Proposed Demonstration Design — Revision 1.3

MMA §623e: ESRD Bundled Payment Demonstration

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A. SCOPE OF BUNDLE

1. Drugs

Proposal: All drugs and biologicals provided by the dialysis facility, with the exception of vaccines, would be included in the bundled payment. The bundled drugs would include EPO/Aranesp, iron, vitamin D, vancomycin, levocarnitine, alteplase and all other injectable drugs administered by dialysis facilities with the exception of vaccines. Vaccines would continue to be covered and paid for when separately billed by a dialysis facility or by another provider.

The bundled payment would include payment for all erythropoietin therapy administered in an outpatient setting. The dialysis facility would be the only entity that would receive payment for outpatient erythropoietin therapy. Epogen and Aranesp would be covered and paid for when administered on an outpatient basis to ESRD patients who are enrolled in the demonstration *only* when administered by the dialysis facility and billed on a dialysis facility claim.

Rationale: See discussion of individual topics, below.

a. Exclusion of vaccines

Proposal: Vaccines and related services / codes would be excluded from the bundled payment. Separate payment would be made for vaccines and related services when administered in a dialysis facility or in another setting.

Rationale: Exclusion of vaccines from the bundle and permitting separate billing with fee-for-service payment would create incentives to provide vaccinations. It is also consistent with other CMS policy on payment for vaccines.

An alternative to exclusion is to include vaccination rates as a P4P criterion. However, to pay for vaccinations through a P4P incentive, the incentive payment would need to cover the cost of the vaccination itself. From a financial perspective, therefore, it would be very nearly equivalent to exclusion of vaccination from the bundle with separate fee-for-service billing. A P4P incentive could still be provided to create an additional incentive for dialysis facilities to achieve target rates of immunizations.

b. Drugs administered in physician offices

Proposal: As noted in the general recommendation concerning bundling of drugs for ESRD beneficiaries, Epogen and Aranesp administered on an outpatient basis to a patient participating in the bundled payment demonstration would be covered and paid for only

when administered in a dialysis facility. That is, payment for Epogen and Aranesp would not be made to physicians or other providers who administer these or related drugs in the office or other outpatient setting. Consideration might be given to applying the same policy to iron and 'vitamin D' to prevent creating incentives to shift administration of these drugs from dialysis facilities to physician offices. Other drugs would continue to be covered when administered in physician offices or other outpatient settings.

Rationale: Drugs that are administered to patients during a dialysis session may also be covered when administered in other settings. Some drugs may be administered during a dialysis session for the convenience of the patient. Other drugs may be administered by the facility because they are an integral part of the treatment that the facility is, in some sense, responsible for. The best example of such a drug is Epogen.

Bundling a drug that can also be administered in another setting requires policy to prevent unintended effects on practice and billing patterns. For example, if Ananesp is substituted for Epogen and is administered in a physician's office instead of being administered by the dialysis facility during a dialysis session, Medicare would be paying twice for management of the patient's anemia.

Aranesp is readily identified, is clearly related to a condition that the dialysis facility is responsible for managing, and is clearly a substitute for a drug that is to be included in the bundle. It would be necessary, therefore, to restrict coverage of Aranesp when administered to ESRD patients in a physician's office.

Iron and vitamin D also account for a significant percentage of total payments for separately billed items and services. In the preliminary analysis of alternative bundle definitions these drugs contributed $16.22 and $11.63 per session, respectively, or just over 25 percent of the total separately billed Medicare allowable charges. Both are also an integral component of the management of anemia, and so a plausible case can be made to treat these drugs in the same way EPO/Aranesp is treated.

Other drugs that are included in the bundle, however, are used in a variety of settings for a variety of purposes that may not involve the dialysis facility directly. Limiting coverage for these drugs outside the dialysis facility may create significant clinical, quality of care, and administrative. Permitting coverage and payment outside the dialysis facility may, however, create incentives to shift the site where these drugs are administered. This issue should receive explicit discussion.

A second question that should receive explicit discussion concerns the coverage of Aranesp and Procrit when administered to oncology

patients who are also receiving treatment in dialysis facilities. Limiting coverage of Aranesp or related drugs in the office setting will mean that the management of oncology-related anemia will become a more significant responsibility of the dialysis facility. The case mix models that have been developed have shown that a number of cancer diagnoses increase resource use by between 5 and 7 percent when using a prior EPO dose-response variable for a period 'distant' from the current month. When the more 'recent' EPO dose-response variable is used and, in particular, when the prior month's hematocrit is used in the model the association between cancer diagnoses and resource use is generally reduced to between 1 and 2 percent. (See page 8 of the material included in tab 7.) Using these case mix models to adjust payment would mean that dialysis facilities would be paid more for treatment of cancer patients. The increase in resource use associated with cancer dialyses is above and beyond any increase measured by the dose-response variable itself.

c. Inclusion of 'other' drugs

Background: The category of 'other' drugs includes all drugs that were not included in bundles 1A, 1B, and 1C. Information on the range of additional drugs that appear on claims submitted by dialysis facilities is provided in the supplemental material included in tab 6.

Proposal: All drugs administered by a dialysis facility would be included in the bundle. Dialysis facilities would not be able to bill and be paid separately for the 'other' drugs that are administered to patients by the facility. However, when these drugs are provided in another setting they would continue to be covered and paid for by Medicare. The dialysis facility would not be required to pay for drugs administered in other settings.

Rationale: The range of drugs administered by dialysis facilities and billed on dialysis facility claims is very broad, but most are received by very small numbers of patients and are associated with relatively small dollar amounts when they are used. The Medicare allowable charge per line item exceeds $100 for 39 drugs. These drugs are generally used infrequently; only one (reteplase) involves more than 1,000 line item charges. The line item count provides a rough indication of the number of monthly claims on which covered charges for these drugs occurs. Some of the more expensive drugs appear to be associated with cancer treatment or treatment of AIDS/HIV.

For purposes of reference, the total number of patient months in 2003 that were available for use in the analysis of alternative bundles exceeded 2.4 million. A drug that appears on 1,000 or fewer line items, assuming each line item corresponds to a single monthly claim, will appear on 0.04 percent or less of all monthly claims in 2003 or 4 or fewer out of every 10,000 monthly claims.

When some of these infrequently used drugs are administered they can add substantially to the facility's cost. However, the extraordinary low frequency of some of these drugs (often less than 10 line item charges across all patient months in 2003) suggests that bundling these drugs may be an artifact of billing practices. In this case, bundling these drugs would cause these charges to appear on a different type of claim. Alternatively, bundling these charges may cause the drugs to be administered outside the dialysis facility.

Alternative for discussion: Instead of bundling all drugs, a list of excluded drugs could be identified that are believed to be a source of unacceptable risk to either patients or facilities if bundled. In developing this list it would be necessary to avoid "unbundling" substitutes for other drugs that are to be bundled.

2. Laboratory tests

Proposal: The bundled payment would include all laboratory tests ordered by the patient's nephrologist or other practitioner responsible for managing the services provided by the dialysis facility (i.e., dialysis and drugs administered by the facility). The tests included in the bundle would include tests ordered by the MCP practitioner and submitted directly to a laboratory (i.e., tests that are not initiated by or through the dialysis facility). The tests included in the bundle would not include tests ordered by a physician other than the patient's nephrologist (or other MCP practitioner) but obtained through the dialysis facility. The dialysis facility (or a related laboratory) would be permitted to separately bill for services that were initiated by the facility but that were ordered by a physician or other provider not directly involved in the management of the care provided by the dialysis facility.

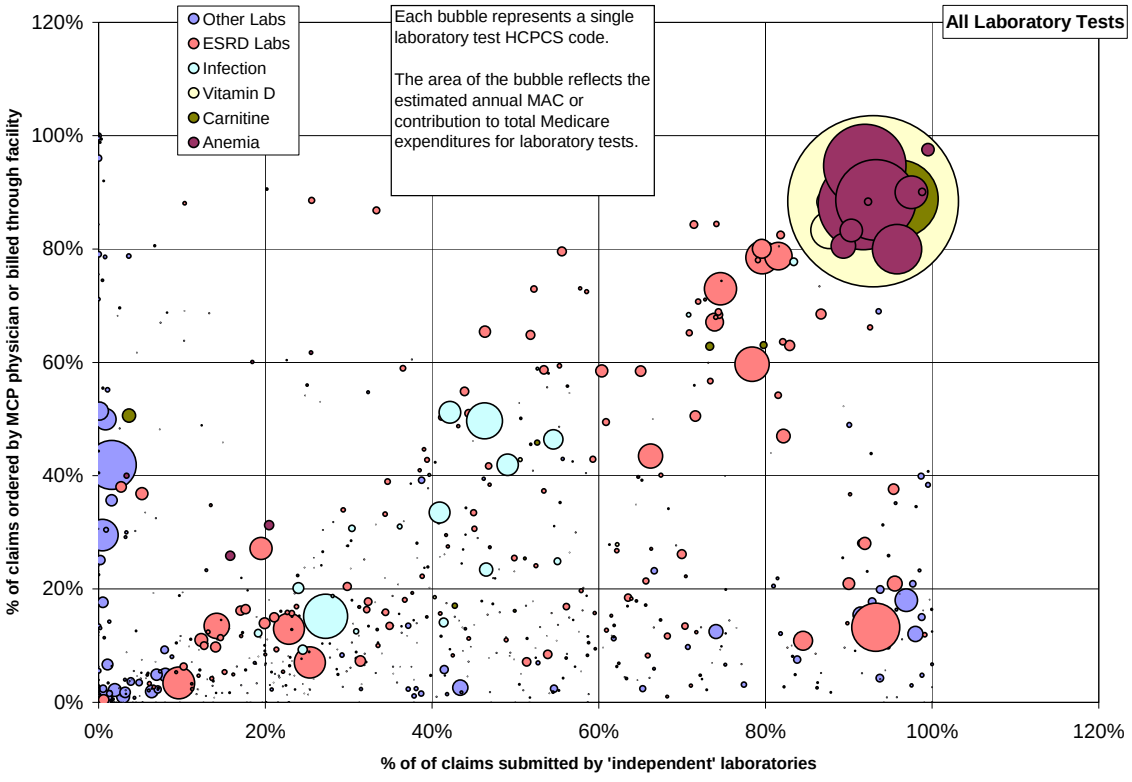
Rationale: Permitting a laboratory or dialysis facility to separately bill for services that are ordered by providers other than the patient's nephrologist (or other practitioners who manage the care provided by the dialysis facility) will encourage facilities to function as a central point for collecting specimens for laboratory testing. Conversely, requiring a facility to pay for all laboratory tests that it initiates by drawing a specimen and submitting it to a laboratory would work against the goal of reducing risk to the patient (preservation of vascular access) by coordinating laboratory work through the patient's dialysis facility.

A broader bundling requirement under which all or most laboratory tests would be bundled would create significant administrative responsibilities for the dialysis facility, would require complex exceptions for tests that cannot be delayed or obtained through the facility, and would have potentially adverse effects on quality of care. For example, if all laboratory tests were included in the bundle, regardless of who ordered or provided those tests, the dialysis facility would be compelled to become a kind of clearinghouse for laboratory testing. Facilities would need to develop the capacity to adjudicate and pay claims for laboratory work performed by other entities. Medicare would need

to establish rules defining the obligation of dialysis facilities to supply laboratory testing data and/or to perform or pay for tests ordered by physicians and other practitioners not affiliated with the facility.

Figure A.2 suggests the complexity of utilization and billing patterns for laboratory services. Each circle or bubble on the chart represents a single HCPCS code (i.e., laboratory test). The horizontal axis of the chart positions each test based on the percentage of all claims for that test that are submitted by independent laboratories. This variable is a proxy for the frequency with which the dialysis facility is involved in initiating the test. The vertical axis of the chart positions each test based on the percent of claims that are either ordered by an MCP physician (carrier claims) or are submitted by dialysis facilities (intermediary claims). This variable is a proxy for the frequency with which the test is ordered for a purpose related to the management of ESRD or, conversely, complications and co-morbidity that may be associated with ESRD but not managed by the facility or its affiliated physicians. The size of the bubbles indicates the relative magnitude of the total Medicare allowable charges associated with the test. The shading or color of the bubbles indicates the broad category or bundle to which the test was assigned.

Figure A.2: Laboratory claims



Source: See supplemental data on laboratory tests (tab 6) for information on data sources and methods.

As these data show, certain tests associated with vitamin D management and anemia are very commonly ordered by MCP physicians and provided/initiated through the dialysis facility. Other laboratory tests vary widely in importance and the nature of the involvement of the MCP physician and facility. Bundling these tests would, however, entail a significant amount of back-and-forth communication and a significant volume of financial transactions between the dialysis facility and other providers.

3. Other services / items

Proposal: The bundled payment would cover all medical/surgical supply items provided by the dialysis facility including all blood and blood products (and blood processing/storage fees) administered by the facility and billed through the facility. Consideration would be given to bundling all other services (other than laboratory services performed on behalf of non-MCP physicians), or alternatively adopting billing guidelines that will prevent these services from appearing on dialysis facility claims.

Rationale: The rationale for this recommendation has three parts. The first part is the rationale for including medical/surgical supplies. The second is the rationale for including blood and blood products. The third is the rationale for potentially bundling all other services.

Table A.3 shows the relative magnitude of payments for 'other' services and provides a context for the following discussion.

Table A.3: Preliminary breakdown of 'other' facility MAC, 2003

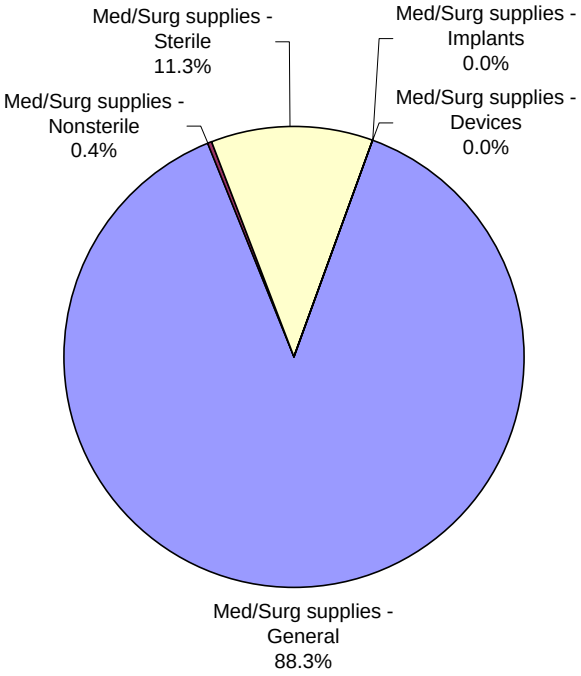
Revenue Center Class	MAC	%
Supplies	21,090,879	94.7%
Imaging	218,873	1.0%
Surgery	3,096	0.0%
Other	946,903	4.3%
Total	$ 22,259,751	

a. Medical/Surgical Supplies

After removing drugs and laboratory tests, supply items comprise nearly 80 percent of the remaining items and services that are billed separately by dialysis facilities. Figure A.3 shows the breakdown of these supply items into sub-categories. More than three-quarters fall into the category of general medical and surgical supplies. It should be noted that the classification of supplies is based on the revenue codes that are used on facility cost reports. The 4-digit revenue code corresponding to general supplies is 0270.

Figure A.3 shows the composition of the medical/surgical supplies category. The sub-category of general supplies dominates the category, accounting for nearly 90 percent of all Medical allowable charges for medical/surgical supplies submitted on dialysis facility claims. Sterile supplies account for just over 11 percent of MAC for supplies on facility claims. Implants and devices account for less than one percent of all MAC for supply items and services.

Figure A.3: Supplies billed by dialysis facilities



An examination of the HCPCS coding of line items on dialysis facility claims identified $14.6 million in Medical allowable charges associated with codes that identify as ESRD/dialysis related supplies or other items and services. Of this amount $12.7 million is associated with the HCPCS code for “syringes, with or without needle”. An additional $818,000 was associated with “blood tubing”.

These supply items appear to be used nearly universally, by all patients and in all patient months. Claims containing covered charges for these services were submitted in 2003 by nearly 98 percent of facilities, for 86 percent of patients, and contain 2.7 million line items. There is no obvious rationale for excluding them from the bundle. The relatively small magnitude (as a percentage of total MAC) of payment for these services also

suggests that bundling these items cannot create significant issues for case mix adjustment. The relatively high percentage of sterile supply items that originate on claims from hospital-based facilities does, however, suggest that not all supply items are related to dialysis and that charges for these services may be affected by changes in billing practices by hospital-based facilities.

b. Blood, blood products, and blood processing

Proposal: Blood and blood products and associated services administered by or through dialysis facilities would be included in the bundled payment.

Rationale: Blood, blood products, and blood processing comprise 17 percent of separately billed items and services other than drugs and laboratory tests. Blood storage and processing comprises 85 percent of these blood-related costs. Leukocytes and packed red cells comprise 8 percent and 6 percent, respectively, of total blood-related costs.

Blood and blood products are both a substitute and complement for items and services included in the bundles, namely erythropoeitin. Excluding blood and blood products from the bundle could lead to the substitution of transfusion for EPO therapy. The encouragement of appropriate use of transfusion therapy is in the interest of patients who do not respond to EPO therapy. As a result, a case could be made to exclude blood from the bundle although the role of appropriate transfusion therapy in anemia management weakens this case.

c. Imaging, surgical services, and 'other' items and services

Proposal: Services other than those already discussed could be either included in the bundled payment or not. Whether or not they are included in the bundled payment, dialysis facilities and other providers would receive appropriate instruction on the correct billing of services on dialysis facility claims.

Rationale: Services that are billed on dialysis facility claims but that are not drugs, laboratory tests, medical/surgical supplies, or blood and blood products include a broad range of medical procedures and services. The larger number of these involve imaging and, to a much smaller degree, surgery. The 'other' category also includes miscellaneous therapeutic services (e.g., respiratory therapy) and diagnostic services (e.g., EKG/ECG and electromyelogram). Claims for these services are submitted for a very small number of patients, and are submitted by a very small number of facilities. For example, claims for EKG/ECG were submitted by 640 facilities on behalf of 4,526 patients in all of 2003. Electromyelogram claims were submitted by 20 facilities on behalf of 783 patients.

It is possible that these claims represent anomalous claims submissions. A likely explanation is that these are claims submitted by hospitals with dialysis facilities, but that the claim was identified as a dialysis facility claim instead of being identified as another type of outpatient hospital claim. An argument supporting this speculation is that the services in question are likely to have been used by a larger number of patients than these data report. However, claims for this larger number of services were not submitted on dialysis facility claims. Instead, they would appear on other types of hospital claims or claims submitted by other providers.

4. Updating scope of bundled services

Comment: Regular analysis of clinical practice and claims data is an essential function for the administration of any health insurance plan or program. Medicare claims experience should be regularly analyzed to ensure that the services that ought to be included in the bundle are, in fact, included and are being paid for as part of the bundled payment. Policy should also be regularly reviewed and updated as necessary to ensure that services that ought not to be included in the bundle are not, in fact, included.

Discussion: Any payment system requires regular updating, and bundled ESRD payment will be no exception. Over the course of the demonstration, updating may be needed to respond to changes in billing patterns. Over the longer term, updating will be needed to reflect changes in technology (e.g., the introduction of new drugs) and practice patterns. These changes could incorporate new technologies into the bundle or could allow them to temporarily "pass-through" as separately billable in order to encourage innovation and gather information helpful in updating the bundle's composition and price.

It would be helpful, after the commencement of the demonstration, for the advisory board to take up the development of monitoring procedures, including recommendations on data to be captured, and criteria that should guide both the evaluation of services included in the bundle during the demonstration and the evaluation of proposed changes to the bundle in response to technological innovation.

B. PAYMENT METHODS

1. Unit of payment

Proposal: The bundled payment would be based on an amount for each dialysis session, consistent with the method of payment for composite rate services.

Rationale: Dialysis facilities and Medicare claims processing systems are familiar with and configured to process claims organized around the session as the basic unit of payment. Adopting a longer unit of payment such as a week or a month would require the adoption of adjustments for 'partial months' or 'weeks' of dialysis, although it would arguably create additional flexibility for dialysis schedules that do not follow the three-times-a-week pattern. Given the high percentage (approximately 70%) of patient months that involve no interruption in the pattern of thrice-weekly dialysis, there is also little practical difference between a per session payment that applies a thrice-weekly limit and a payment for a longer period of time.

2. Structure of payment

Proposal: The bundled payment would be calculated by adding the 'composite rate' payment and a 'bundled services' payment for services that are currently billed separately. Each component of total payment would be adjusted separately for case mix. That is, two distinct case mix adjustments would be used. One would be applied to the composite rate. The other would be applied to the newly bundled services. The solicitation would outline the method of implementing the bundled payment and solicit comment on this proposal from organizations interested in participating in the demonstration and the renal disease community.

Rationale: The structure of the bundled payment is a largely technical matter. There are two basic options for structuring the bundled payment. The first option would make a supplemental payment on a per session basis for separately billed items and services that operates alongside, but independently of, the composite rate. The second option would combine the separately billed payment with the composite rate.

The difference between these two options is, at some level, more cosmetic than substantive although they may be viewed by providers as fundamentally different. Ideally, the composite rate component and the separately billed component would be combined. This would be consistent with other payment systems, including the DRG-based hospital inpatient payment system. However, patient-level data on resource use are available only for the separately billed services. This may argue for adopting a two-component approach at least for the demonstration.

a. Option 1: Separate adjustments/payments

The first option would establish a separate session-based payment that would replace line-item billing on a fee-for-service basis for separately billed items and services. The total payment to a dialysis facility for a patient would be the sum of two components: (1) the facility's composite rate, multiplied by the composite rate case mix factor for the patient; and (2) the "separately billed" bundled payment add-on, multiplied by the separately billed case mix factor for the patient.

Separate case mix factors would be computed for each patient, one describing the relative 'cost' of composite rate services for the patient and the other describing the relative 'cost' of separately billed services for the patient.

The composite rate component would be adjusted using the 'standard' composite rate case mix adjustment. The case mix factor for separately billed services would operate in a similar manner, although the variables used in the formula and the weights attached to those variables would differ.

b. Option 2: Combined adjustments/payments

The second option would combine the composite rate and separately billed services into a single payment amount. This option would resemble both the DRG-based payment system used for hospital services and the HCC-based payment system that is being phased in by the Medicare Advantage program.

Following this model, the bundled ESRD payment system would combine the composite rate and an add-on for separately billed services to arrive at a single 'bundled' payment rate. This 'bundled payment rate' would then be multiplied by a case mix factor that reflects the effect of patient characteristics on the expected cost of all services included in the bundle, i.e., both composite rate services and separately billed services.

This approach could be implemented by estimating a separate case mix model. However, because patient level resource data are not available for composite rate services, it would make more sense to mathematically combine the composite rate and separately-billed case mix adjustments into a single adjustment. However, this approach is substantially similar to simply adopting option 1, the two-component approach to bundled payment.

3. Cost sharing

Proposal: Patient cost sharing under the bundled payment would be calculated based on a uniform coinsurance rate applied to the bundled payment amount. The coinsurance rate would need to be adjusted to reflect the fact that laboratory services are not, under current law, subject to the same cost sharing as drugs and composite rate services.

Rationale: The discussion rationale for this recommendation is divided into two parts: a brief review of the current structure of cost sharing and a discussion of the impact of bundled payment on cost sharing relative to that current structure.

In addition, separate recommendations and rationales are provided to address the issues of bad debt reimbursement and cost sharing for dual-eligible beneficiaries.

a. Current structure of cost sharing

Currently, with two significant exceptions, most of these services provided by dialysis facilities are subject to a 20 percent coinsurance requirement. The exceptions are laboratory services, which do not have any coinsurance requirement, and blood which is subject to the blood deductible.

Table B.3.a. Schedule of cost sharing / coverage requirements

Service	Cost sharing	Coverage requirements
Dialysis (CR)	20% coinsurance	Frequency limit (3x week)
Injectable drugs	20% coinsurance	Administered by dialysis facility Incident to physician services
Self-admin. Drugs	20% coinsurance	
Vaccines*	None	
Laboratory tests	None	
Blood	3 pint deductible No cost sharing for storage, processing or administration fees	Administered by dialysis facility Incident to physician services
Supplies	20% coinsurance	Reasonable & necessary

* If vaccines excluded from the bundle, however, the coinsurance issue does not arise.

b. Bundled cost sharing payment

Cost sharing under a bundled payment would be straightforward if all of the components of the bundle were subject to the same cost

sharing requirements and if the amount of payment under the bundled payment system bore a reasonably close relationship to actual resource use.

Because cost sharing differs for the various services to be included in the bundle, the calculation of a cost sharing amount is more complicated. The variation in payment for components of the separately billed services further complicates the calculation of a cost sharing amount.

As a practical matter, this problem is small because it is largely caused by the absence of cost sharing for laboratory services. Because laboratory payments are a relatively small percentage of the additional services (less than 10 percent of separately billed items and services and less than 5 percent of the total bundle including the composite rate) the effective coinsurance rate for the bundle is only slightly below 20 percent (~19 percent).

A more serious problem is created by the potentially large differences between payment and actual resource use for individual patients. Table B.3.b illustrates the problem.

Table B.3.b. Effects of 'prediction errors' on cost sharing

	Patient A	Patient B	Patient C
Current policy			
Actual resource use (MAC)	$1,200	$1,600	$2,000
Coinsurance rate	20%	20%	20%
Patient's financial liability	$240	$320	$400
Bundled payment			
Predicted payment (prospective rate)	$1,400	$1,600	$1,800
Coinsurance rate	20%	20%	20%
Patient's financial liability	$280	$320	$360
Actual resource use (MAC)	$1,200	$1,600	$2,000
Effective coinsurance rate	23%	20%	18%

In this example, the effective coinsurance rate varies from 18 percent for a patient whose actual resource use is substantially higher than predicted use to 23 percent for a patient whose actual resource use is substantially lower than predicted. As this example illustrates, the ability of case mix adjustment to match actual and predicted resource use has significant implications for the impact of bundled payment on patient cost sharing. A case mix adjustment that closely matches payment to actual resource use will have a negligible impact on patient cost sharing.

It should be noted that the effect of bundled payment on cost sharing is not affected by the extent to which the limitations of the case mix measure 'average out' at the level of the facility. A patient's cost

sharing obligation is not affected by the average payment to the facility. This issue is an additional argument for seeking or favoring a case mix adjustment that more closely matches predicted to actual resource use. The issue of case mix adjustment is discussed in the next major section, below.

Finally, a significant difference between other prospective payment systems, e.g., the inpatient hospital payment system, and the bundled payment system should be noted. Those other payment systems may exhibit large differences between actual and predicted payment. Under the DRG-based inpatient hospital system, actual payment may be substantially higher or lower than actual payment. These differences do not, however, affect patient cost-sharing obligations because the hospital benefit includes a uniform deductible for all admissions occurring within a single benefit period.

c. Reimbursement of bad debt

Proposal: Medicare would continue to reimburse facilities participating in the demonstration for bad debt as under current policy. This will require bad debt amounts to be pro-rated based on estimated payments attributable to composite rate services and payments attributable to the separately billed services that are bundled with the composite rate.

Rationale: Under current law, dialysis facilities are reimbursed for bad debt (unpaid coinsurance) on composite rate services. They are not reimbursed for bad debt on separately billed items and services. The demonstration authority does not waive these requirements. As a result, it will be necessary for facilities participating in the demonstration to apportion any uncollected coinsurance between composite rate cost sharing and separately billed cost sharing.

d. Dual-eligible cost sharing

Proposal: CMS will need to assess the interaction of cost sharing under the demonstration with State Medicaid policies. CMS would need to negotiate or modify the design of the demonstration to ensure that State cost sharing obligations are not affected for patients treated at facilities that participate in the demonstration. Alternatively, states that have incompatible requirements for Medicaid patients could be excluded from the demonstration. A third alternative is to exclude dual-eligible patients from the demonstration.

Rationale: Medicaid supplements Medicare coverage by covering some or all of any cost sharing (coinsurance and deductibles) required by Medicare and by covering services not covered by Medicare. As discussed above, the effect of bundled payment on cost sharing obligations (more specifically on coinsurance obligations) will depend

substantially on the ability of the case mix adjustment to match predicted to actual resource use. If the payment under the bundled payment system differs substantially from payment under the current payment system, then state cost sharing obligations for dual eligible beneficiaries will change. These patient-level differences will, however, tend to average out over all dual-eligible patients. Whether this expectation is borne out will require additional analysis for the sites participating in the demonstration.

The extent to which issues related to Medicaid coverage can be resolved may determine whether facilities in a particular state are able or willing to participate in the demonstration.

e. Medicare as Secondary Payer (MSP)

Proposal: MSP provisions would apply to the demonstration in the same manner as they apply under current law. The total amount of any Medicare payment for a patient whose primary coverage is not Medicare would be determined based on a comparison of the amount paid by the primary payer and the amount that Medicare would pay under the bundled payment system.

Rationale: There is not provision in the statute to apply a different MSP policy. The information needed to calculate the case mix adjusted bundled payment amount should be available to the dialysis facility that provided the services for which secondary payment is being sought.

4. Updating prices / rates

Proposal: A formal process for updating payments under a bundled payment system needs to be developed. During the demonstration, however, payment rates for facilities participating in the demonstration would be determined by updates to payment amounts under the standard Medicare payment systems. To the extent that facilities participating in the demonstration achieve savings, and to the extent that these savings flow directly to Medicare, payment rates would be adjusted upward.

Discussion: Conceptually, any prospective payment system needs to specify a method for updating prices. Updates generally consist of four components: a factor that represents changes in input prices (inflation); a factor that reflects the impact of changes in technology; a factor that reflects the impact of changes in medical practice; and a factor that reflects the impact of changes in provider efficiency or productivity. Additional adjustments may be made to reflect the effect of changes in coding on payment and the effect of changes in patient characteristics that are not reflected in case mix adjustment.

In the case of the ESRD bundled payment demonstration, the components of the bundled payment rate are all services that Medicare pays for under some

form of fee schedule. The statute does not provide for a separate updating method or amount. Therefore, it will be necessary (for purposes of the 3-year demonstration) to simply update the components of the bundled fee by the same factors that apply outside the demonstration.

Over the long run (outside the context of the demonstration) a formal method for calculating an update may need to be developed. It is possible that such a method could be tested in the demonstration, although doing so would have a budgetary impact (i.e., if the fee updating method used in the demonstration results in a payment amount that differs from payment under the updates that would be applied to standard Medicare fee schedules). Of course, it will be difficult to perform a head-to-head comparison of payments if the bundled payment incentives result in changes in practice patterns or provider efficiency or productivity.

The method used to adjust payments for case mix may, however, have a significant implication for the updating of payment amounts. If the case mix adjustment uses a measure of prior EPO dose-response, then reductions in EPO use (setting aside questions related to quality) will result in reductions in payment. Changes in EPO use will, in other words, produce savings for Medicare and will result in a net reduction in program outlays. It will be difficult, if not nearly impossible, to precisely quantify these effects. However, to the extent that monitoring and evaluation finds such savings they should be returned to the demonstration participants in the form of an across-the-board update to payment amounts.

C. CASE MIX ADJUSTMENT

The preliminary case mix modeling suggested that case mix adjustment relying principally on demographic and diagnosis characteristics is likely to substantially over- and under-predict resource use (and more specifically use of EPO). It also suggests that the difference between predicted and actual use of resources is quite consistent for a single patient across months. Finally, it suggests that even though the difference between predicted and actual resource use for individual patients tends to average out at the facility level, the difference remains substantial. Whether this difference reflects unmeasured case mix differences or medical practice is unknown and largely unknowable based on currently available data. It is, however, consistent with evidence of large intrinsic differences in patients' response to EPO therapy from clinical trials and practice guidelines.

To explore the possible merits of including measures of prior use and response to EPO therapy in a case mix adjustment, a series of analyses were undertaken. These analyses are described in the separate paper included in tab 4.

An additional analysis of the relationship between patient volume and risk was conducted to provide some broad parameters against which to evaluate the performance of case mix models. See tab 3 for a separate paper addressing this issue.

1. Preliminary Recommendation

Proposal: The case mix adjustment would include a measure of prior dose-response for EPO and a limited set of additional patient characteristics, but see the questions for discussion, below.

Rationale: Proceeding with a prospective payment for EPO that does not adequately adjust for variation in required maintenance dose has significant implications for both effectiveness of care, risk to patients, and equity, as well as significant financial implications for the Medicare program and dialysis facilities. Case mix models that do not include measures of prior dose-response do not appear to yield predictions of resource use that are sufficiently close to actual resource use.

2. Questions for discussion

The paper on case mix modeling concludes with a series of questions for discussion. These are:

1. Prior dose-response is likely to be needed in any case mix model. The selection of a period to be covered by the dose-response variable is not obvious, however. Advice is needed on the choice of an appropriate period. Several alternatives can, obviously, be considered: (1) the period used in models 4 and 6 through 13 (the 6^{th}, 7^{th}, and 8^{th} months prior to the current month; (2) the three months prior to the current month; and

(3) a somewhat longer period immediately adjacent to the prior months (e.g., the 4 or 5 months prior to the current month).

2. Using a dose-response variable has administrative implications for the collection of information on claims forms. It also has implications for the nature of the incentives that are created. For example, as structured in these models, an increase in a patient's hematocrit will in and of itself cause a reduction in future payment. However, a reduction in dose in response to the higher hematocrit will further reduce future payment. This simplistic analysis, however, considers only the effect of changes in dose on payment. It does not consider the effect of changes in dose on costs or net income. Does the proposed dose-reponse variable provide a viable starting point for further development and refinement? What kind of refinements might be tested in the demonstration?

3. The prior month's hematocrit appears to be an important predictor of resource use. It also may be important clinically because it is the hematocrit in the current month that affects dose adjustments. However, including it in a case mix adjustment could create incentives to reduce EPO dosage as a lower hematocrit results in higher payment. Additional discussion of this issue and a recommendation is needed.

4. An adjustment is likely to be needed for the initial months of dialysis. However, the period of time that should be covered by this adjustment is unclear. It is clearly longer than one month, and probably shorter than 12. Input on the structure of such and adjustment would be useful. For example, would separate adjustments for the initial month of dialysis and for the first three full months of dialysis be seen as administratively viable?

5. The way in which the diagnosis variables should be included in the model is unclear. In the near term, the approach that makes the most sense on technical and statistical grounds is to distinguish between complicated and non-complicated patients or, possibly, between patients with no complications, moderate complications, and severe complications. Over the longer run, it may be appropriate to develop a more refined set of diagnostic categories. Would such an approach be acceptable to clinicians and to facilities?

D. MODALITY

Comment: It is frequently stated that the payment system should not create financial incentives for either patients or facilities that favor one modality over another. Choice of modality, it is generally said, should be determined principally by the clinical needs of the patient and the patient's preferences, willingness, and ability to take on the responsibilities associated with a particular modality. In general, however, financial incentives under the current payment system are seen as favoring in-center dialysis over home dialysis and peritoneal dialysis. The question for the bundled payment demonstration is how and to what extent bundled payment can create more neutral incentives affecting choice of modality.

1. Peritoneal dialysis vs. hemodialysis

Proposal: Separate bundled payment amounts would be established for hemodialysis and peritoneal dialysis patients. These payment amounts would be based on the best available data on actual resource use for the separately billed services for these two groups of patients. In establishing payment rates, specific attention would be given to ensuring that available data do not artificially understate resource use by peritoneal dialysis patients. Payment amounts for PD would need to include the costs of training. Additional analysis would be performed during the demonstration to better understand the sources of differences in resource use for these two groups of patients.

Rationale: The goal of the demonstration should be to create financial incentives that are neutral with respect to choice of modality. To the extent that current payment policy creates incentives that favor hemodialysis (HD) over peritoneal dialysis (PD), the creation of 'neutral' incentives may require reduction in payment rates for HD and an increase in payment rates for PD. The requirement that payments under the demonstration be budget neutral will prevent the 'correction' of any imbalance in financial incentives simply by raising PD rates without an offsetting reduction in HD rates. However, the amount paid for HD and PD patients should reflect the resources used by each group. In other words, the relationship between HD and PD payment rates should reflect the relative difference in resource use by HD and PD patients. The relative profitability (or profit potential) of HD and PD should be the same so that financial incentives have a minimal influence on choice of modality.

The cause of differences in resource use between PD and HD patients further complicates the identification of financial incentives. For example, if the greater reliance on subcutaneous administration is partially responsible for lower EPO use by PD patients relative to HD patients, and if facilities increase reliance on subcutaneous administration for HD patients, and if increased reliance on subcutaneous administration reduces use of EPO by HD patients, the profitability of HD patients may increase relative to PD patients. In this case, the bundled payment would create an incentive favoring HD over PD. If, however, there is some intrinsic difference between HD and PD patients that reduces the prevalence or severity of anemia in the PD population, then

failing to recognize this difference in payment rates would create financial incentives favoring PD over HD.

Alternative for discussion: The differential in payment rates for HD and PD patients could be reduced based on an estimate of program savings achieved by PD.

Rationale: In setting payment rates for peritoneal dialysis, consideration could be given to the savings that may be associated with peritoneal dialysis. To the extent that bundled payment reduces the bias favoring in-center hemodialysis, it will increase the rate at which incident patients choose peritoneal dialysis. Increased reliance on peritoneal dialysis could result in reduced expenditures for Medicare to the extent that complications and co-morbity is reduced in frequency or severity (e.g., lower rates of anemia would result in lower use of EPO and lower total expenditures for drugs related to the treatment of anemia). This assumes, of course, that incident patients who are not yet eligible for Medicare, and the facilities that provide their treatment, would have the same incentives under whatever payment system is used by the patient's primary payer.

2. Home hemodialysis

Proposal: Home hemodialysis would be paid under the same rate structure as in-center hemodialysis patients. To the extent that data are available and sufficient to support analysis, an effort would be made to identify the difference in resource use, including costs or payments related to training, for home and in-center hemodialysis patients. During the demonstration, analysis would, to the extent possible given the number of home hemodialysis patients participating in the demonstration, focus on documenting the magnitude and causes of differences in resource use between in-center and home hemodialysis.

Rationale: Given limitations on the time and resources available it has not been possible to analyze the extent to which home hemodialysis patients have a pattern of resource use that differs from in-center hemodialysis patients. The number of home hemodialysis patients likely to participate in the demonstration is small, though it may increase. It may even be desirable to encourage the submission of applications by facilities with well-developed home hemodialysis programs in order to obtain experience that could be used to inform the development of payment policy on this issue. The solicitation process itself provides an opportunity to explore whether using the same payment for in-facility and home hemodialysis is appropriate.

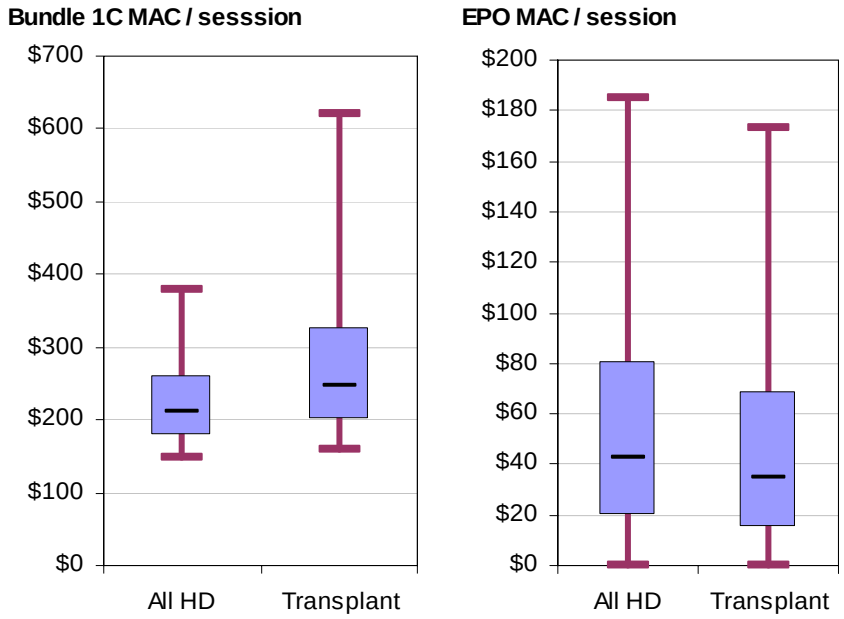
3. Transplant patients

Proposal: Transplant patients would be excluded from the demonstration project. Under a bundled payment system, it is probable that special payment rules will be required for the services used by patients in the weeks preceding transplant and to pay for services in the immediate post-transplant period.

Prior to the start of the demonstration an additional recommendation would be developed to address the point in time at which payments under the bundled payment system would be discontinued for transplant candidates and recipients.

*Rationa*le: The pattern of resource utilization for transplant patients is substantially unlike that of dialysis patients. The payment system should avoid creating any financial penalty for transplantation, but the precise point in time at which payment under the bundled payment system would be insufficient has not yet been determined.

Figure D.1: Use of resources (per session) by patients receiving a transplant



Source: Preliminary analysis of alternative bundles, table 1C-1, pp. 111 & 113.

Figure D.1 presents data from the preliminary analysis of bundles for total resource use, including both composite rate and separately billed services. It compares the variation in total per session resource use (MAC) for bundle 1C and use of EPO per session for all hemodialysis patients and for hemodialysis patients who received a transplant during the month. The solid box represents the range covered by the 50 percent of patients between the 25th and 75th percentile. The 'whiskers' identify the 5th and 95th percentiles. Although individual components of the bundle (e.g., EPO) actually displayed somewhat less variation in 'transplant' months than in all months, total resource use (on a per session basis) was both higher and more variable for months in which a transplant occurred.

E. OUTLIER POLICY

Background comment: 'Outlier' payments are used in some payment systems (specifically the inpatient hospital payment system) to provide additional payment for patients that incur extraordinary costs.[1] An outlier payment generally performs a function that is similar to a 'stop-loss' insurance policy. It does not prevent a facility from losing money, but instead limits the loss that the facility incurs when a patient incurs extraordinarily high costs.

Proposal: As part of the solicitation, three outlier payment policy options would be described. The first would be the simplest: no outlier payments would be offered. Facilities would be entirely 'at risk' for the difference between predicted payment under the bundled payment system and payment under current policies. The second option would limit losses on individual patients. The third would limit losses for the facility as a whole. The solicitation would ask applicants to specify whether an outlier policy would be a desirable or necessary feature of a bundled payment system, to comment on the proposed policies, and to outline a proposed outlier policy if it believes one to be necessary. To the extent that an outlier policy is incorporated into the design of the bundled payment system, the policy would need to be budget neutral.

Rationale: Until decisions on case mix adjustment are made, it is not possible to say whether an outlier policy is needed. However, the question of an outlier policy will undoubtedly be a significant issue for potential applicants. The issues related to outlier policy are discussed in the following sections.

1. Evidence of the need for outlier payments

Whether an outlier policy is needed and the kind of outlier policy that is needed will depend substantially on the ability of the case mix adjustment to match payment to actual resource use. In particular, the need for an outlier policy will increase to the extent that the case mix adjustment cannot predict patients with substantially above average costs.

The need for an outlier policy in the bundled payment demonstration may also be affected by the relatively small size of dialysis facilities. This issue, as noted in the discussion of case mix adjustment, is addressed in the paper on the relationship between patient volume and facility risk. (See tab 3.)

Medicare allowable charges (per session) are known to vary widely. In and of itself this suggests that an outlier policy may be needed. However, the ability of case mix models, particularly those including a measure of prior EPO dose-response, also account for a substantial amount of the patient-to-patient

[1] It is possible to define both 'low cost' and 'high cost' outliers. A 'low cost' outlier would be a patient who uses far fewer resources than the typical or average patient. This discussion will focus exclusively on policies for high cost outliers.

variation in resource use. The preliminary impact assessment of Model 9 suggested that a model using prior dose-response would substantially increase the ability of a model to match payment to resource use even for relatively high cost patients. Nevertheless, nearly a quarter of facilities had predicted resource use that was more than two deciles *lower* than actual resource use. Over an entire year, a quarter of facilities were expected to experience a 'loss' of more than $9.30 per session.

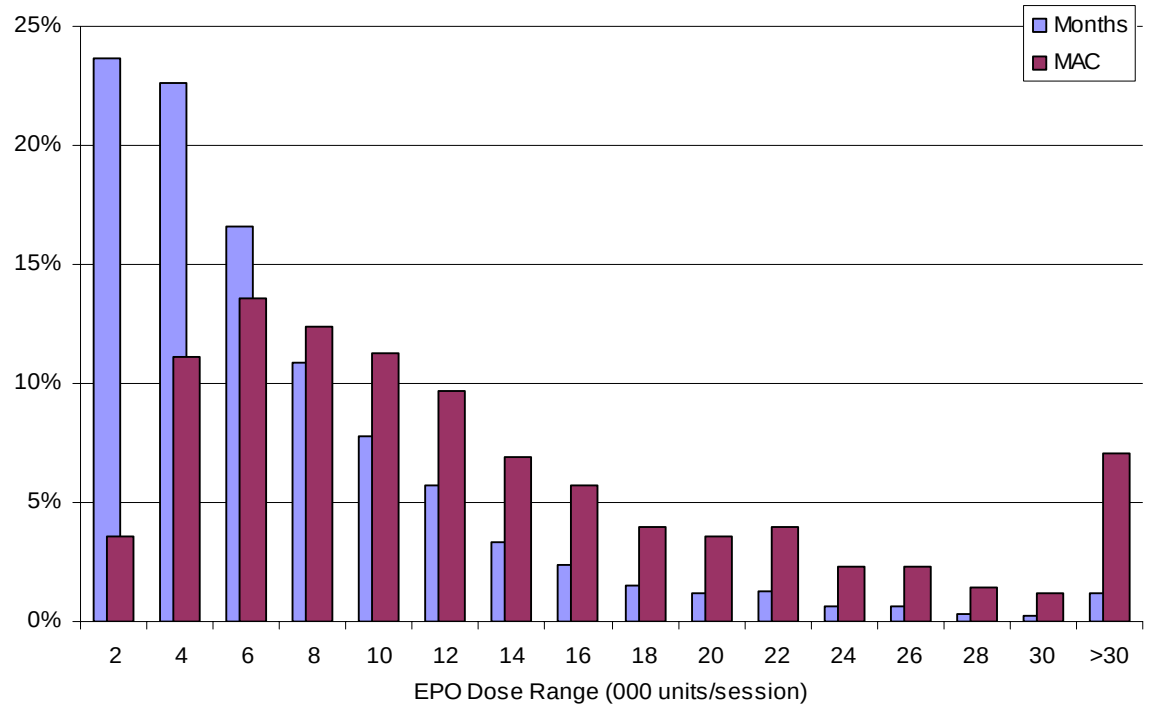
The additional impact assessments currently under development will provide additional information on the potential need for outlier payments.

2. Identification of outlier cases

If an outlier policy is needed, a method or definition of 'outlier' or 'high cost' patients will be needed. In the DRG-based inpatient hospital payment system, outliers are defined as patients with an estimated total cost that exceeds the payment by a specified dollar amount.

Because EPO accounts for the majority of separately billed resource use (MAC), high cost patients will tend to be patients who use large amounts of EPO. Figure E-1 displays data presented by KECC at the second meeting that shows the distribution of EPO use. According to these data, the 13 percent of patient months that involve an EPO dose greater than 12,000 units per session (~36,000 units per week) account for 38 percent of EPO use. It does not, however, suggest the existence of a sharp or discontinuous point which separates high-use EPO patients from low-use EPO patients.

Figure E-1. Distribution of patients by EPO use



EPO is not, of course, the only resource used by patients. The preliminary data on alternative bundle definitions also showed that drugs such as Vancomycin, while accounting for only a small percentage of average Medicare allowable charges, added substantially to the costs incurred by a the small pecentage of patients who used them. Unfortunately, a definition of 'outliers' that relies on total resource use (i.e., patients with MAC substantially above the bundled payment) will not distinguish between patients whose costs are attributable to EPO and patients whose costs are attributable to other resources.

The correlation of prediction errors over time documented in the preliminary case mix analysis suggests that a patient that is high cost in one month will continue to be high cost in succeeding months. The relatively small difference in the variation in per session resource use when measured over the course of a month and when measured over the course of a year also suggests that differences in actual and predicted resource use tends to persist over time for a single patient. However, case mix models that include the prior dose-response variable reduce this correlation substantially.

These patterns suggest that patients using substantially more than predicted resources are likely to be relatively common and are likely to be found in all facilities. Some facilities may be more likely than others to have a panel of patients that includes a disproportionate number of high cost patients,

although the extent to which this occurs will need to be evaluated after a more refined case mix measure has been developed.

3. Outlier payment method

There are essentially two ways of approaching payment for outlier patients. One approach focuses on the individual patient. The other approach focuses on the impact of outliers on the facility.

The first approach attempts to limit the losses that a facility can incur on an individual patient. One variation of this approach reimburses the facility a percentage of the amount by which the estimated 'cost' incurred by an outlier patient exceeds a specified dollar value (referred to as the outlier threshold). The inpatient hospital payment system uses this method. This approach limits, but does not eliminate, losses on outlier patients. It has two shortcomings that may be significant when the facilities receiving payment treat a small number of patients. It only partially offsets the losses incurred on individual patients; that is, it reduces but does not eliminate losses caused by patients with extraordinary needs. Second, it does not address the problem of recurring losses resulting from systematic clustering of outlier patients in certain facilities.

A variation on this approach that overcomes these limitations is to pay for outlier patients using a different payment method than is used for non-outlier patients. The simplest approach would be to pay for 'outlier' patients using the current payment method (i.e., based on Medicare allowable costs/charges). This approach could substantially eliminate losses on outlier patients and could mitigate the problem created when outlier patients are systematically concentrated in certain facilities. Given what is known about costs of dialysis patients and the small size of dialysis facilities, this variation (paying separately for outlier patients) is likely to be more effective than the more conventional approach of paying an additional amount to cover a portion of outlier 'costs'.

A substantially different approach to outlier payment focuses on the impact of outliers on the facility instead of focusing on individual patients. In essence, this approach limits the aggregate losses that a facility could experience during a month. The simplest way of implementing this policy would be to establish a risk corridor. A facility whose total bundled payment is within the corridor (e.g., ±5 percent of fee-for-service payment) would be fully at risk. A facility whose total bundled payment falls short of fee-for-service payment by more than the specified amount would receive additional payment from Medicare to cover a portion of its losses. A facility whose total bundled payment is higher than fee-for-service payments by more than the specified amount would return a portion of the 'savings' to Medicare. Such a system would have a considerable administrative overhead, requiring regular and ongoing reconciliation of fee-for-service and bundled payments.

F. PAY-FOR-PERFORMANCE

A fundamental strength of traditional fee-for-service payment is that it closely matches payment to actual resource use. What is done to a patient—the services the patient receives—determines payment. The more services a patient receives—for whatever reason—the higher the payment. This strength of traditional fee-for-service payment becomes its fundamental weakness: it fails to create financial incentives that encourage and enable improvements in quality.

Pay-for-performance (P4P) attempts to shift the focus of payment away from what is done "to" a patient and to focus instead on what is done "for" the patient. Instead of paying a provider more when things go "wrong" (e.g., when a patient contracts an infection and requires additional treatment), P4P looks for ways of paying a provider more when things go "right". Instead of paying a provider more to "fix" problems after they occur, P4P looks for ways of paying more for "doing things right the first time." Instead of paying a provider simply based on what that single provider does, P4P looks for ways of encouraging collaboration and cooperation across providers.

The *Quality Chasm* project of the Institute of Medicine has identified five goals for performance improvement in health care that provide a useful framework for thinking about the role of P4P in payment system design.

- Safety: Does a payment method encourage or discourage efforts to reduce the risk of patient injury?
- Effective: Does a payment method encourage the reduction of excessive treatment, i.e., use of drugs with little or no benefit for the patient? Or does it unduly constrain the resources available for needed care or create incentives to skimp on care?
- Patient-centered: Does a payment method enhance or impede the extent to which patient preferences (e.g., for modality) and values guide care?
- Timely: Does a payment method encourage prompt response to changes in patient needs?
- Efficient: Does a payment method encourage improvements in the productive use of the resources needed to provide care? Does it increase or decrease administrative expenses for providers, patients, or the Medicare program?
- Equitable: Does a payment method promote the availability of high quality care to all patients regardless of ethnicity, geographic location, or socioeconomic status?

MedPAC, organizations representing providers, and organizations involved in the implementation of P4P programs also emphasize an additional set of operational requirements or considerations:

- The performance measures used in a P4P system must be seen as reflecting the impact of provider actions on performance. A provider's performance cannot be determined by factors beyond his/her/its control.

- Related to this point, performance measures must be adequately adjusted to reflect clinically and administratively significant patient characteristics that affect performance. These case mix adjustments must be widely accepted by the affected providers.

- The measures and performance standards that are adopted must allow providers to demonstrate improved performance. They must be applicable to a broad range of care and a substantial percentage of patients. They should focus on areas in which improvement is possible, not on areas in which performance is already high.

- The amount of payment under a P4P system must be commensurate with the costs incurred by the provider to achieve improvements (or specified levels) of performance, including the cost of measuring performance.

- Recognition should be given to both current levels of performance (measured against an absolute or normative standard) and improvement in a provider's own performance over time.

Prospective bundled payment itself creates an implicit incentive or reward for improved efficiency and, to a more limited degree, effectiveness (as defined above). However, bundled payment has two primary limitations when viewed from the perspective of pay-for-performance:

- It perpetuates the fee-for-service practice of paying a provider more when things go 'wrong' than when they go 'right'. For example, the case mix models discussed in section C and in the paper under tab 4, would result in lower payments as a patient's hematocrit rises, higher payments when a patient is hospitalized, and higher payments following an episode of significant infectious disease. A provider that effectively manages anemia, prevents infection, and avoids unnecessary hospitalization may receive lower payments under this adjustment.

- It focuses narrowly on the resources and activities that occur within the dialysis facility, and leaves untouched the incentives influencing the behavior of physicians and other providers—even though those actions may affect the treatment provided in the dialysis facility.

These two limitations suggest an approach to the design of a P4P component of the bundled payment demonstration. Specifically, the P4P component could provide a means of recognizing performance in a limited number of key areas such as anemia management or vascular access. These P4P incentives would offset financial losses caused by reduced use of resources (e.g., EPO) that is caused by or associated with improvements in performance or outcomes. Second, the P4P component could provide a means of aligning the incentives between the dialysis facility and other 'external' providers such as nephrologists or vascular surgeons.

1. Dimensions and measures of performance

Proposal: The P4P component of the bundled payment demonstration could outline two alternative approaches. The first would focus more narrowly on the measurement of dimensions of performance that are closely related to activities that occur within the dialysis facility. The second would focus more broadly on additional dimensions of performance that involve providers outside the immediate organization purview (i.e., the 'walls') of the dialysis facility. Interested applicants should identify whether they are prepared to participate in either, both, or neither of these P4P components.

Rationale: The dimensions of performance that might be addressed by a P4P component of the bundled payment demonstration broadly fall into two categories:

1. Measures of performance that are closely related to the activities that occur inside the dialysis facility and are paid for through the bundled payment; and

2. Measures of performance that are related to activities that affect the demands placed on the dialysis facility or the ability of the facility to manage the resources covered by the bundled payment but that are not under the direct control or influence of the facility.

The implications for both providers and for the Medicare program differ substantially between these two alternatives. The first is administratively simpler than the second, although still requiring the resolution of many complex issues. The second will require a larger amount of both formal and informal cooperation and collaboration between dialysis facilities and the providers involved in the care of the patients they treat.

The primary goal of the P4P incentives directed at 'internal' or 'directly related' aspects of performance is to more directly introduce an element of paying for the outcomes that the facility (and its affiliated providers) achieve *for* the facility's patients. 'Internal' incentives might rely on measures of:

- The adequacy of dialysis
- Management of anemia
- Management of renal-related bone disease
- Other measures of clinical quality

The primary goal of the P4P elements directed at 'external' or 'indirect' aspects of performance is to align incentives between dialysis facilities and other providers, including nephrologists, other physicians and other institutional providers. 'External' P4P incentives might rely on measures of:

- Vascular access
- Management of anemia
- Management of infection
- Hospitalization rates

As is evident from the appearance of anemia management on both lists of possible measures, the line between 'internal' and 'external' incentives does not strictly conform to the organizational boundaries of the facility. Some of the more narrowly 'internal' aspects of performance involve, for example, the nephrologists affiliated with a dialysis facility. This reality has significance for the question of who might receive P4P incentive payments and how those payments are made.

2. Sources of standards and measures

Proposal: The solicitation would propose use of measures in any P4P component of the bundled payment demonstration that have been established and endorsed broadly by the renal care community. A specific recommendation on the best source of measures from the advisory board would provide useful guidance for staff as would a recommendation on the process that should be implemented to vet, adapt, and approve measures for use in the demonstration. The solicitation would ask applicants to identify those measures that they believe should be used and provide a supporting rationale.

Rationale: The largest and most complex set of questions to be addressed in the design and implementation of a P4P program concerns the source of the measures that it will use. Should the bundled payment demonstration adopt or adapt an existing set of measures, e.g., the CPM measures, measures used in K/DOQI guidelines, or measures identified in the CMS core data set initiative? Alternatively, should the demonstration attempt to devise its own set of measures? In either case, what process should be followed to adapt or refine performance measures, most of which were developed for purposes of quality assessment and quality improvement, for use as the foundation for a system of performance-based payment incentives? To what extent are methods of risk adjusting performance measures necessary and available? How will the adequacy of risk-adjustment methods be evaluated? What should be done if methods of risk-adjustment are deemed to be inadequate by the providers participating in the program/demonstration?

From a practical perspective, adopting and adapting an existing set of measures is likely to be more feasible than developing a new set of measures. A basic infrastructure for collecting this information is already in place. Moreover, any set of performance measures that is developed *de novo* is very likely to include many of those that are already included in existing systems. These systems are the product of sizeable efforts by large numbers of organizations and individuals from all segments of the ESRD community.

Whatever their perceived limitations, they represent a consensus on the current issues and opportunities for quality improvement and provide at least a starting point for efforts to develop a set of P4P measures.

3. Nature of performance benchmarks

Proposal: The performance standards that are adopted would include both measurements against benchmarks and measures of improved performance over time. That is, providers would be given credit for the absolute level of their performance, but they should also be given an incentive to improve performance regardless of the level of their current performance. A recommendation by the advisory board on the relative weight that should be given to the two types of measures (current performance/benchmark and improvement) would be helpful.

Benchmarks that have been established and endorsed by the renal care community would be used to measure of levels performance against an absolute standard. Improvement would be measured over the span of the most recent prior period for which complete data have been reported. For example, improvement would be measured on a year-to-year basis instead of choosing a single base period and freezing it in place. Alternatively, the base period against which improvement is measured could be periodically updated (e.g., every three years). A discussion by the advisory board of the extent to which these more technical issues in performance measurement should be addressed in the solicitation would be helpful a process for modifying or adapting benchmarks and determining whether risk adjustment methods are necessary and/or adequate.

Rationale: P4P programs and similar quality incentives generally recognize that both types of measurement (i.e., against an external standard and against past performance) are useful. The goal of P4P is to encourage improvements in performance. Providers that have the largest improvements to make should receive credit and support for those efforts to improve performance. An external or absolute standard may not achieve this goal, whereas an improvement standard will. Providers with strong performance should receive some recognition of the investment in quality improvement that they have already made, but should also have an incentive to strive for further improvements.

4. Source of funding

Proposal: The two types of P4P measures (those related directly to the bundled payment and those related to activities outside the direct control or influence of the facility) could have different funding sources. In general, the component of P4P that is focused on ‘internal’ measures could be funded from savings achieved in the use of resources covered by the bundled payment, although to the extent that P4P incentives are available to physicians or providers other than the dialysis facility separate funding would need to be identified. A P4P component focused on ‘external’ measures or aspects of

performance would need to be funded using external sources. An 'external' P4P component would be feasible only to the extent that funding from external sources (e.g., savings resulting from lower rates of hospitalization) is available. To the extent that these 'external' sources of funding are used, payment of P4P incentives may need to be tied to documented savings.

Rationale: There are three alternatives for funding the 'internally focused' component of a P4P program:

1. Using savings achieved for the Medicare program in the use of resources covered by the bundled payment amount.
2. Withholding or reserving a portion of the bundled payment to be distributed based on performance measures.
3. Using savings achieved for the Medicare program in the use of resources other than those covered by the bundled payment amount that are attributable to improved performance on 'internal' measures (e.g., adequacy of dialysis and anemia management).

The third of these, additional funding, is an option only to the extent that strong evidence can be marshaled that bundled payment will lead to improvements in outcomes (e.g., reduced prevalence of anemia) that will in turn lead to program savings by reducing hospitalization rates or use of Medicare covered services other than those paid for by the bundled payment.

There is only one alternative for funding an 'externally' focused component of a P4P program: savings achieved in the use of services or resources other than those covered by the bundled payment amount. The most significant of these services is inpatient hospital care, and the most likely example of such a performance incentive involves vascular access.

5. Eligibility for and payment of incentives

a. Eligibility for incentive payments

P4P incentives could be paid to dialysis facilities, the physicians affiliated with the dialysis facility, other physicians involved in the care of the patient (e.g., cardiologists, oncologists, or vascular surgeons), and other providers (e.g., clinical laboratories or hospitals). These entities and individuals are connected to one another by a variety of organizational affiliations, agreements, and formal or informal relationships. There is not a single corporate or organization model into which all possible arrangements can be subsumed. It is not realistic, for example, to require all providers/entities that participate in a P4P program to establish a corporate entity or shell that will be used to administer P4P payments. Even if such an entity were established, it is unlikely that beneficiaries could or would be required

to receive all care through the providers participating in the arrangement.

b. Method of paying incentives

Because of the complexity of Medicare regulations governing financial arrangements among providers, it is likely that CMS will need to assume the responsibility of paying incentives to entities that have the legal authority to receive payment and allocate payment among individual providers. For example, it is generally illegal for one physician to directly pay another physician for providing (or not providing) a covered service. It is, however, legal for a physician practice to bill Medicare and receive payment and to establish a variety of compensation arrangements with individual members of the practice. These arrangements might include fee-for-service payment or payment based on a salary; they might include various 'bonus' or 'incentive' compensation provisions.

6. Implementation / feasibility issues

a. Data reporting

The amount of data that will be needed to support P4P is considerable. Realistically, this information cannot be captured through claims systems. Data systems designed to capture quality-related information will be needed. The only feasible alternative is to piggy-back the P4P component of the bundled payment demonstration on an established data system.

b. Performance measurement / monitoring

The calculation of performance measures will need to occur as an 'off-line' activity. That is, it cannot simply be integrated with or driven by claims systems. Many of the performance indicators used in any P4P system are likely to be rates, which will require the careful tabulation of data for some defined period of time, an effort to ensure complete reporting, and the analysis of the resulting data to calculate measures for participating providers and to compare those measures to the relevant standards. Measurement of improvements will require the maintenance and analysis of time series data for individual providers, and provision will need to be made for the auditing and reconciliation of performance measures with the participating providers.

c. Financial reconciliation

The calculation of incentive payments will also need to occur as an 'off-line' activity. That is, it cannot be integrated into the claims systems. To the extent that payments are subject to budget neutrality

requirements and to the extent that the funds available for disbursement through P4P are dependent upon the demonstration of savings, methods of capturing the data needed to apply these requirements, performing the required calculations, and auditing the results will need to be established.

To the extent that a dialysis facility or other organization distributes incentive payments to individual providers, procedures for tracking and potentially auditing distributions will be needed.