Informational Meeting Responses

Organizations should carefully review the written responses as they contain updated information.

Please regularly check the Question and Answer link on our website: http://www.cms.hhs.gov/healthplans/research/esrd_demo.asp. We will continue to respond to questions submitted prior to the application deadline using that format.

I. Capitation Model

A. Risk Adjustment

1. **The risk adjustors appear to be based on data that is 2 years behind the year to which they are applied, is this correct?**

   The risk adjusters for any payment year will ultimately be based on the diagnosis data from the calendar year immediately preceding. Initially, for January 2004, data from July 2002 through June 2003 will be used to set interim payment factors. About mid-2004, CMS will recompute risk factors based on data pertaining to January 2003 through December 2003. Thus, there will be no lag between the data period and the payment period.

2. **How are rates adjusted to 2004?**

   A dialysis ratebook for 2000 was derived from the costs for all the dialysis months and the risk factors for the people on dialysis were used to standardize the rates. The Office of the Actuary then used the National Growth Rates for each of the following years to derive the 2004 rates.

3. **How often will an individual member's risk adjusted payment change – monthly, annually? If annually, what will be used as the adjustment date – the calendar year, the contract year, or the member's anniversary date?**

   The risk-adjusted payment can change during the year if a person moves into or out of long-term institutional status or moves into or out of ESRD status. The risk factor for an individual is computed as of January of the payment year. For the M+C program we are using data from the prior July - June data collection year to determine the initial factors. Later in the payment year we move the data collection period to the prior January – December. New factors are computed and retroactive adjustments made for the first half of the year for most organizations. There are no midyear changes in payments related to birthdays. Age categories are assigned based on age on February 1 of the payment year.

4. **How will demonstration sponsors notify CMS of changes in co-morbidities associated with different risk adjustors? Will sponsors be required to certify monthly enrollment information, including current co-morbidities and other risk adjustment factors? What validation of the reported diagnoses will be necessary to establish or change an individual's risk adjusted profile? What is or will be the role of the CMS Form 2728 in this process?**

   Organizations will submit diagnosis data to CMS. The process will be similar to that under M+C risk adjustment. The developmental period of the demonstration will offer a period when CMS and organizations will work together on operational requirements. We will work out the time schedule for how often this information is to be submitted.

5. **The solicitation proposes to pay 21.5% of the risk-adjusted Medicare cost for Medicare beneficiaries as secondary coverage to other primary insurers. How will this be administered? Will the primary payer's payment influence the Medicare secondary payment amount and administration? Will the risk adjusted payment be the same regardless of the amount paid by the primary payer?**

   This amount for beneficiaries with Medicare secondary payor (MSP) will be paid through the customary managed care payment system. The type and extent of payment for the primary payer will not influence this payment amount. The 0.215 factor is an average found in CMS data. Specific coverage for individuals varies considerably.

6. **The ESRD payment rate is based on risk adjustments for co-morbid conditions and demographics applied to individual beneficiaries. Will payments to demonstration sponsors be made on the basis of a single weighted blend of all patients or on an individually calculated amount for each member?**

   Payments will be based on an individual calculated amount for each member.

7. **Is the cost of organ acquisition included in the transplant payment rate?**

   We have included all costs found in claims for the beneficiary. CMS is considering alternatives in paying the organ acquisition costs reflected in hospital cost reports.

8. Is there a modified payment for kidney-pancreas transplants?

The numbers published on the website are averages for all patients receiving kidney transplants including those with simultaneous pancreas transplants. In the 2000 data simultaneous transplants were paid under the DRG for kidney transplants. The only distinguishing feature on the hospital claim is the degree to which outlier payments were present for the simultaneous transplants. Only about 5% of the transplants were for both organs. We are currently considering whether the two procedures should be distinguished and how we could make an accurate assessment. The data for 2002 have a DRG for the double transplant and will be examined when complete data are available. This analysis will take a few months as data from all claim types must be collected to reflect the full difference.

9. How are beneficiary pre-transplantation evaluations covered? (These are presently passed through the organ kidney transplant center.)

Pre-transplant evaluations are captured in two places. To the extent they occur during the month of the transplant they are captured in those costs. To the extent they occur prior to this time they are captured and averaged into the monthly payment for dialysis patients.

10. Are medications (immunosuppression) included in the calculated post-transplant payment?

Yes, immunosuppressive drugs are included in the post-transplant payment. These represent an additional payment to the customary risk adjusted payment for the individual.

11. Please clarify the "New Enrollee Dialysis Model" – does this approach apply to patients who are new to Medicare or new to Dialysis status (i.e., for whom chronic kidney disease has progressed to ESRD)?

The new enrollee model is used for beneficiaries who do not have a full year of Medicare Part B data available to make a fair risk adjustment estimate. Examples are those new to Medicare and those who have not bought Part B for the data period; but continuing Medicare beneficiaries who develop ESRD will generally be under the full risk model. Transplant payments are not sensitive to diagnoses so are paid without reference to a new enrollee model.

12. For the dialysis modality, is there a differential payment for different types of dialysis (e.g., peritoneal dialysis, standard hemodialysis, daily hemodialysis, home-based, nocturnal, etc.)

We have not differentiated among modalities in determining payment at this time.

13. **Vascular access costs and ESRD patients' total costs are to a large extent determined by their type of vascular access (AVF, PTFE graft, Cuffed Catheter) which is typically determined prior to program entry. Access type however is not one of the factors listed in the HCC list used for risk adjustment. Will risk adjustment for the patients access type at entry to the extended fee for service bundled payment program be included as part of the reconciliation?**

    Risk adjustment will only take into account factors in the HCC model.

B. Managed Care Eligibility, Delivery, Marketing

1. **In the capitated options, can program contractors propose to serve beneficiaries in specific dialysis units, or must contractors serve all eligible ESRD beneficiaries in the geographic region?**

    In the capitated options, demonstration organizations must serve all eligible ESRD beneficiaries in the defined region. However, they can choose specific facilities for the demonstration. They must show in the application that they are committing significant facilities and resources to cover the potential participating beneficiaries in the area's population.

2. **What is the acceptable age range for the demonstration?**

    Organizations are permitted to exclude patients under 18 years old, if this exclusion is justified. We expect all other ages to be eligible for the demonstration.

3. **What is the impact on our solicitation response regarding disenrollment, if hospice treatment is selected?**

    According to the solicitation, hospice patients are not eligible if they select the hospice benefit prior to enrollment. If a capitated organization seeks to exclude hospice patients as a covered group if the patients select the hospice benefit after being enrolled in the demonstration, the organization must describe this situation, including its likelihood and all circumstances affecting the patients, and make a justification for the exclusion.

4. **Are post-transplant patients allowed to enroll in the demo demonstration? If so, how will marketing be handled for this set of eligible beneficiaries? How is CMS planning to obtain the names of these post-transplant patients?**

Yes, for the capitation model, post-transplant patients will be allowed to enroll in the demonstration. In general, the health plan will market to these patients. We may consider an outreach activity to inform beneficiaries of the demonstration.

5. **Is there a provision allowing us to convert existing Medicare+Choice (M+C) members from a health plan to the demonstration? If so, please describe any selection criteria and/or specific rules for enrollment. How will the marketing be handled for this set of beneficiaries?**

   Managed care organizations under the demonstration will be able to enroll existing M+C members. However, the organization must enroll all members from the original M+C plan in the new specialty plan. In addition, the organizations must show how it can accommodate growth in capacity to enroll new enrollees from the fee-for service sector, and how it will market to these patients.

6. **Is there a targeted percentage of participating beneficiaries required in each of the three modalities (dialysis, transplant, functioning graft)?**

   No, there is no targeted distribution among these 3 modalities.

7. **For the capitated model, will organizations be able to expand their service area after the start of the demonstration?**

   Demonstration organizations may submit requests for service area expansions after the start of the demonstration. They will be reviewed on an individual basis.

II. Fee-for-Service Option

A. Creation, Composition, Pricing of Bundle

1. **Can the list in Appendix I of items covered under the bundle be broken out for those electing the fee for service model with vascular access and the fee for service model without vascular access? Similarly, what is the providers responsibility under both options for the costs associated with radiology, vascular access management, bone disease management, health screening including mammography, etc.?**

   ***ESRD-related services* are those services necessary to manage an ESRD patient's kidney disease and any related comorbidities. To determine if a service is ESRD-related, the following criteria must be met:**

   - **the service is included in Appendix I***
   - **the service is provided in the outpatient setting (e.g., dialysis facilities, physician offices, outpatient hospital departments, and ambulatory surgery centers)**
   - **the service does not include the professional component, and**
   - **the service is for the treatment of kidney disease or for any comorbid conditions included an individual patient's most recent 2728 Medical Evidence Form (Note: in this demonstration, 2728's are required at enrollment and then annually thereafter).**

   *** the list in Appendix I will be evaluated annually during the demonstration to consider changing practice patterns, new technology, and changes in benefits.**

   Yes, this list can be broken out for those electing the fee-for-service model with vascular access and without vascular access. In Appendix I, section A. Drugs and section B. Labs/Radiology are included in both the bundle with and without vascular access. Services under section C. Vascular Access are included only in the expanded bundle with vascular access. Note that providers are responsible for vascular access services in both expanded bundle options, either through the reconciliation or through the bundle and the reconciliation. Thus, the only difference between the two is in the areas of cash flow and administration.

   The demonstration provider's responsibility is for the cost of *ESRD-related services* (see definition above).

2. **Please define what laboratory tests are included in the bundle. Are they routine laboratory tests or all laboratory tests? Do these tests include the primary care of the patient? What happens when consultants (e.g., cardiologists) order tests which are part of the bundle?**

   To the maximum extent feasible, laboratory tests necessary for the management of kidney disease and associated comorbidities, regardless of provider-type and location in the outpatient setting, are *ESRD-related services* and are included in the bundle. Consultants and primary care providers who perform lab tests that do not meet the criteria would still bill them separately.

3. **Why are phosphate binders included in the expanded bundle since, as an oral medication, they are not currently covered by Medicare?**

   Phosphate binders should not have been included in the list of services in Appendix I. Their costs were not included in the payment rate. Thus, they would continue to be billed separately. CMS will evaluate updating the bundle as necessary to reflect changing practice patterns and new technologies.

4. **How will payment be made for intravenous medications administered in a dialysis facility that are not included in the expanded bundle?**

   Payment for Medicare-covered services that are not part of the expanded bundle will be made separately.

5. **The HCPCS codes listed in the vascular access extended fee for service bundled payment are outpatient and procedure codes. Are the costs of inpatient vascular access-related procedures and hospitalizations (under the DRG's) excluded from in the $15 per treatment payment?**

   Yes, inpatient vascular access-related procedures will be paid for under inpatient prospective payment.

6. **Many incident patients present to outpatient dialysis facilities without a permanent access (AVF or PTFE graft) or require secondary procedures (surgical revisions, angioplasties etc) related to their original access placement prior to program entry. Were the costs of initial permanent access placement or revisions of access that fail to mature included in the $15 per treatment payment for vascular access services?**

   Since these vascular access procedures occurred prior to the patients' first dialysis, their costs would not have been included in the claims used to establish the bundled payment for vascular access services.

7. **Many of the listed vascular-related HCPCS codes are frequently used for non-vascular access related procedures. For example, chest x-rays (71020 Radiologic examination, chest, two views, frontal and lateral) are used to diagnose and evaluate pneumonia, congestive heart failure, etc. HCPCS 93925 (Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study) is typically used for the evaluation of peripheral vascular disease and to follow patients after bypass surgery. Who covers the non-vascular access related uses of the listed designated codes and how will this be determined?**

   If a participating organization accepts the bundled add-on payment for vascular access services, it is financially responsible for vascular access *ESRD-related services*. Thus, the participating organization would be responsible for paying other providers who perform vascular access services related to dialysis.

   If entities provide radiological services such as chest x-rays that are not *ESRD-related*, Medicare will pay for them separately.

8. **Vascular access type (percentage of AVF, grafts and cuffed catheters) is likely to be included in the new Clinical Performance Measures. How will the additional costs involved in meeting these standards (evaluation for and placing AVF, catheter reductions, etc) be covered in the extended fee for service bundled payment model?**

   Additional costs would be covered either by the quality incentive for vascular access or through the annual reconciliation (where sponsors who provide more appropriate vascular access care will share gains that are achieved through lower access-related hospitalizations).

9. **What drugs are included in the fee-for-service (FFS) drug bundle?**

   Drugs presently included are: Erythropoietin (both Epoetin Alpha and Darbepoetin), Iron Supplements, Vitamin D, and Levocarnitine. Please refer to question (II)(A)(3) for discussion of Phosphate Binders.

10. **What drugs are excluded from the fee-for-service (FFS) expanded bundle and how are excluded drugs to be billed?**

    Separately billable drugs that are not included in the FFS bundle would still be billed separately just as if the participating organization was not in the demonstration.

11. How will home dialysis training be paid?

For the fee-for-service model, home dialysis training is not included in the expanded bundle, so it is separately billable.

For the capitated model, all services, including home dialysis training, are incorporated into the payment rate.

12. What case mix assumption was utilized to set the access care bundle?

There was no case-mix assumption. All claims of patients with ESRD who met the criteria in the answer to question (II)(A)(12) were used in the calculations.

13. Can CMS explain the cost and utilization assumptions, methodology and data sets that it used to derive the drug and vascular access care bundles?

Calculations were based on Medicare claims data for:

- **both outpatient and physician/supplier settings,**
- **calendar year 2001,**
- **patients with at least one dialysis bill during the year, and**
- **payments dated after the first date of Medicare ESRD service.**

Additionally, calculations were limited to "stable patients" (defined as those who had between 8 and 16 Medicare ESRD services per month). If a patient did not meet this criterion, then all costs and ESRD services for the month were excluded from the calculations.

14. By whom was the analysis performed?

The analysis was performed by University of Michigan, Kidney Economic and Cost Center (http://www.med.umich.edu/kidney/), under contract to CMS.

15. How did the analysis adjust for issues such as Medicare secondary payor (MSP), missing claims, etc. which would cause an underestimate of the actual cost per patient?

All claims of patients with ESRD were totaled and then divided by the number of dialysis treatments to determine per treatment Medicare costs. In the demonstration, Medicare will continue to pay MSP similar to current practice and thus, costs exhibited under the demonstration are expected to be similar to the costs used to build the bundle price.

16. **How will CMS handle new drugs that come into the market during the next four years? Will they be billed at fee-for-service (FFS) rates?**

    Exactly how the bundle will be updated to reflect drugs that will come out on to the market is a policy decision still to be made.

17. **What population mix was used to define the bundled rates for drugs and access care?**

    There was no population-mix assumption. All claims of patients with ESRD who met the criteria in the answer to question (II)(A)(12) were used in the calculations.

B. Adjustment of Bundle

1. **The solicitation states that payment rates for the expanded bundle categories are based on Medicare claims from July 2000 through December 2001. How will rates be brought forward to estimate 2004 levels?**

   The rates will be recalculated using more recent data prior to the start of the demonstration.

2. **Will the calculations and assumptions be fully transparent to demonstration sponsors?**

   Yes, we will show all calculations to sponsors.

3. **When will the final 2004 rates be established? If the rates will not be established before October 2, what assumptions should be utilized by demonstration sponsors in addressing the solicitation requirement to "outline calculations of budget neutrality" if risk-sharing is proposed?**

   Rates will be recalculated to reflect the most recent data available either late 2003 or early 2004 prior to the start of the demonstration. However, in the meantime, the applicant can use an estimated trend factor for inflation.

4. **The additional bundle payments appear to be payable for each dialysis session. How will this be applied to patents receiving peritoneal dialysis, patients requiring hemodialysis more frequently than 3 times a week, or patients receiving short daily or nocturnal hemodialysis?**

   For peritoneal dialysis, we will use research statistics to convert treatment to a weekly or monthly payment. This will reflect how the composite rate pays for peritoneal dialysis presently. For other types of dialysis, we will only pay for a frequency that Medicare currently pays for dialysis.

5. **Is there flexibility in what products or services are included in the bundled rate?**

   Once the bundle is defined, it will remain constant until redefined. We anticipate re-evaluating the bundle on an annual basis to reflect changing practice patterns, new technology, and changes in benefits.

C. Reconciliation and Payment in Fee-for-Service Option

1. **Under the fee for service model, please define how Medicare costs will be calculated?**

   Under the fee-for-service model, Medicare costs will include the payment for the original composite rate, the bundle add-on, and all claims paid by Medicare outside of the bundle. Medicare costs are the amounts paid by the Medicare fiscal intermediaries and carriers.

2. **Is the Medicare co-payment associated with the add-on payment for the expanded bundle billable to the patient?**

   Yes, the Medicare co-payment associated with the add-on bundle is billable to the patient.

3. **Is it Medicare's expectation that something less than the traditional 20 percent co-payment will be billed and collected from beneficiaries?**

   No, we expect organizations to bill and collect coinsurance required by Medicare program rules.

4. **What is the nature of the dollar amount of the 1% subtraction from the payment for the expanded bundle? Why is this deducted?**

   The dollar amount is one percent of the payment for the add-on bundle for treatment, i.e., one percent of $72.35 per treatment. The deduction is to generate a small savings for the Medicare program and to help guarantee budget neutrality. Page 33498 of the Federal Register notice states that the add-on bundle price reflects a one percent discount for CMS.

5. **Has the evaluation contractor been awarded, if so, who is it?**

   No, the evaluation contractor has not been awarded. There is a competitive solicitation occurring concurrently. Information will be available later on.

6. **Will retroactive annual reconciliations be made to payment rates?**

We will update payment rates annually (e.g., risk-adjusted capitation rates will be updated according to the methodology for the M+C program).

7. **Will hospitalizations be tracked in FFS bundled payment model?**

   Yes, hospitalizations will be tracked. CMS will receive claims information on hospitalizations, as well as other Medicare services.

8. **Will the FFS providers be responsible for hospitalization costs? If so, how will they be reimbursed for them?**

   Hospitals will receive fee-for-service payment as usual from intermediaries. Demonstration sites will not be responsible for paying hospitals. Demonstration sites will be responsible for hospitalization costs in a reconciliation that compares total Medicare expenses for a patient against what the risk-adjusted payment for the beneficiary would have been.

9. **How is the quality withhold handled during the reconciliation process for the fee-for-service model?**

   The five percent quality withhold will be deducted from the expanded bundle payment that the organization receives. Similarly, this amount will be deducted from the target based on the capitated payment amount.

   For example, an organization will receive $68.05 ($71.63 * 0.95) per treatment for the expanded bundle. Assuming 13 treatments per month, this is equivalent to a quality withhold of $46.54 per month ($3.58 * 13) for the expanded bundle. The equivalent amount will be deducted from the monthly capitated rate against which fee-for-service expenditures are compared during the reconciliation process.

III. Budget Neutrality/ Risk Sharing

1. **How soon after submission of a certified revenue and expense report will a final reconciliation occur? Could a sponsor advance the process by submitting a report earlier?**

   Yes, submitting the certified revenue and expense report as soon as possible will advance the process of the final reconciliation. However, reconciliation cannot occur until one year after the end of each operational year.

2. **How will a target medical loss ratio (MLR) be calculated? Will the calculations and assumptions be fully transparent to demonstration sponsors?**

   The applicant should propose an MLR that will be reviewed by CMS. Yes, we will keep the demonstration sponsors fully informed of any proposed changes in the target calculation.

3. **Is "symmetrical risk" the appropriate contracting model given the disparity in relative risk profiles between demonstration sites and CMS?**

   CMS is limited by rules of budget neutrality in terms of the extent to which it can expose Medicare funds to loss. We have attempted to create a demonstration that gives significant incentive to organizations to improve on and test new methods of care delivery. Symmetrical risk sharing is a requirement. It means that both entities share the same amount of either gains or losses. It is not apparent that the risk profiles between CMS and sites are different. If they are, risk adjustment should compensate for this.

IV. Quality

1. **Has CMS defined targeted quality outcomes standards associated with quarterly incentive payments?**

   CMS will use outcomes reported in the Annual Report for Clinical Performance Measures project, which reports national outcomes from a sample over a specified time period in the previous year. Targets based on baseline measures will be set from the outcomes of the organization's dialysis facilities participating in the Clinical Performance Measures project. See p. 33501 of the Federal Register notice for the description of how CPM measures will be used in the assessment of the quality incentive.

2. **How will quality performance be measured in a multi-facility or multi-site proposal – at the sponsor level (including all sites in a single calculation), at the site level (including patients at multiple dialysis facilities in separate calculations), or at the individual dialysis facility?**

   For organizations participating in the demonstration with multiple facilities, quality performance will be measured on the basis of the individual facility.

3. **If a sponsor proposes separate capitated and fee-for-service (FFS) models, will quality performance be measured separately for each model?**

   Quality performance will be measured separately for each model. If an organization proposes separate capitated and FFS models, they must be submitted as two separate proposals.

4. **Will CMS consider a threshold above the mean national performance for a quality indicator at which a 20 percent annual improvement is no longer a reasonable expectation?**

   Probably not, the goal of this requirement is to reward high quality. We would need to examine the specific indicator and situation. We do intend to look into questions such as this during the implementation planning period. We will keep demonstration sites aware of findings.

5. **How will the 5% quality withhold be "budget neutral" if payments not received by some sponsors for failing to achieve established targets are not included in a pool for distribution to sponsors that achieve the targets?**

   We believe that the sort of pool suggested is administratively infeasible. We also believe that the targets set for the incentive are reasonable and that they should be able to be reached by all participating organizations.

6. **How frequently will quality performance be measured and withholds released? To prevent the withhold from becoming a cash flow deterrent to investment in improved patient outcomes, would CMS consider an expedited reconciliation process in which quality withholds are adjudicated quarterly, one quarter in arrears (e.g., performance for the first quarter of 2004 would be adjudicated and payments released within 10 days of the close of the second quarter of 2004)?**

   We are planning quality performance to be measured on an annual basis. We will consider every method to expedite the process of making payments to the organization.

7. **Is the reference to a CMS pilot project for the electronic submission of clinical ESRD data a reference to the VISION system? When will CMS determine whether to require demonstration sponsors to utilize this system? If demonstration sponsors are required to invest additional resources to interface with the VISION system, how will these costs be offset by CMS?**

   Yes, the reference is to VISION. We will determine whether VISION is required for the demonstration and the potential financial impact during the next few months.

8. **How will changes in Medicare payment systems for novel therapies and new benefits be incorporated into payment and reconciliation systems where there is no prior cost history?**

   We anticipate re-evaluating both the composition and the cost of the bundle on an annual basis in order to account for changes in practice patterns and new technologies. The effect of new benefits on total program costs will be monitored during the demonstration.

   Additionally, payment rates would be adjusted in accordance with any changes in underlying program payment policies.

9. **The quality indicators are primarily related to dialysis performance, yet the 5% withhold appears to extend to all medical payments. This will create a substantial imbalance between the two proposed models. Would CMS consider limiting the quality withhold for the capitated model to the same amount withheld under the FFS model?**

   No. Under the capitation model there is greater range and extent of services that is under the control of the demonstration organization.

10. **Why does CMS require an equivalent level of drug utilization while capping reimbursement? How will this be monitored, given that dosing levels vary frequently in response to changes in patient health condition? What will happen to providers that do not meet your standard for maintaining pre-demonstration drug utilization levels?**

    Our purpose for developing the add-on bundle including drugs is that we believe that current financial incentives lead to excessive utilization of certain separately billable drugs. Additionally, there is literature that documents that the effective quantity for certain drugs varies based on the method of administration. Data on patients in the demonstration will be used along with Clinical Performance Measures (CPM) data to monitor that patients receive medically necessary services and medications.

11. How will quality of care be monitored?

Quality of care will be monitored several different ways.

A number of quality indicators will be used to monitor quality of care, measuring improvement over time and against national rates. Five indicators, specifically reflecting dialysis care and outcomes for 100 percent of the demonstration population, will be used to determine the quality incentive payment. Other indicators, including those for disease management efforts, will be collected and analyzed, but will not be used for the incentive payment.

Organizations will be required to include written quality improvement policies and procedures, a written patient education program, a standing quality improvement committee, a patient grievance and appeal system, and a provider credentialing system. In capitated models, we will use customary HEDIS measures and other quality monitoring processes defined in contracts, which we intend to be consistent with quality monitoring and measurement in the M+C program.

12. How often will quality of care indicators be collected?

The quality of care indicators will be collected quarterly.

13. Who will collect and analyze quality of care data?

CMS will perform this function.

14. What will be the consequences if a provider is not meeting quality of care standards?

The contractor may not earn the full incentive payment. Inferior care will be examined by CMS and necessary action will be taken.

15. Will there be a process of appeal?

There will be no formal appeal process. However, we will consider any requests from demonstration sites to re-examine quality measures.

16. Will CMS require a minimum threshold number of patients enrolled in the demo before the 5% incentive for quality is applied?

We expect participating organizations will enroll all of their patients in the demonstration. Accordingly, they should have enough patients to make calculations statistically meaningful.

17. Will quality indicators change to reflect improvements in clinical practice standards during the course of the demonstration?

This is possible. We intend to use CMS's Clinical Performance Measures (CPM) for the quality indicators and we will work within the existing CPM framework to update as necessary.

18. How are quality indicators calculated? Are they adjusted for the case-mix of the demonstration population?

Quality indicators are calculated based on the percentage of patients that achieve an indicator that is defined according to the Clinical Performance Measures (CPM), e.g., Kt/V greater than or equal to 1.2 or percentage of new patients receiving an arterial venous fistula. To calculate this percentage, the number of patients enrolled in the demonstration in a facility who achieve an indicator (e.g., Kt/V greater than or equal to 1.2) is compared to the total number of demonstration enrollees in the facility. The percentage of patients in a participating organization meeting these goals will be compared to baseline measurements, for improvement targets, and national performance measures, as determined by the CPM project. There is no case-mix adjustment of baseline measures.

19. Will bone and mineral quality measures be included in the quality indicators?

Bone metabolism is not included in the indicators used for the quality incentive but it will be included in the indicators used for the evaluation process.

20. Is performance on the quality measures compared to performance by the health plan, regional averages, or national averages?

Demonstration organizations may earn one half of one percent for achieving each of the threshold <u>and</u> the improvement targets for the five quality measures. Improvement targets are based on the health plans' improvement over time. Threshold targets are based on nationwide performance. Therefore, in order to earn back the full 5% quality withhold, an organization must improve over time and perform better than the nation on each of the quality measures.

V. Administrative Costs

1. **We are concerned that participating in the demonstration could lead to excessive medical losses. How is CMS addressing this concern? Will there be a mechanism to assist a demonstration if such losses occur? How will CMS ensure that centers participating in the demonstration remain financially stable (i.e., maintain current level of profitability and patient access to care)?**

   Inherent in the disease management demonstration is an element of risk which participating organizations undertake with full knowledge. However, we believe that there are incentives for more efficient and effective care of patients. In the fee-for-service option, the amount of loss per patient is capped at the amount of the add-on for the bundle and this risk is shared with CMS. We are also allowing risk-sharing arrangements in the capitated model. However, an organization should assess the potential for loss and should not submit an application unless it believes it is financially viable for the organization.

2. **Is there a mechanism within the structure of the demonstration to address the potential for medical liability claims arising from insufficient or lack of continuity of care, which may result from the design of the demonstration?**

   An organization that believes it cannot participate in this demonstration without increasing its exposure to medical liability claims should give serious consideration before submitting an application.

3. **Has CMS estimated the amount of administrative expenses, such as the cost of establishing and operating the various components of the care delivery system and the costs related to complying with CMS's requests, that demonstrations will incur as a result of the demonstration? Were such administrative expenses taken into account when the agency determined the risk-adjusted rates?**

   We assume that applicants will budget the appropriate administrative expenses. CMS does not plan to set any caps on administrative expense but will review this during the medical loss ratio (MLR) review process. Administrative expenses must be reasonable.

4. **Will CMS reimburse demonstration organizations for the significant start-up costs and fees that will be incurred as a result of the demonstration, as was the case in the first demo project? Or, were such start-up costs considered in calculating the risk-adjusted rates?**

   There are no start-up funds available for this demonstration initiative.

VI. Legal Issues

1. **How will CMS ensure that the demonstration complies with the HIPAA Administrative Simplification regulations? How will this compliance be monitored? Who will monitor it?**

   In general for demonstrations, the responsibility falls on the organization to make sure it complies with HIPAA. Health care organizations are obligated to comply, subject to serious penalties if they fail to comply. Demonstration status does not change the obligations or penalties.

VII. Other

1. **What are the rules with respect to billing non-Medicare payors? Please give example of how a non-Medicare payor would be restricted to demonstration payment rules.**

   The rules of a demonstration organization billing supplemental payors would have to be worked out with the State insurance department. Under the demonstration, an organization receiving a fully capitated payment may pursue the possibility of billing existing Medigap policies held by a beneficiary participating in the demonstration, or bill Medicaid, for the amount of cost-sharing that otherwise would be paid under Medicare. The demonstration organization may attempt to make such arrangements with Medigap plans, State Medicaid agencies, and State insurance regulators.

2. **Since the OMB approval for the demonstration has expired, has an extension been received? We understand a three year extension is in the process of being granted, however, the demonstration is for four years. Can you explain this apparent discrepancy?**

   OMB approval pertains to the application form. The approval period only covers the application process not the demonstration period.

3. **If significant losses or contingencies are encountered, are there "early" out options for providers?**

   Yes, the demonstration organization may be able to terminate participation before the end of the full demonstration period. However, for the protection of the
   beneficiaries, the demonstration contract for the capitation model is likely to stipulate a period of time for which the organization is required to provide

services. In the M+C program, there is process of annual renewals by which a provider commits to providing services for a calendar year.

4. **In the event of early exit or the end of the demonstration, will CMS assist in transitioning affected patients to other providers and ensuring continuity of care?**

   Yes, CMS will assist in this task. During the implementation planning period, organizations will be expected to develop a phase-down plan to assist affected patients and ensure continuity of care.

5. **How will the demonstration format be modified if Medicare coverage is extended to prescription medications as proposed in the pending Medicare reform legislation? How would other potential changes in Medicare law (e.g., AWP reform) be taken into account?**

   We anticipate re-evaluating both the composition and the cost of the bundle on an annual basis in order to account for changes in practice patterns and new technologies. The effect of new benefits on total program costs will be monitored during the demonstration.

   Additionally, payment rates will be adjusted in accordance with any changes in underlying program payment policies.

6. **What is meant by the phrase "coordinate all services utilized by patients receiving dialysis throughout the organization"? Does this impose an obligation beyond the scope of currently accepted disease management practices?**

   Yes, we cannot conceive how an organization conducting disease management for ESRD patients could be effective if it did not coordinate all the services for which it is being paid and which it is obligated to provide. Thus, since the capitated payment for ESRD patients is based on the total costs for all Medicare covered services an enrollee receives, the organization receiving such payment is expected to coordinate all those services.

   Such coordination is presently being undertaken in disease management programs by the use of care managers, protocols, patient education and data systems. A goal is to reduce unnecessary and duplicative services in a manner that produces better care for the patient and financial savings for both the organization and the Medicare program.

7. **In designing the demonstration, did CMS review clinical data demonstrating that drug utilization is severely impacted by patient weight and race? If not, are you concerned about the potentially discriminatory effect on heavy patients and black patients?**

   Yes, we did review this clinical literature and we are aware that drug utilization is related to certain types of patient characteristics. This is why case-mix adjustment occurs in the capitated model and why we request that all patients in a particular clinic be included in the demonstration for the fee-for-service (FFS) model.

   Interested organizations will need to describe their affected population in the award process and demonstrate that it is representative. Additionally, patient characteristics will be submitted for all patients enrolled in the demonstration and monitored so as to minimize selection bias.

   We have made it a requirement that applicants state how they will reach out to disadvantaged populations.

8. **What mechanisms are in place to monitor "cherry picking" the Medicare patient population for enrollment in the demonstration? What safeguards and mechanisms are planned to prevent demonstration participants from "cherry picking" the Medicare patient population for enrollment in the demonstration?**

   To the extent facilities do not enroll all patients, we will analyze the health status of patients enrolled and not enrolled in the demonstration.

9. **Has CMS estimated the impact of adverse selection on non-participating providers due to "participating" providers' "cherry picking" behavior?**

   No, because we do not believe this is a potential problem. However, if we suspect this is a problem, we will evaluate and respond to the situation appropriately.

10. **What assurance will CMS give non-participating providers that any inducements offered in the demonstration will not spill over into non-demonstration areas?**

    In general, there is no assurance that there is not a spillover of demonstration methods to neighboring areas and providers.

11. **Will CMS make additional reimbursement available to defray the costs of provider inducements offered under the demonstration?**

No, there is no additional reimbursement. The goals of the capitation and bundled payment models are to allow the organization to achieve greater efficiencies while using disease management tools to improve the quality of care.

12. **Because CMS plans to use the results of the demonstration to evaluate changes within the existing ESRD reimbursement system, how will the agency ensure the validity of the results? How will it ensure there is no selection bias?**

    Our evaluation team will be comprised of skilled researchers using appropriate techniques to measure whether the project achieves its financial and clinical objectives

13. **What is the minimum number of patients CMS estimates a provider should treat in order to safely assume risk under this demonstration?**

    We have not established a threshold for an organization to be able to safely assume risk under the demonstration. Organizations receiving capitation payments must be licensed by the State to bear risk.

14. **How will demonstration facilities be chosen? Will CMS attempt to create a representative patient sample population in the demonstration?**

    Many factors will go into the process of choosing facilities, including the strength of applications, how well they explain their goals and how they plan to achieve them, and an organization's capability and experience. The evaluation criteria are listed in the solicitation. Additional consideration may be given to geographic diversity and patient populations.

15. **How will case mix adjustment be calculated? How will it be applied? By facility? By patient? By geography?**

    For both models, risk adjustment (case mix adjustment) applies at the patient level. In the capitation model, it is used adjust the payment rates. In the fee-for-service model, risk adjustment is used in the reconciliation process to determine what payments would have been under the capitation model.

16. **Can this demonstration be expanded to pre-ESRD patients?**

    No, this demonstration is targeted for ESRD patients. There may be future disease management demonstrations that are more appropriate for the pre-ESRD population.

17. How will the demonstration affect physician payment?

Under the capitated option, demonstration organizations will negotiate and contract with participating providers. As in the Medicare + Choice (M+C) program, physicians will retain the autonomy to decide whether to contract with the organization.

Under the fee-for-service option, physician payment is not affected. The expanded bundle does not include the professional component of the services. Physicians will continue to be paid under the physician fee schedule.

18. Can you please provide a distribution of risk scores for Medicare beneficiaries receiving dialysis?

Distribution of Risk Scores for Medicare Beneficiaries Receiving Dialysis

Percentile	Risk score no msp adjustment	Risk score[a] msp adjustment
Max	2.834	2.834
95	1.566	1.562
90	1.426	1.421
80	1.279	1.272
70	1.182	1.172
60	1.103	1.093
Median	1.045	1.025
40	0.986	0.963
30	0.921	0.890
20	0.864	0.801
10	0.792	0.279
5	0.743	0.193
Min	0.648	0.139

Number of observations= 271309

Data: Individuals receiving dialysis in 2000. The sample includes individuals that meet the criteria to be risk adjusted using the dialysis CMS-HCC model and individuals who were risk adjusted using the dialysis new enrollee model.

[a] - The predicted dollars for individuals with Medicare as secondary payer are multiplied by .215.