MMA §623(e) ESRD Bundled Payment Demonstration

Open Door Forum Briefing

November 2, 2005
2:00 PM – 4:30 PM EST
1-800-837-1935 (ID: 1732902)

- The purpose of this briefing is to provide the ESRD community with an overview of the direction that we have outlined in the draft solicitation for the demonstration. Comments should focus on features that may influence the willingness of providers and patients to participate in the demonstration or that may be a source of confusion. We are not requesting but would be able to use written comments if submitted by November 7.
- We believe the approach outlined in the draft solicitation substantially implements the recommendations adopted by the Advisory Board at its July meeting. Any departure from those recommendations has been based on a consideration of implementation issues, statutory authority, and the examination of how the proposed payment system will operate:
  - The Advisory Board recommended the exclusion from the bundle of certain drugs related to cancer treatment. We are evaluating the need for this exclusion. We remain open to the possibility of such exclusions should they prove necessary, and do not intend to hold participating dialysis facilities accountable for chemotherapy costs.
  - The Advisory Board recommended that the demonstration include an explicit update to payment rates. We understand the importance of updating, but have determined that we do not have the authority under MMA §623(e) to implement such a policy. We remain committed to updating payment rates related to the demonstration, and the issue will continue to be a focus for the demonstration.
  - Consistent with the Advisory Board recommendations, the draft solicitation includes two pay-for-performance (P4P) components. However, the Advisory Board did not have an opportunity to review or comment on the specific features of these components as outlined in this briefing and described in the draft solicitation.
  - The Advisory Board recommended development of separate rates and adjustments for peritoneal dialysis patients. Based on further analysis of the data presented to the board and a close examination of how the proposed payment system would operate, we have decided to propose a single rate structure. This issue will, however, be the focus of continued study and may be revisited before the start of the demonstration.

Agenda

- Purpose
  - Lay out timeline / strategy for demonstration
  - Review an outline of the draft solicitation
- Topics
  - Statutory Background & Demonstration Timeline
  - Background & Problem Definition
  - Overview of Demonstration
    - Bundled payment & consolidated billing
    - Prospective payment for bundled services
    - Pay-for-performance for bundled services

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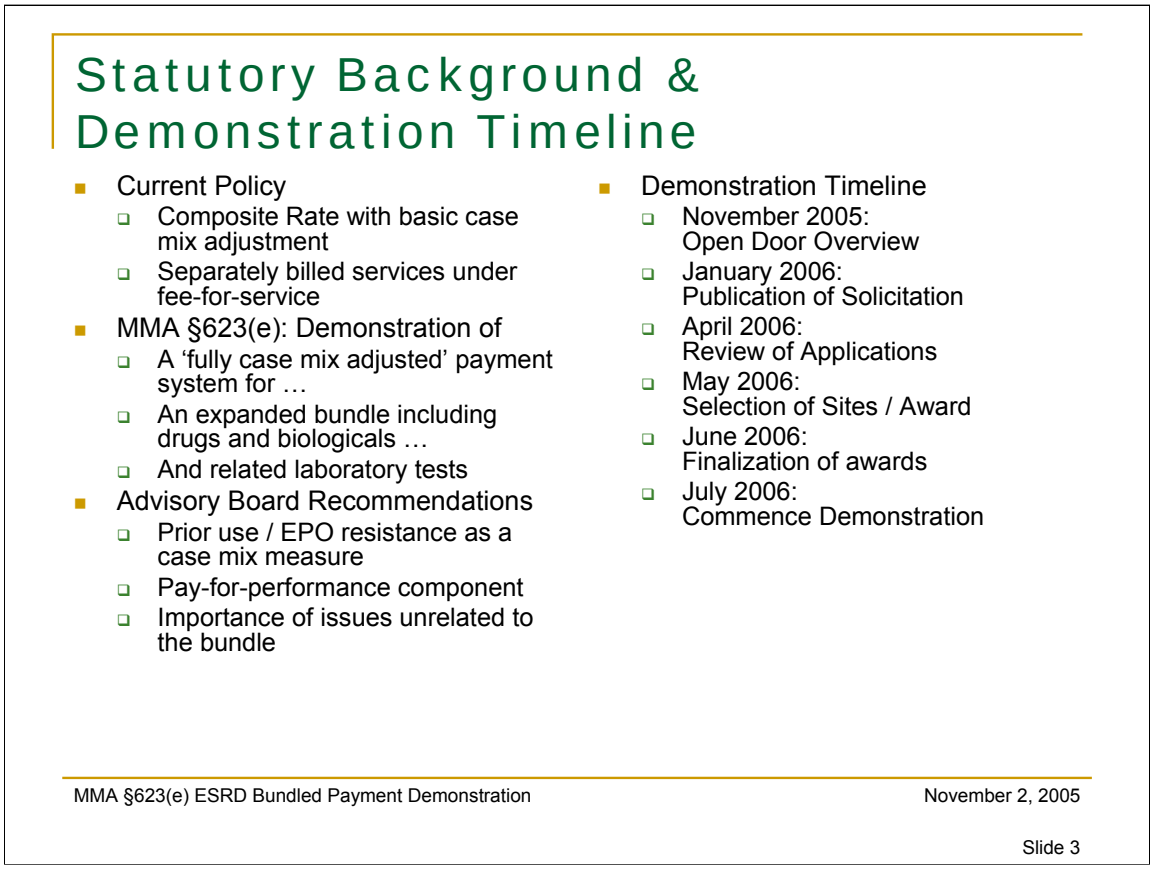
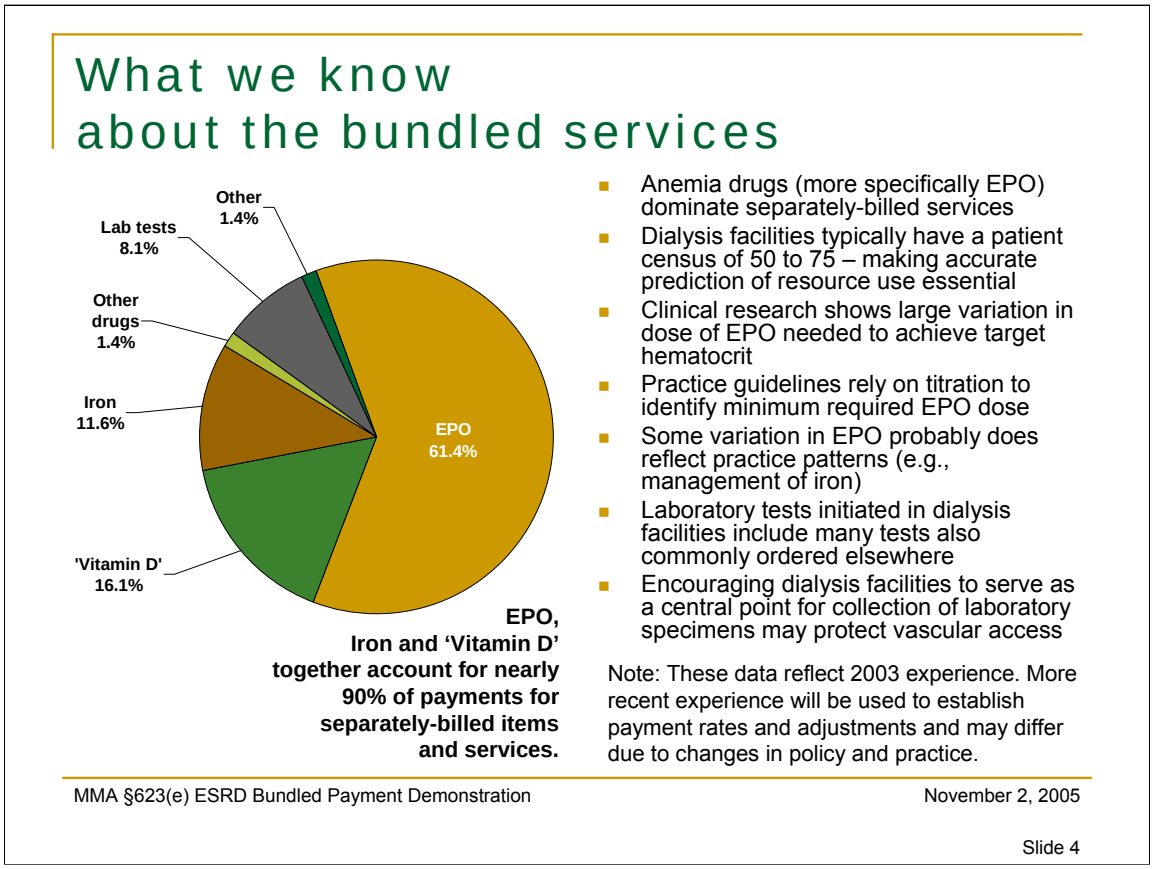
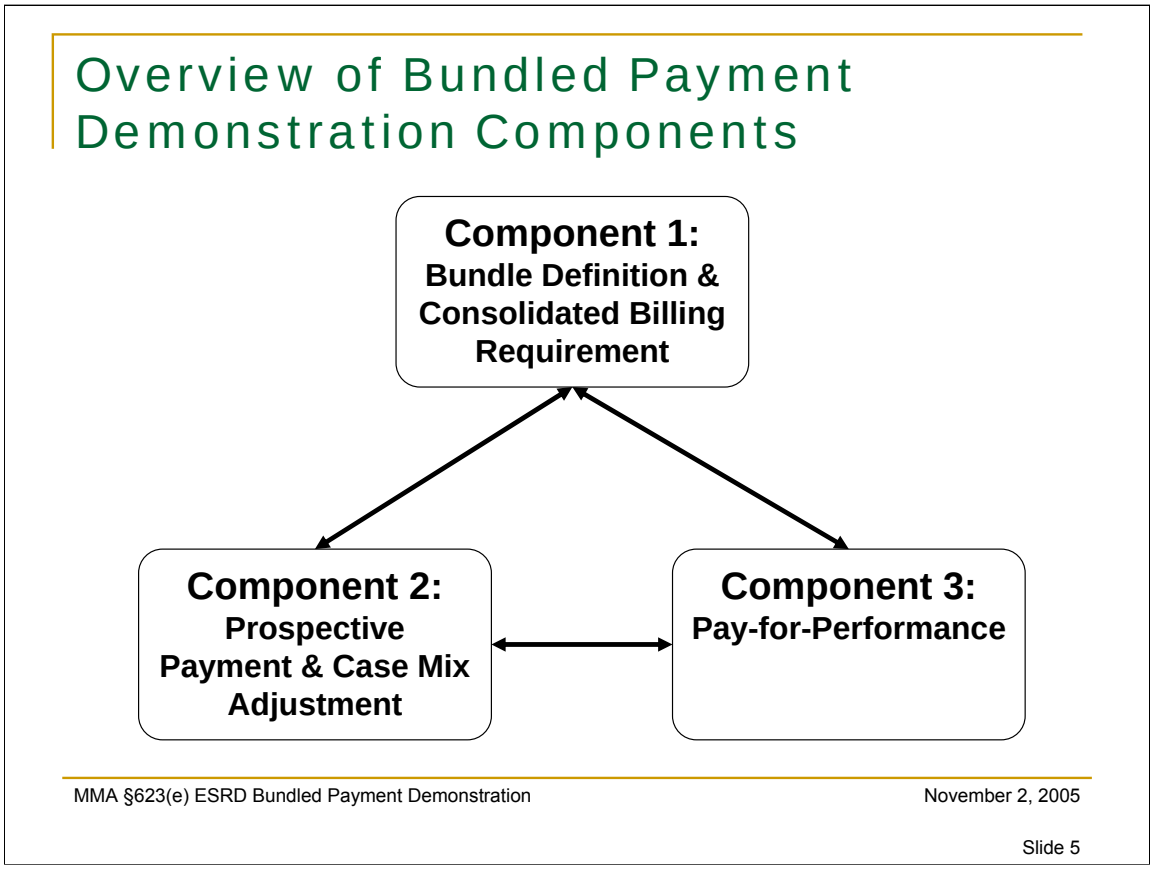
- This briefing begins with a review of the statutory background for the demonstration and the timeline that we are attempting to adhere to.
- From there it moves on to a summary of what has been learned from the analyses conducted for the Advisory Board and from the Advisory Board discussions.
- It then discusses the key components and features of the proposed demonstration as outlined in the draft solicitation. In general, the demonstration has three components:
  - The first component is the definition of the bundle of services for which payment will be made and related consolidated billing rules.
  - The second component is a prospective payment system for that bundle of services, including the method of case mix adjustment.
  - The third component defines an approach to implementing pay-for-performance for both the bundled services and, more broadly, for management of ESRD.
- Our purpose in presenting this information to the ESRD community at this time is to gauge the level of interest in and reactions to possible features of the demonstration before beginning the formal clearance process. It should be noted that any information contained in this briefing is subject to revision prior to publication of the solicitation based on comments and guidance obtained during the clearance process.



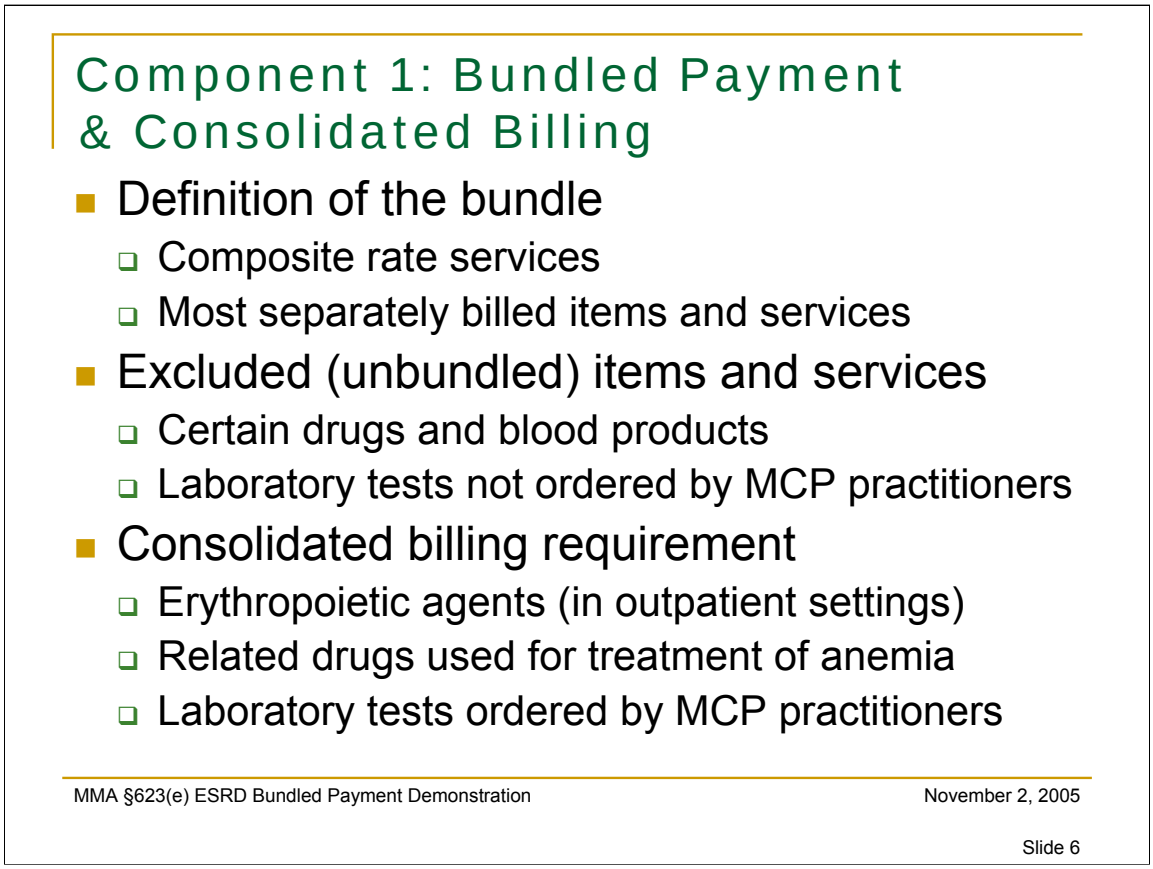
- Section 623(e) of the Medicare Modernization Act, directs the Secretary to undertake a demonstration of a "fully case mix adjusted" payment system that bundles drugs and related laboratory tests with the composite rate payments.
- Section 623(e) also established an Advisory Board to make recommendations concerning the design of the payment system to be evaluated in the demonstration project.
    - The advisory board reviewed extensive information on possible components of the bundled payment and alternative approaches to case mix adjustment.
    - To overcome the limitations of case mix adjustments based solely on demographic and diagnostic information, the Board recommended the adoption of a measure of EPO resistance based on the patient's use of and response to erythropoietic agents in the three months prior to the month for which payment is to be made.
    - It also endorsed the inclusion of a pay-for-performance component and urged CMS to use pay-for-performance to broaden the focus beyond the management of the services included within the scope of the bundle.
    - Finally, it noted the importance of addressing issues such a choice of modality that are not directly related to the question of how to define and pay for the bundled services.



- The extensive analysis conducted for the Advisory Board meetings identified a number of issues that are relevant to the design of the bundled payment demonstration.
- The services that are candidates for inclusion in the bundle are dominated by drugs related to the treatment and management of anemia. Erythropoietic agents, by themselves, comprise more than 60 percent of allowable charges for separately billed items and services that appear on dialysis facility claims.
- The small size of facilities (average census less than 60) makes the accurate prediction of expected resource a critical requirement for any prospective payment system. Further adding to the importance of accurate prediction is the fact that dialysis facilities generally have a stable census of patients that changes only slowly from month to month.
- Clinical research consistently shows large variation across patients in the dose of EPO that is needed to achieve and maintain a target hematocrit or hemoglobin level. The maintenance dose is, consistent with dosing and practice guidelines, found through a process of titration. While practice variation contributes to variation in dose (e.g., management of iron stores or use of transfusion), it is also consistent with substantial underlying variation in the individual physiologic response to erythropoietin. A growing body of evidence suggests that dosing is generally consistent with practice guidelines.
- It is virtually impossible to identify a specific set of laboratory tests that are uniquely associated with the management of the other services that would be included in the bundle. The laboratory tests initiated in dialysis facilities include many tests that are also commonly ordered in other settings by physicians and practitioners with no relationship to the dialysis facility. A potentially important quality-of-care goal for the demonstration is to encourage dialysis facilities to assume a more central role in the collection of laboratory specimens as part of the broader effort to protect vascular access.



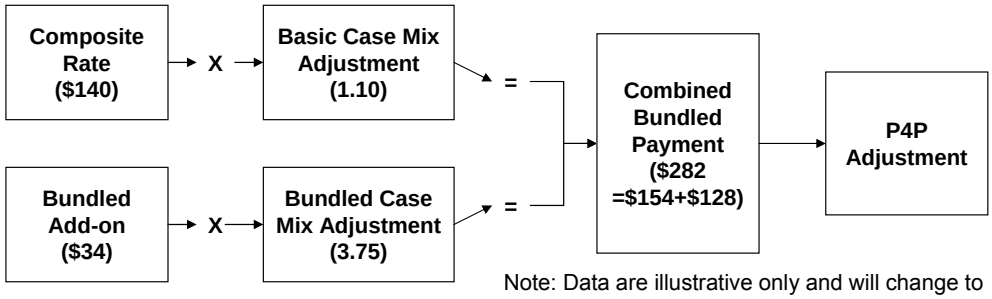
- The overall design of the demonstration can be divided into three broad components.
- The first component is the definition of the bundle and the associated consolidated billing requirement. This component defines the services that will be paid for through the bundled payment. However, in another sense, it defines the services that the dialysis facility is expected to or responsible for providing. It also defines the services that Medicare will not pay for directly.
- The second component is a prospective payment system. It will answer both the “how” and the “how much” questions related to the bundled payment. That is, it will define how payment will be made and how the amount of payment will be determined. It includes a method of case mix adjustment for the bundled services.
- The third component defines the role and operation of a pay-for-performance (P4P) arrangement. The draft solicitation envisions a substantial role for pay-for-performance. The purpose of the P4P component is two-fold: to take a substantial step towards a payment system that bases payment on what is achieved for patients instead of basing payment exclusively on the services provided to patients; and, to establish a framework to facilitate the alignment of incentives across and among facilities, physicians, and other providers.



- The first component of the bundled payment demonstration defines the bundle of services that will be paid for and related consolidated billing requirements.
- In proposed bundle will include nearly all services provided by or initiated through the dialysis facility. Separate payment outside the bundle will be made only for those services that are specifically excluded from the bundle. This means that the bundle will include composite rate services, nearly all drugs administered by the dialysis facility, laboratory tests that are ordered by the physicians and practitioners responsible for overseeing the patient's treatment in the dialysis facility, most blood and blood products administered by the dialysis facility, and medical/surgical supply items.
- The only services that are excluded from the bundle will be certain high cost drugs that are infrequently used and certain blood products such as leucocytes. Dialysis facilities will also be able to draw laboratory specimens on behalf of physicians or other practitioners that are not responsible for managing the patients treatment at the dialysis facility. Separate payment will be made for these "non-MCP" laboratory tests.
- The consolidated billing requirement defines those services that will be paid for only through the bundle. These services include erythropoietic agents, related drugs used for the treatment of anemia (iron and vitamin D analogues), and laboratory tests ordered by "MCP practitioners". The purpose of the consolidated billing requirement is to prevent the unbundling of, and duplicate payment for, services that are included in the bundled payment.

Component 2: Prospective Payment for Bundled Services

- Unit of payment: dialysis session
- Dual payment rates & case mix adjustments
- Possible outlier / risk-sharing policy?



Note: Data are illustrative only and will change to reflect current policy and practice prior to publication of the solicitation.

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- The second component of the bundled payment demonstration is the prospective payment system that defines how payment for the bundled services will be calculated.
- The unit of payment in the demonstration will continue to be the dialysis session. All current requirements related to coverage of dialysis sessions will continue to apply.
- For purposes of the demonstration, a dual payment rate will be adopted. Payment will be divided into two components.
  - The composite rate and basic case mix adjustment will determine the portion of the payment attributable to the dialysis session.
  - A separate bundled payment add-on with a separate case mix adjustment will be used to calculate the portion of the payment attributable to the newly bundled services.
  - These two components will be combined into a single or combined bundled payment. This bundled payment will be used as the basis for P4P payments related to the bundled services.
- The solicitation will outline two options for mitigating the risk inherent in any prospective payment system. These two options are: (1) a conventional outlier policy under which additional payments will be made for patients incurring unusually high costs; and (2) a risk-sharing or stop-loss arrangement to limit aggregate losses at the level of the facility. These options will be budget neutral, and the solicitation will describe the amount of protection that would be provided and the approximate reduction in payment rates that would be necessary to fund that level of risk reduction.

Component 2: Prospective Payment The EPO Resistance Measure

- Factors included in case mix adjustment measure
  - Demographic characteristics: age, sex, race
  - Duration of renal replacement therapy and starting HCT
  - Patient size (weight or body surface area)
  - Co-morbid conditions
  - EPO resistance
- The EPO resistance measure
  - Relies on prior use to predict current / future use
  - Use of erythropoietic drugs divided by hematocrit
  - Averaged over three previous months

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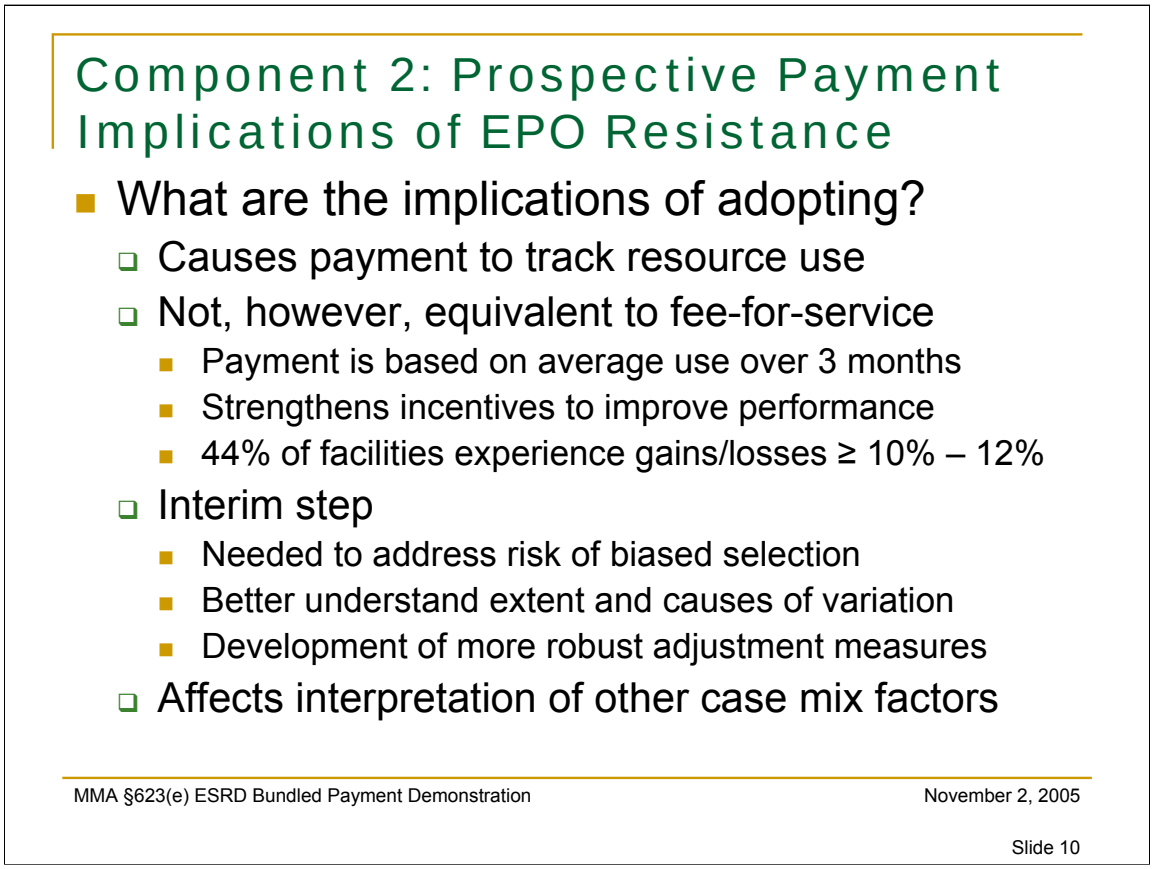
- The case mix adjustment that will be applied to the bundled services add-on relies on a number of factors to 'predict' resource use:
  - It includes several demographic characteristics that were found to show a statistically significant and material relationship to resource use: whether the patient is female, whether the patient is under 18 years of age, and whether the patient is African-American.
  - It provides an upward adjustment for patients in their early months of dialysis and adjusts payment based on the patient's starting hematocrit.
  - It includes a measure of patient size and includes an adjustment or adjustments for several co-morbid conditions.
- The case mix adjustment also includes a measure of EPO resistance.
  - This is unusual in a prospective payment system. It means that a patient's use of erythropoietic agents and hematocrit in a prior period will be used to predict resource use—and adjustment payment—in the current period.
  - The specific measure that is proposed will divide the patient's hematocrit into the patient's allowable charges (per session) for erythropoietic agents.
  - The average value of the EPO resistance measure during the three prior months will be used to adjust the current month's payment.

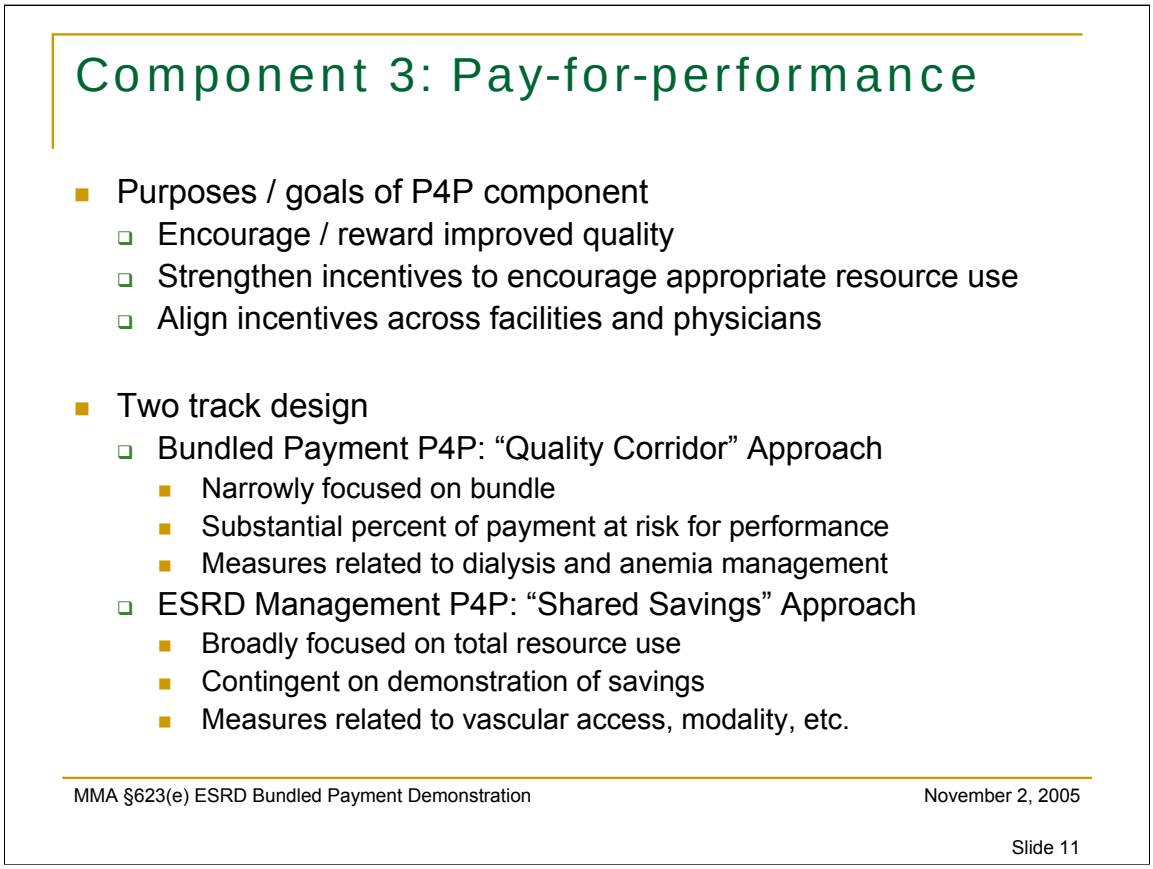
Component 2: Prospective Payment Why EPO Resistance?

- Why is prior-use measure needed?
  - Limited explanatory power of other measures
  - Prediction errors persist over time
  - Intrinsic variation in erythropoietin dose
  - Use generally consistent with practice guidelines
  - Predicting use for small numbers of patients

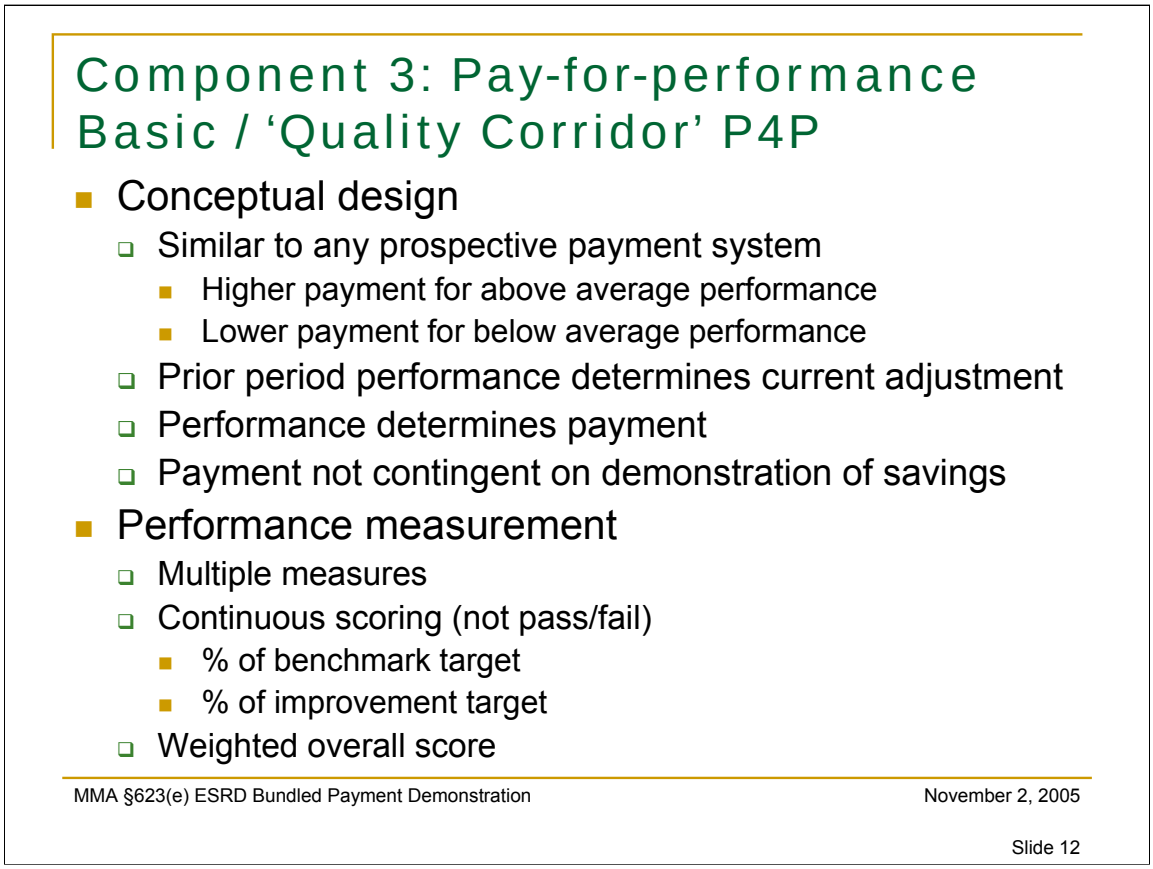
- Reliance on a measure reflecting prior resource use in a case mix adjustment is unusual and controversial. The Advisory Board recommended the adoption of such a measure primarily because statistical models that did not include such measures had very limited explanatory power.
- In addition the difference between predicted and actual values for models that did not consider prior experience also persisted over time; patient's with higher than predicted resource use in one month tended to also have higher than predicted resource use in prior (and subsequent) months. This pattern strongly suggests that the statistical model does not include important patient characteristics that are predictive of resource use.
- This suggestion is consistent with a substantial body of clinical research that finds wide variation in the dose of erythropoietic agents that is required to achieve and maintain a target hematocrit. It is also consistent with evidence-based practice guidelines that call for reliance on dose titration to determine dosing.
- Moreover, the typical dialysis facility has a census of fewer than 60 patients that is quite stable from month-to-month. As a result, a more highly predictive measure of resource use is needed to avoid a pattern of gains and losses that reflect the good fortune or misfortune of a facility in having a patient census that simply requires less or more resources to achieve targeted clinical outcomes.



- Reliance on a measure of prior resource use is unusual in a prospective payment system. The adoption of an EPO resistance measure has several implications for providers who may choose to participate in the demonstration. The EPO resistance measure will cause payment to more closely track resource use at both the patient and facility level. Payment will be higher for a patient who requires a large dose of erythropoietic agent merely by virtue of that fact. However, changes in dose will also produce changes in future payment.
- The prospective payment for the bundled services will not, however, be the same as fee-for-service payments.
    - Payment will be based on average use or resources over the three prior months, not the actual use of resources in the current month. As under any prospective payment system, a facility will have incentives to reduce unnecessary resource use at least in the near term.
    - An analysis of the impact of using the proposed measure on facility-level payment indicates that 44% of facilities will experience an increase or decrease in payment of more than 10 to 12 percent.
- The proposed measure should also be viewed as an interim step in the development of better case mix measures. It is necessary to address the risk of biased selection in the context of the demonstration. The demonstration will be an opportunity to better understand the extent and causes of variation in resource use and to develop a more robust case mix adjustment.
- Finally, the measure will affect the interpretation of the weights attached to other case mix factors. In a model that includes EPO resistance, the weight given to other patient characteristics will reflect the statistical relationship between that characteristic and resource use holding constant the 'EPO resistance' of the patient.

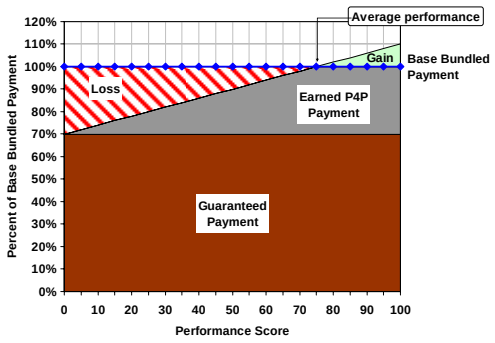


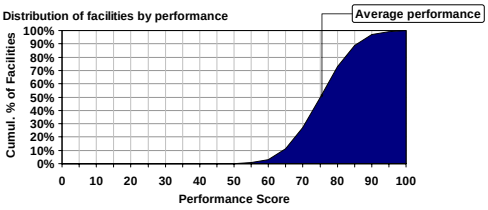
- The third component of the demonstration is the implementation of a pay-for-performance feature. The goals of this component are:
  - First, the P4P component should encourage or reward improved quality.
  - Second, it should encourage and reward providers who more effectively and efficiently manage anemia and address the concern that the adjustment of current period payment based on prior period resource use perpetuates the incentives created by traditional fee-for-service payment methods.
  - Third, the P4P component should create an opportunity to align incentives between and across facilities, physicians, and other providers.
- The P4P component in the draft solicitation has a two-track design.
  - All participants in the demonstration will be required to participate in the first track which is narrowly focused on services paid for through the bundle. This track adopts a "quality corridor" approach to P4P. A substantial percentage of the bundled payment will be "at risk" for performance on measures that are related to dialysis and anemia management. P4P payments would be contingent only on performance.
  - Participants in the demonstration will have an opportunity to participate in a second track, more broadly focused on ESRD management and total resource use. This track adopts a "shared savings" approach to P4P. Payments in this second track would be contingent on both performance and demonstration of savings. The measures that would be used in this track would be more broadly related to management of ESRD, e.g., vascular access, modality, etc.



- The basic policy underlying the basic P4P or "quality corridor" approach is that a facility will earn a portion of its payment based on its performance and not based simply on the services that it provides or costs it incurs.
- The concept underlying this design is broadly similar to the concept underlying any prospective payment system.
    - Under prospective payment, a facility with costs below the average receives a payment that exceeds its costs. The payment to a facility with above average costs is below its costs.
    - Under this P4P arrangement, a facility with above average performance receives a payment that is higher than the bundled payment amount—which reflects the performance of the average facility. Payment would be less than the average for a facility with below average performance.
    - P4P payment is based entirely on performance; it is not contingent on savings.
- A facility's performance score would be based on multiple measures. The draft solicitation anticipates using the CPM measures as a starting point for defining these measures, and will seek input from applicants on the measures that might be used.
    - Performance will be measured against both a benchmark target that is the same for all facilities and against an improvement target that reflects the starting or baseline performance of the individual facility. Improvement targets are expected to require closing a percentage of the 'gap' between baseline and benchmark performance.
    - Performance on individual measures will be aggregated into an overall score. The score for a prior period will determine payment in the current period, although methods of making payment more nearly concurrent with performance are being sought.

Component 3: Pay-for-Performance Basic / 'Quality Corridor' P4P





- Operation of P4P formula
  - A percent of payment is 'at risk'
    - Guaranteed payment (70%)
    - Maximum incentive (10%)
    - 40% of payment 'at risk'
  - 'Break-even' performance score
    - Determined by relationship of
      - Guaranteed payment
      - Maximum incentive
    - In this example: 75 percent
    - Reflects average facility performance
- Distribution of incentives
  - Equal likelihood gain/loss
  - Few if any facilities paid only guarantee amount
  - Most facilities fall close to 'break-even' score
  - All facilities could operate above 'break-even' point

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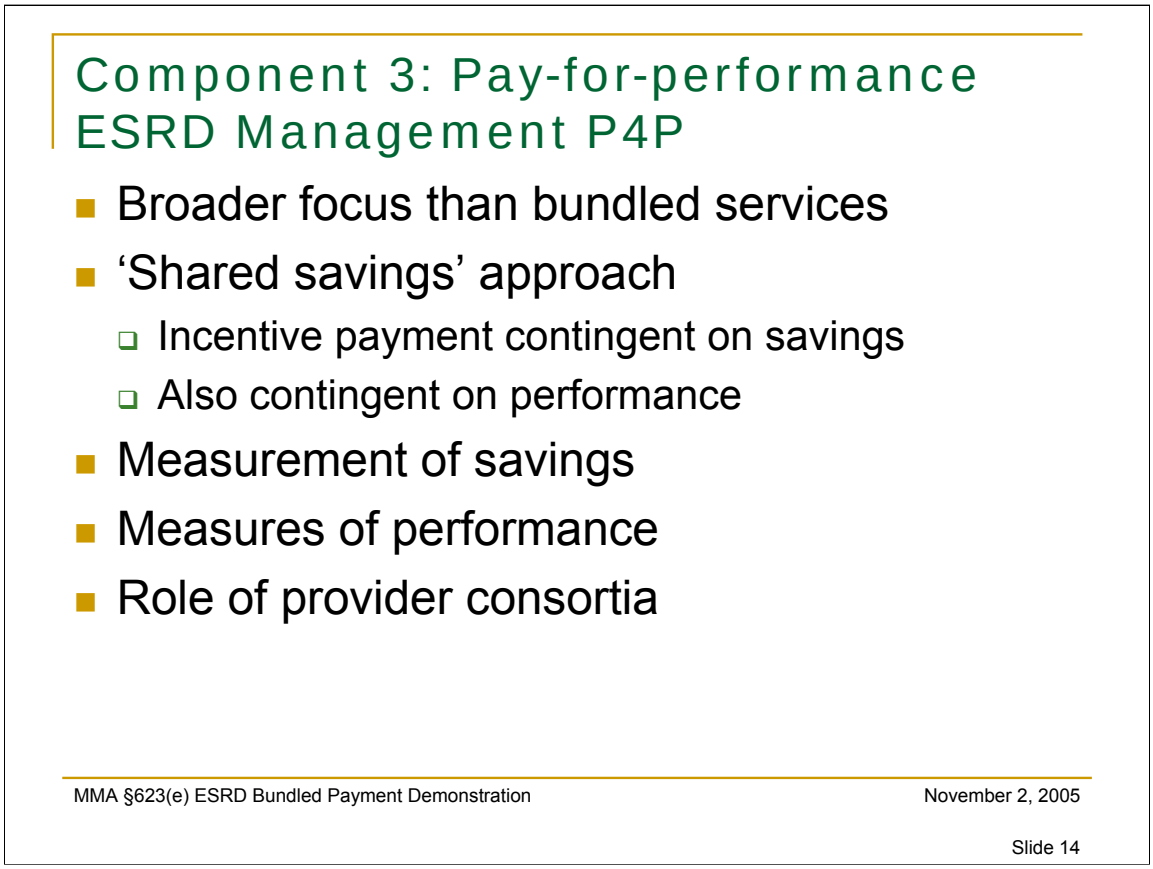
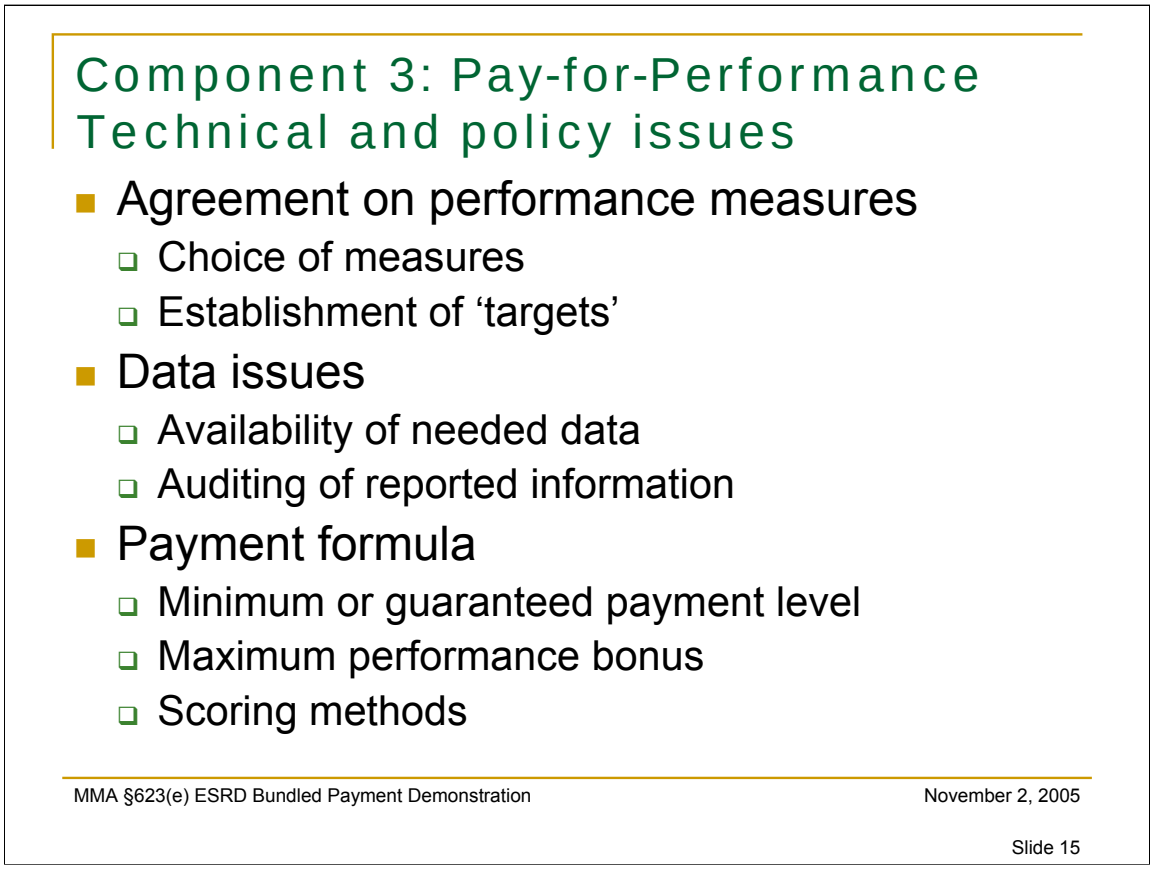
- The basic 'quality corridor' or bundled payment P4P formula would put a fixed percentage of potential payment for the bundled services 'at risk' for performance.
  - The formula would establish a guaranteed payment level or percentage of the prospective payment that would be paid regardless of performance.
  - It would also establish a maximum incentive payment—a percentage above the prospective payment amount that a facility with maximal performance would be paid.
  - These two determine the percentage of potential payment that is 'at risk' for performance. For example, if the guaranteed payment level is 70 percent and the maximum incentive is 10 percent, approximately 40 percent of the potential payment is at risk for performance.
- The relationship between the guarantee and the maximum incentive also determines a 'break-even' point or performance score at which a facility will receive 100 percent of the prospective payment. In the example given, this 'break-even' score is 75.
- The performance targets would be established at a level such that an 'average' facility would achieve the 'break-even' score and all facilities could do better than that.
  - Very few, if any, facilities would receive only the guaranteed payment amount.
  - The average facility should be as likely to operate above the 'break-even' score as below.
  - Most facilities will fall close to the 'break-even' score.
  - All facilities should have a reasonable chance of operating above the 'break-even' score.



- The second P4P track adopts a 'shared-savings' approach and focuses more broadly on the management of ESRD. The goal of this 'shared-savings' P4P is to encourage the formation of consortia or cooperative arrangements among dialysis facilities, physicians, and other providers for the purpose of addressing issues in the clinical management of ESRD that transcend the abilities or interests of any single entity. For example, achieving the goals of the FistulaFirst initiative requires the coordination of efforts by dialysis facilities, nephrologists, vascular surgeons, and other providers. Similarly, promoting home dialysis modalities requires efforts that go beyond the capabilities of the dialysis facility.
- The ESRD management P4P track will necessarily rely on a 'shared-savings' approach. The providers participating in the P4P arrangement will have an opportunity to share a portion of the savings that are achieved by improving performance. The payment of incentives will be contingent on savings, as well as on achieving performance targets for a set of ESRD management measures.
- The draft solicitation proposes to measure savings by comparing actual Medicare expenditures for covered services to a fee-for-service benchmark derived from the payment rates that are established under the Medicare Advantage program for ESRD patients.
- The draft solicitation also proposes to adopt a set of performance measures broadly similar to those used in the ESRD Disease Management demonstration. However, it also requests suggestions for additional measures.
- The details of the P4P "shared-savings" component will be determined by CMS following consultation with the participants in the demonstration.
- Finally, the draft solicitation anticipates that applications will include broadly based consortia including facilities, physicians and other providers.



- Implementing either of the pay-for-performance options will require the solution of a broad array of technical problems and the resolution of a substantial number of policy issues. The draft solicitation will seek input from applicants on a number of these issues. CMS anticipates needing to work closely with participants to address the myriad details necessary to implement any P4P arrangement.
- One set of issues involves the agreement on and definition of performance measures. The specific measures to be used and the development of operational definitions for each measure will require considerable effort by both CMS and the demonstration sites. A related set of questions involves the establishment of performance targets for both benchmark performance and performance improvement. At the present time we anticipate using the CPMs as a starting point, but look forward to a discussion of these issues in applications from interested organizations.
- A second set of more technical questions concerns the methods that will be used to capture, analyze and apply the data needed to measure performance. Performance information will need to be captured on a real-time basis for 100 percent of patients. The precise frequency of data collection, methods of capturing the data, and methods of verifying or auditing the data will need to be defined.
- A third set of issues involves the details of the payment formula and scoring methods. We anticipate the need for an extensive discussion of these issues during the bidders conference that we anticipate holding following the publication of the solicitation.