the facility itself would be responsible for all of the services mentioned earlier that its patients receive, including oral self-administered ESRD drugs.

We expect that ESRD facilities would establish arrangements with pharmacies in a manner that would facilitate beneficiary access to renal dialysis service drugs or provide those drugs directly.

The consolidated billing approach confers to the ESRD facility itself, the Medicare billing responsibility for all of the renal dialysis services that all of its patients receive.

We believe that this approach would mitigate duplicate payments for situations such as lab tests or drugs ordered or administered by physicians.

However, we recognize that there would be instances where services would be furnished to ESRD patients that would be outside of the services in the ESRD bundle and we will address this through administrative issuances.

Home dialysis supplies and service furnished under Method 1 and Method 2 regardless of home treatment modality are also required by MIPPA to be included in the bundle.

Therefore, we propose that the Method 2 home dialysis approach would be eliminated and all home dialysis would be provided under Method 1 effective January 1, 2011. This is because after that time we are no longer authorized to pay DME suppliers.

Next slide. In the next slide, I'll talk about further analysis. In order to prepare for the final rule there are number of activities that we will do to ensure that we've developed a strong model for the PPS.

We will update all of our data sources with the most current data available and re-run all of the analyses that we used to make decisions on what was included in the bundle.

We expect to include available payment data from Part D claims from calendar years 2006 through 2008 in our development of the regression based

case mix adjusters for the overall payment models and will address their inclusion in the final rules.

We expect to use 2008 claims data to establish the base rate. And we plan to update the wage index values by using the latest hospital wage data issued before January 1, 2011.

And finally we will thoroughly review all the comments that we receive during the comment period and consider incorporating them into the regulation.

As we mentioned in the proposed rule, there were issues that developed subsequent to the proposed rule being published that we are currently evaluating for inclusion in the final rule.

We are considering a proxy to capture the cost associated with ESRD drugs for those patients without Part D coverage. One possible approach we discussed would be to include payments under the Retiree Drug Subsidy Program.

We also need to consider the extent to which the 50% rule that pertains AMCC laboratory tests, separately billable under the current system, should continue in relation to the outlier policy and the ways in which outlier payments would be computed under the PPS.

We believe that any dosing reductions associated with any application of the ESA claims monitoring policy would be factored in to determining eligibility for outlier payments.

And now I am going to turn this show over to Jean Moody-Williams to talk about the quality incentive program.

Jean Moody-Williams: Thank you very much and if we could turn to Slide 4 we will move to talk about MIPAA section 153-C, which requires (unintelligible) to create a Quality Incentive Program, which I will refer to as the QIP, to promote improved quality of care for ESRD patients.

The QIP helps ensure the quality of services delivered under bundled payments. Generally the QIP must include and TMX must select measures, which I'll talk about shortly.

We must establish the performance standards that apply to the individual measures, specify a period of performance, develop a methodology for assessing the periods of performance and performance of each provider and facility. And then we must provide the "apply the appropriate' methodology for a payment reduction.

We have included a conceptual model in the rule for comment. On Slide 36 we look at the QIP and note that we have a performance standard that's included in the conceptual model and we are considering adopting a national performance standard that is equal to the average performance of all dialysis providers and facilities on each measure based on 2008 data.

This data will be posted on dialysis facility compare in November 2009. Special rule allows the performance standard to be the lesser of the facilities performance rate and the national performance rate for each measure.

So we would look at the provider facilities specific rate for the base year if the performance was below the national average.

Regarding the period of performance we are also considering a period of performance from January 1, 2010 through December 31, 2010 or some portion of that time.

Regarding the performance scoring, the models that are included in the conceptual model weights the measures equally. We invite your comments in this area.

For payment reduction, by law, CRS has the authority to reduce the payment by up to 2%. On Slide 36, we express the goals of the QIP in which we attempt to align payment with quality and in sync provide quality and safety for beneficiaries.

We are also attempting to promote efficiency and we want to be sure to minimize the risk of unintended consequences that could be associated with a bundled payment system.

In particular we will be concerned about under utilization, access, potentially increasing healthcare disparities, impact on vulnerable facilities or other unintended consequences.

We are also having a goal to improve transparency for beneficiaries and other stakeholders.

On Slide 37, we began a discussion of the measures. While the model is conceptual, we are actually proposing the measures reviewed. We have proposed three claims based measures focused on anemia management and hemodialysis adequacy.

Our rationale for these measures include the fact that they fulfill the statutory requirements, the measures have been in use for several years by facilities and

are publicly reported and CMS has data available to develop and test the various models.

Providers and stakeholders are also familiar with these measures as well as the beneficiary. Additionally we have a very short time frame to implement the QIP and to finalize the measures limiting the time that's available to develop new measures.

On Slide 38 we look specifically at the claim space measures, which include anemia management, the percent of patients whose hemoglobin is less than 10 and the percent of patients whose hemoglobin is greater than 12.

Under hemodialysis adequacy we will look at the percent of patients whose URR is greater than 65%. Anemia management and hemodialysis measures were mandated by MIPAA 1853-C and both measures reflect the current FDA labeling guidelines in addition to being reported on dialysis facility compare since 2001.

Moreover the calculations that a provider facility averages at both the local, the state and the national levels for these measures has been consistent since the inception of dialysis compare.

CMS wants to make clear that again that this is a conceptual model with the exception of the three measures that we're proposing. The model described represents our current thinking and consideration for payment year 2012, however we anticipate that this program will evolve and as we go through our additional analysis it will continue to evolve as we receive public and entity feedback as well.

On Slide 39, we did want to address, as well, public reporting. We will publish a proposed rule on public reporting requirements at a later date,

however at this time we are seeking public comments regarding how to best implement the public reporting required.

And with that I will turn it back over to me for a question and answer period.

Natalie Highsmith: Krista if you could just remind everyone on how to get into the queue to ask their question. And everyone please remember when it is your turn to re-state your name, what state you are calling from and what provider or organization you're representing today.

And also please be mindful that because this is a proposed rule that your comments today are not formal submissions and we encourage you to follow the formal submission process that is outlined in the federal register notice.
Krista?

Operator: At this time I'd like to remind everyone if you would like to ask a question, please press star and the number 1 on your telephone keypad. Our first question comes from the line of Richard Berkowitz from Illinois. Your line is open.

Richard Berkowitz: Hi. I'm Richard Berkowitz and I am founder of the Next Stage Users Group. We are a group, we're probably the largest group in the country, of people who use the next stage dialysis machine.

If you can refer to Page Number 13, one of my concerns is the fact that training is now part of the bundle and where as before I think centers were getting paid \$20 per training session which in itself was not enough.

But I find it ironic that when we're talking about the patient level adjustments, which is the 47.3% adjuster, one of the reasons for it is initial home training, but I think if you look at the data I think you'll find that a great majority of the

people who start home training or home dialysis, do it after a long stay in center, which means if they would start in center under Medicare, the centers would get the 47.3% adjuster and there would be no money left over for the training, which I had to go through, which was quite intensive.

I find that this might be a disincentive to home dialysis, which is not what we're trying to do so it might be an inadvertent disincentive because if training centers are not getting sufficient funds to pay for their nurses to do the training, they might not want to continue their programs at the same rate they're doing it now, which in effect might affect the people who are currently on home dialysis, like myself.

So that is basically my comment on that.

Janet Samen: Okay, well listen, thank you very much for expressing that. I mean, we included training in the bundle consistent with the requirements of MIPAA.

Richard Berkowitz: But the question is whether that was sufficient considering what the cost of what training is and so I really do find it ironic that the adjuster infers that it's for home training, but in essence it may not be that at all.

Janet Samen: You may be very well correct, but thank you very much.

Richard Berkowitz: Thank you.

Operator: Our next question comes from the line of Cynthia Schuster from Virginia. Your line is open.

Cynthia Schuster: Hi. Yes, my name is Cynthia Schuster. I'm calling from Virginia. I have a more technical question. I wanted to confirm that myelodysplastic syndrome was intended to be a case mix adjuster on the separately billable side?

There's a, two tables in the proposed rule contradict each other on whether it's included.

Terri Deutch: Hello. We did recognize that we had inadvertently left out the codes that would be required to indicate that presence. The one that we eliminated was a topic and a heading and as we indicated in the proposed rule, we were not going to acknowledge headings a code that would be live for determining if there would be eligibility for the adjustment.

So we are aware of that and we do apologize and we will make sure that we include that in the final rule.

Cynthia Schuster: Okay. I just wanted to make sure I was interpreting it correctly.

Terri Deutch: You did interpret it correctly.

Cynthia Schuster: Okay. Thank you.

Operator: The next question comes from the line of Kelly Yori from Pennsylvania. Your line is open.

Kelly Yori: Hi. My name is Kelly Yori. I'm calling from Davita. And I have a question about the bundle. Has there been any consideration to the formatting of our services meaning right now we send itemized services over, LIDS line item data service.

The concern that I have is not more or less with the Medicare claims submission, but how secondary payers will react to the claim itself specifically the Medicare remit.

We do have some Medicaid's that are considered bad debt, so they pay up to the allowables base do Medicare payment. My concern is that this Medicare is going to be making a payment only on the treatment, how are the states going to allocate back to their fee schedule what they may have paid if they were primary.

Janet Samen: This is Janet Samen. We do plan on an outreach campaign to talk to states, to find out, you know, to present this issue and figure out a solution because we need the detail on the claims for appropriate payment for future analysis, but we realize that they will complicate, that may complicate some of the secondary payers or the payment of co-insurance.

So we recognize that as an issue and it's something that we're planning towards.

Kelly Yori: Okay. On that note, with the outreach, I was hoping to hear that, but will you be keeping providers up to date or abreast of how these states and or other payers are planning on dealing with it and even solicit help as needed.

I personally know that the bundle was coming. I've reached out to some payers already to send some test claims and I would certainly be more than grateful to assist you with anything. So please keep that in mind.

Janet Samen: Yes, thank you very much.

Kelly Yori: Thank you.

Operator: The next question comes from the line of Dori Schatell of Wisconsin. Your line is open.

Dori Schatell: Hi my name is Dori Schatell from the Medical Education Institute in Wisconsin and one of the things that we (unintelligible), but I wanted to echo Rich Berkowitz's concern about incorporating training for home hemodialysis into the bundle.

I heard in your comment that you said that congressional intent was to include training, however it does acknowledge in the MIPAA document that under the increased costs that the first four months includes training, which would suggest that that's an acknowledgment that the cost of home training are actually not usual care and should not be included.

I had a question about the 2728 and who completes it because I believe I heard that the assumption was that the nephrologist gets the 2728 form?

Natalie Highsmith: Right, you are fading in and out, can you talk a little closer to the microphone, please?

Dori Schatell: Do you have any data to support that the 2728 form is in fact completed by a nephrologist because that has not been my experience.

Janet Samen: We believed it was by facility staff. We thought it was more a facility staff.

Dori Shatell: And are there any data corroborating the validity of what is in the 2728 because an awful lot is riding on those data.

Janet Samen: No.

Dori Schatell: Okay because unfortunately garbage in, garbage out. It's really important if we're basing a whole bundle on 2728 that the 2728 data collection be accurate and I'm not convinced that they are.

Jean Moody-Williams: We agree and we are looking into the validity of the data for the 2728, particularly as we move into quality improvements.

Dori Schatell: Okay. And what I wanted to say earlier and I'm not sure you could hear me because I had my phone on speaker is I wanted to echo Richard's concerns about training. Seems to me that by saying that the first four months includes the cost of training, that's an acknowledgment that those costs are not usual care and should not be included in the bundle.

And my final quick comment is that any change in the total bundle payment for a patient changing that patients 20% co-insurance payment and there are some tremendous potential impacts on patients from bundling any oral medications and the laboratory tests and the even the co-morbidities that I don't think have been fully explained.

Janet Samen: Thank you.

Operator: The next question comes from the line of Lori Spalding from New York. Your line is open.

Lori Spalding: Hi. This is Lori Spalding from New York. I would just like to understand a little bit better about the four-year phase in period.

So if we're dispensing or contracting with pharmacies to provide these Part D meds and we have, you know, additional expenses that were, you know, previously we didn't have to worry about and if we, how exactly is the payment, how does this all work?

If I phase in over four years, do I initially start the first year start providing those services and I get reimbursed at 75% of my old and 25% how and how are these services paid for if I transition in?

Janet Samen: Okay. The way the payment would be computed is in the first year you would identify all of the services on the claim. We would price them as if it were under the current composite payment system and attach the use the same sources of pricing that we currently do under the current system for drugs.

And then we would also compute 100% of what the payment would be under the PPS and then we'd take the appropriate percentage depending on what year of the transition you're in.

So in the first year it will be 25% of the old payment approach and 75% of the new. Second year it's 50/50. Third year it will be 75% of the new system and 25% of the old and then we're at 100%.

But we compute it all at 100% under both methods.

Lori Spalding: So we would then contract with say the labs and they the pharmacies and pay them directly as if they were receiving it from you folks and we just receive it from you according to which way its.

Janet Samen: Right. Because we are not allowed after January 1, 2011, we are not allowed to pay anyone other than the ESRD facility for all of the services in the bundle, so we have no authority to pay a lab after January 1, 2011 or a Part D plan or any other provider.

Lori Spalding: Right. My last comment there is I wonder if they've actually realized the total amount paid for Part D's because I'm afraid that a lot of our patients hit the donut hole historically around April, May, June, July, so if you're looking at you know, what you've paid out for Part Ds, if what doesn't include when they hit the donut hole and they have to pay out of pocket you know are you really missing maybe half of what they're paying for these medications.

So it might be better to look at what an average dialysis patient pays on medications and you know, and look at that over a 12-month period versus looking at what you've been billed for.

Janet Samen: My understanding is that when we analyze the Part D data, we were aware of the amounts. Now if you're saying that those prescriptions were never filled.

Lori Spalding: Right.

Janet Samen: That is, there may in fact be a gap in the data for prescriptions that were not filled, but all we can do is look at the data that we had for Part D.

Lori Spalding: Well that's what I'm afraid of is that, you know, I think if you see that you know, you see a number that's a certain rate for the first few months and then it seems to dive at the end of the year. Patients don't fill their prescriptions or they cut their doses in half, those kinds of things.

Janet Samen: Fluctuations over the course of the year. We did see fluctuations in the use of Part D.

Lori Spalding: Right. They tried to get samples and that sorts of things. But I thank you for toady and I will be submitting some comments to your site.

Janet Samen: Great. Thank you.

Lori Spalding: Thank you.

Operator: Your next question comes from the line of Bill Peckham from Washington. Your line is open.

Bill Peckham: Hi. This is Bill Peckham and just to follow up on again on that Part D and how you captured the cost. I was trying to understand when you were on Slide 33 of how the retiree drug subsidy connects to that.

And in addition to people not maybe taking their meds towards the end of the year, for Medicare primary beneficiary to have employer group health plan secondary, the you know, Medicare isn't paying for those drugs now, but under the bundle they will be.

So I'm wondering how you captured, can you explain it just again how you captured all current drug expenditures that for the beneficiaries that will now be covered under the expanded rule, how did you get all the medication costs into that?

Janet Samen: Well, we know that approximately 2/3s of the ESRD patients have Part D. We also know that 15% of them don't have any Part D claims. So there is at least this third of the patients that are currently getting coverage for prescription drugs from an employer plan, a union plan or out of pocket or some other way.

And we do make payments under the retiree drug subsidy program per person to help those employer plans continue to provide prescription drug coverage.

And so we just mentioned that as one possible approach to trying to account for additional monies paid under Medicare. The statute tells us to add up everything that's paid under Medicare with respect to this and then, you know, advance that to 2011 and take 2% off of it.

That's basically the process, so we were limited to amounts that Medicare paid. These retiree drug subsidies are monies that Medicare pays. So we're looking into whether there is some way we could use that information.

Bill Peckham: It just seems like there is a cautious after the proposed rule goes into effect away from private insurers to Medicare. So, on the one hand you're limited to the budget neutrality and paying 98% of all current payments, but you're covering more people it seems like, that 33% or so.

Is that 33% of Medicare beneficiaries or Medicaid beneficiaries? I guess that is one question.

Janet Samen: Well there are people who are eligible for the Medicare ESRD benefits and those would be at least Medicare beneficiaries.

Bill Peckham: So you're maintaining the budget neutrality, but you're extending benefits to more people or in effect more people are covered. So it seems like then it means that payment is less for each individual.

Janet Samen: Well, this is an issue that we're grappling with for the final rule, but I appreciate your insight.

Bill Peckham: And just to follow that up, to me as a patient and somebody who spends a lot of time trying to understand the reimbursement and I would like to have a lot of confidence in that number, in that, you know, 198 being enough to cover the services that beneficiaries need.

But we're going to go forward with something, but can you talk a little bit more about how you're going to confirm that these adverse consequences, does CROWN Web play a role in that? And if so what is Crown Web's role in making sure this is working?

Janet Samen: Well CROWN Web is going to be a system that's going to collect measures, collect data so that we can expand the quality improvement program. So that

is just like, it's like a data collection and so that is how we would, I mean, the three measures that are proposed in here are based on information from Medicare claims from ESRD facilities.

But in the future, we would expect that that would be expanded through the data that's collected through Crown Webb.

Bill Peckham: But I mean in the initial years there won't be any collecting of data as far as is there an increase in hospitalizations or is there an increase in mortality.

I guess mortality is one of the dialysis facility compares, but I mean, are you going to be looking to see, I mean if suddenly if more people are going into the hospital to get their pair of thyroids taken out, I mean, is that data going to be collected?

Lynn Riley: Well we have that data. We have all of the Medicare claims data.

Bill Peckham: It's just normally it's reported, you know, two years later through the annual dialysis report and so I was hoping.

Janet Samen: No, I think the point is that we understand that there may be unintended consequences and we do plan to monitor for changes in either what happens to patients or how facilities react, so we're that is, that's going to be part of implementing this system. We'll be figuring out a way to monitor.

Natalie Highsmith: Okay, Bill. I hate to cut you off in the middle of your comments, but we do need to go ahead and end the call now and I will let Janet give closing remarks.

Janet Samen: And I just wanted to thank everyone for participating and urge you that, you know, to send us your concerns in writing, make your public comments and we will analyze them for the final rule.

Natalie Highsmith: Okay Krista can you tell us how many people joined us on the call today?

Janet Samen: Oh and I'm sorry. One other item and that is we are having a town hall meeting on the 23rd of October from 9 to 12. There's information on the ESRD payment webpage and in the notice that was published in the federal register, which gives some of the logistics for how you can participate in that town hall meeting like by phone.

The registration at this point is closed, but we have a variety of speakers that will be participating and giving us their views on the proposed PPS.

Natalie Highsmith: Okay. Krista can you tell us how many people joined us on the call today?

Operator: We had a total of 646 participants today.

Natalie Highsmith: Okay. Remember everyone please remember to follow the instructions to submit your formal comments in the federal register. Thank you.

Operator: This concludes today's conference call. You may now disconnect.

END