KIDNEY CARE PARTNERS

December 11, 2009

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1418-P: Medicare Programs; End-Stage Renal Disease Prospective Payment System; Proposed Rule

Dear Acting Administrator Frizzera,

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for the End-Stage Renal Disease Prospective Payment System (Proposed Rule).[1] KCP is an alliance of members of the kidney care community that includes patient advocates, dialysis care professionals, providers and facilities, and manufacturers to improve the quality of care for individuals with both chronic kidney disease (CKD) and irreversible kidney failure, known as End-Stage Renal Disease (ESRD). We are pleased to have the opportunity to comment on the Proposed Rule.[2]

KCP's mission, individually and collectively, is to ensure that:

Chronic kidney disease patients receive optimal care;
Chronic kidney disease patients are able to live quality lives;
Dialysis care is readily accessible to all those in need; and
Research and development leads to enhanced therapies and innovative products.

Our comments focus on the following areas in the order presented in the Proposed Rule:

Oral Drugs Without An Injectable Equivalent

- KCP Questions CMS' Legal Authority to Include Oral Drugs without an Injectable Equivalent in the Payment Bundle and Is Concerned that its Proposal Imposes Burdens on Patients and Providers

[1] 74 Fed. Reg. 49922 (Sept. 29, 2009).
[2] Also, we are pleased to submit a joint letter from Kidney Care Partners and Kidney Care Council that raises a number of technical questions and concerns (see Attachment A).

- If CMS Determines to Move Forward with Its Proposal, the Agency Must Develop Adequate Data to Ensure Appropriate Reimbursement and Track Patient Outcomes Following Implementation, and CMS Should Delay Implementation of Policy Until such Issues are Addressed

Diagnostic Laboratory Tests and Other Items and Services

CMS Understates the Proper Reimbursement for Laboratory Tests in the Bundle and Should Adopt a Defined List of ESRD Related Diagnostic Tests

Home Dialysis

CMS Should Maintain Home Dialysis Training Services Outside of the Bundle or Create a Separate Payment Recognizing the Incremental Costs of Training Services

Unit of Payment

KCP Supports CMS' Decision to Implement a Per Treatment Unit of Payment as it is Consistent with Statue and Avoids Adverse Beneficiary Impacts and Operational Difficulties

Base Rate Calculation

CMS Should Clarify its Methodology for Selecting the Base Year for Determining Spending and Establishing the Base Rate

CMS Lacks Legal Authority and an Empirical Basis for Excluding Actual Claims Data When Calculating the Unadjusted Rate per Treatment and Should Restore the Excluded Values

Adjustments to the Base Rate including the Outlier and Transition Payments

CMS Should Apply the Outlier Adjustment to the Base Rate After the Two Percent Payment Adjustment is Applied

The Secretary Does Not Have Legal Authority to Apply an Additional Payment Adjustment During the Transition Period, and KCP Believes that the Proposed Timing and Underlying Methodology are Flawed

Case-Mix Adjustors

CMS Should Maintain Use of Existing Case-Mix Adjustors and Implement Adjustors For Patient Race and Sex

Low-Volume Facility Adjustor

CMS' Proposal Includes Criteria and Data that are Problematic and may Result in Inaccurate Adjustments

Pediatric Patients

CMS Should Develop a More Appropriate Single Category Case-Mix Adjustor for All Pediatric Patients Regardless of Age or Modality, and the Agency Should Consider Postponing the Application of the Bundled Payment to Pediatric Patients Until More Accurate Data Can Be Collected and Analyzed

Administrative Burden on Patient and Providers

CMS Imposes a Significant Administrative Burden on Both Patients and Providers by Including Oral Drugs and Laboratory Tests in the Bundle Resulting in Burdensome Cost-Sharing Amounts for Items and Services for which there is Currently No Cost-Sharing Obligation and Increasing Contracting Requirements for Providers

Quality Incentive Program

In the Area of Hemoglobin Management, CMS Should Retain the <10 g/dL Measure and Use a 10-12 g/dL Measure Instead of the Proposed >12 g/dL Measure
CMS Should Align the Quality Baseline Data Year for the QIP with the Baseline Payment Year Data for the Bundle
CMS Should Weight Each Measurement Area Equally, Rather Than Weighting the Total Performance Score Two-Thirds Anemia Management and One-Third Dialysis Adequacy
Given the Limited Scope of QIP, the Maximum Payment Reduction Should be Significantly Less than Two Percent
CMS Should Begin Data Collection Now to Avoid Unintended Consequences Associated with Implementation of the Bundled Payment System

I. Proposed ESRD PPS Bundle

A. Other Drugs and Biologicals and their Oral Equivalents

1. KCP Questions CMS' Authority to Include Oral Drugs without an Injectable Equivalent in the Dialysis Bundle

CMS proposes to include two classes of oral drugs – calcimimetics and phosphate binders – with no injectable equivalents in the statutory definition of "renal dialysis services" such that payment for these products would be included in the single payment amount made under the new prospective payment system.[3] KCP questions whether CMS has authority to implement this proposal under the applicable statute. Furthermore, we believe that the current proposal could have

[3] 74 Fed. Reg. at 49928-29, 49936-38.

a serious, adverse impact on beneficiaries and may constrain appropriate access to medically necessary products.

i. MIPPA Does Not Clearly Authorize CMS to Include These Oral Drugs in the Payment Bundle

a. KCP Questions Whether Oral Drugs with No Injectable Equivalent Fall Within the Statutory Definition of "Renal Dialysis Services" for Purposes of the Bundle

According to the Proposed Rule preamble, CMS justifies the inclusion of these products within the statutory definition of "renal dialysis services" because the relevant new section refers to ESRD drugs "for which payment was (before the application of this paragraph) made separately under this title and any oral equivalent form of such drug or biological."[4] The Agency reasons that the use of "this title" means that all ESRD drugs payable under Title XVIII of the Social Security Act (SSA) must be in the ESRD bundle, including drugs payable under Medicare Part D.[5] KCP believes that the Agency is selectively reading the language of the statute and that the more appropriate approach is to read the language as a whole.

The entirety of Section 1881 of the Act addresses Medicare benefits for ESRD beneficiaries, and Section 1881(b) specifically focuses on payments to dialysis facilities. Under this section, the statute sets forth a specific definition of "renal dialysis services" for purposes of the bundle that contains four specific categories of products; thus, any product falling outside of these categories is not eligible to be included in the bundle under the current statute.[6] The oral drugs in question clearly do not fall within the first two categories included in the definition – they are not currently included in the composite rate and they are not erythropoiesis stimulating agents.[7] Additionally, KCP questions whether these products fit within the third category of products, as they are not separately billable drugs and they are not the oral equivalent form of a separately billable drug.[8] In fact, the current policy included in CMS Manual guidance specifically directs that Medicare coverage of separately billable drugs is limited only to products that cannot be self-administered by a patient (such as injectable drugs) and that are administered in the facility by staff.[9] Both calcimimetics and phosphate binders are currently dispensed by a pharmacy for home use by the patient, a use that does not fit within the statute or manual guidance, and they are not the oral equivalent of a product that would fit within those parameters.

Finally, common principles of statutory construction suggest that the fourth category included in the definition of "renal dialysis services," which includes "other items and services,"[10]

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[4] 74 Fed. Reg. at 49928-29.
[5] 74 Fed. Reg. at 49928.
[6] 42 U.S.C. § 1395rr(b)(14)(B).
[7] 42 U.S.C. § 1395rr(b)(14)(B)(i), (ii).
[8] 42 U.S.C. § 1395rr(b)(14)(B)(iii).
[9] Provider Reimbursement Manual, Part I, § 2711.2(B)(2), *accord* "Medicare Reimbursement for New end Stage Renal Disease Drugs," Department of Health and Human Services Office of Inspector general Report No. OEI-03-06-00200 (March 2006), at p. 1.
[10] 42 U.S.C. § 1395rr(b)(14)(B)(iv).

should not apply to the drugs in question.[11] Under these principles, it is assumed that the language included within a statute is incorporated for a purpose and should be read in context of the surrounding language of the Act. If the reference to "other items and services" included in this clause is interpreted to mean all drugs currently available to Medicare beneficiaries, it would render the remaining categories of the statutory definition unnecessary. Under that interpretation, the products in the second and third categories would already be covered in the fourth category, making the preceding clauses of the definition redundant. Rather, under the most logical construction of the definition, Section 1881(b)(14)(B) can be read to conclude that drugs and biologicals that are not the oral equivalent of a separately billable drug should not fit within the bounds of any of the four categories included in the definition of "renal dialysis services" and, therefore, should not be eligible to be included in the bundle as it is defined by statute.

Nonetheless, CMS argues that Section 1881(b)(14)(B)(iii) includes calcimimetics and oral phosphate binders.[12] This interpretation is questionable, as evidenced by the fact that references to "this title" in other subsections have not been interpreted so broadly. For example, Section 1881(b)(13) establishes a methodology for "payment amounts under this title for separately billed drugs and biologicals…". In implementing that section, CMS seems to understand that the language addresses payments made separately to dialysis facilities, and it did not bring in calcimimetics and phosphate binders into the payment system. The same interpretation should be applied here. Currently, dialysis facilities are not reimbursed for calcimimetics and phosphate binders – Medicare payments for these products are made under the Part D benefit to pharmacies. Consequently, read in its full context, it is questionable whether the statute grants CMS the authority to include in the bundle those oral drugs for which Medicare now pays pharmacies as part of Part D.

Moreover, a close reading of this clause as a whole reveals that the only oral drugs that the Agency should bring into the ESRD bundle are those that are the oral equivalent form of an ESRD drug that has been separately billable. In other words, the clause brings into the bundle those products currently paid for under Section 1881(b)(13) and "any oral equivalent form of such drug or biological."[13] Because this provision uses the modifier "such," the "drug or biological" in this clause should only refer to non-oral (i.e., injectable) products since there cannot be an oral equivalent form of an oral drug. Yet, by including calcimimetics and phosphate binders in the ESRD bundle through clause (iii), CMS is effectively viewing these products as "other drugs and biologicals [for which payment is separately made]" within this clause. Indeed, CMS acknowledges that there is no injectable form of those products, so they should not fit within Section 1881(b)(14)(B)(iii) as an oral equivalent form. They can only fit within this clause as a currently separately billable drug or biological but again, that part of clause (iii) can only be for injectable products, which calcimimetics and phosphate binders are not. Thus, CMS' proposal to include these products in the ESRD bundle under clause (iii) is questionable under the statute.[14]

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[11] See Duncan v. Walker, 533 U. S. 167, 174 (2001) (it is "a cardinal principle of statutory construction" that "a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant").

[12] 74 Fed. Reg. at 49928-29.

[13] 42 U.S.C. § 1395rr(b)(14)(B)(iii) (emphasis added).

[14] Although the Agency principally relies on clause (iii) in proposing to include Calcimimetics and Oral Phosphate Binders in the ESRD bundle, it also states its belief that the language in clause (iv) also authorizes these products to be included in the bundle. 74 Fed. Reg. at 49928. Again, for the reasons stated earlier, this view fails to look at section 1881(b)(14)(B) as a whole because that interpretation of clause (iv), that allows CMS to include all drugs and biologicals

b. The Purpose of the Bundled Payment System Can Be Fulfilled Without Including Oral Drugs with No Injectable Equivalent

In the Proposed Rule, CMS also states that interpreting the statute to not include calcimimetics and phosphate binders in the ESRD bundle is unduly constrained and would defeat the purpose of the new payment system.[15] According to CMS, the purpose that would be defeated would be the inclusion of all services furnished to ESRD patients "in a comprehensive bundle to which a reasonable payment amount can be empirically attached."[16] Contrary to CMS' reading of the statute, exclusion of these products from the bundle is not only appropriate under the statute, but it would fulfill the purpose of the new system. The comprehensive bundle Congress envisioned is a bundle of services furnished by dialysis facilities. Since calcimimetics and phosphate binders are not furnished by dialysis facilities, their exclusion would not make the bundle less comprehensive than Congress intended. Additionally, this is not an area where cost shifting out of the bundle is an issue. The cost for the oral drugs in question, calcimimetics and phosphate binders, are not incurred in Medicare Part B currently, and as these drugs are not equivalent to drugs in the bundle, there would be no need to prevent cost-shifting when the bundle is implemented if the orals remain in Part D. Therefore, avoiding cost-shifting is not a sound policy rationale for inclusion of oral drugs that do not have injectable equivalents. Moreover, Medicare has limited financial exposure in Part D given the design of the overall benefit. Conversely, the inclusion of oral drugs in the bundle could ultimately result in a shift of treatment costs onto patients and facilities, which is not consistent with the purpose of bundled payment.

2. Inclusion of Oral Drugs without Intravenous Equivalents in the Bundle Could Adversely Impact Beneficiaries and Facilities

In addition to the questionable interpretation of CMS' statutory authority with regard to this policy, the current CMS proposal creates several issues that could adversely impact the ability of dialysis patients to access oral drugs critical to their appropriate plan of care. First, KCP is concerned that the Proposed Rule does not provide the equitable and accurate reimbursement necessary for facilities to procure and provide these additional drugs as medically appropriate and that CMS does not currently have necessary data to determine appropriate reimbursement. In addition, the proposed policy will have a direct impact on beneficiaries, some of whom could experience increased coinsurance that may pose an insurmountable financial burden. Finally, dialysis facilities may face significant legal and operational barriers to acquiring and dispensing these drugs, including complex distribution issues under State pharmacy law.

KCP encourages CMS to address the issues articulated above prior to moving forward. Nonetheless, the potential for adverse consequences on patient care under the current proposal requires us to continue to oppose inclusion of additional oral drugs in the dialysis payment bundle until the community's quality, dispensing, licensure and reimbursement concerns are addressed.

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in the bundle, would render superfluous clauses (ii) and (iii) of this provision. Agencies may not interpret one clause of a statute to render another clause of the same statute meaningless.

[15] 74 Fed. Reg. at 49928.

[16] Id.

i. Failure to Provide Adequate Reimbursement for Oral Drugs under the Bundle Will Harm Quality of Care and Beneficiary Access to Products and Services

Recognizing that financial stability is a core component of an effective, high-quality dialysis delivery system, KCP is deeply concerned with the reimbursement rate for oral drugs proposed under the bundle. Equitable and accurate reimbursement is essential to ensuring that facilities have the ability to procure and provide these oral drugs as medically appropriate, especially where facilities are dealing with third parties through contract or otherwise. Although KCP questions CMS' authority under the statute to include oral drugs without an injectable equivalent, it is clear that for all items the Agency intends to include in the definition of "renal dialysis services," it has an obligation to fully fund the items and services that it will require dialysis facilities to furnish under the new payment system before moving forward with such changes.[17] As such, the $14 payment adjustment CMS proposes to compensate facilities for new coverage of oral drugs is woefully insufficient and falls short of CMS' responsibility to furnish adequate reimbursement for covered items and services. In fact, analyses conducted by several KCP members who have experience in this area conclude that the actual costs associated with furnishing such drugs amount to at least $45, with some members reporting a range of up to $100 depending on a patient's clinical characteristics. The currently proposed adjustment allowance would not only leave facilities self-funding a large portion of these new costs, but it would also jeopardize the quality of care delivered to patients as physicians and facilities grapple with trying to meet patients' medication needs with insufficient resources.

KCP is committed to working with CMS to develop equitable and sustainable payment rates for all components of a proposed bundle, but KCP cannot emphasize enough the burden on facilities, and the basic issues of fairness, that are involved where facilities must procure bundled products and services from third parties based but are not provided with adequate resources.

ii. Including Additional Oral Drugs in the Bundle Could Have Significant Consequences on Beneficiary Coverage and Coinsurance Responsibilities

KCP believes that the Agency's policy in this area must, above all else, ensure appropriate beneficiary access to medically necessary drugs and biologicals. Patients with kidney failure must have appropriate access to all medications prescribed by their physicians, and physicians should have autonomy to prescribe the most appropriate drugs within classes of medications. Under widely accepted clinical practice, dialysis patients routinely take numerous kidney-related oral medications that do not have separately billable, intravenous equivalents. Changes in Medicare policy should not adversely impact patients – both those receiving their kidney-related oral drugs through private payers and those receiving drugs through Medicare Part D, and KCP must oppose policy proposals that threaten to do so.

As noted earlier, KCP is concerned that some beneficiaries could be adversely impacted through increased copayment under the policy included in the Proposed Rule. Under the currently

[17] 42 U.S.C. § 1395rr(b)(14)(B)(ii).

envisioned ESRD PPS, the cost of these oral drugs will now be included in the payment for all of the ESRD items and services included in the bundle. The beneficiary will be responsible for 20 percent of the total ESRD PPS payment, which has the potential to increase the copayment amount owed by the beneficiary in certain circumstances. In order to better understand the implications of this change on patients, KCP conducted a basic review of the coinsurance implications based upon a beneficiary's current drug coverage, noting, however, that the circumstances of individual beneficiaries' coverage varies widely and that the issues involved in assessing specific impacts are extremely complex. As seen in the following examples, the ramification of shifting these products to Part B can be substantial:

- For patients who currently have Part D coverage of oral drugs without a low-income subsidy, the proposed policy could result in a significant increase in their financial responsibility and require a substantial out of pocket investment in order to maintain the same level of care as before bundling. In fact, modeling based upon data furnished by KCP members concluded that the typical patient in this category would experience an increase that could exceed $800 annually, a large financial commitment for a chronically ill patient. This increase may be due, in part, to differences in cost-sharing obligations as well as increased utilization resulting from increased compliance with recommended treatment guidelines. Nonetheless, the resulting difference in cost-sharing could pose a significant burden for patients and should be considered by CMS.
- Patients who currently have Part D coverage and qualify for the low-income subsidy, in many cases, may be required to pay coinsurance on these drugs for the first time as their current Part D coverage caps their financial responsibility at very low dollar amounts. Given the financial position of the patients qualifying for this assistance, it is likely impossible for them to meet the new obligation that will be created by putting these drugs in the bundle under Part B, meaning they will need to find additional sources of financial assistance or may not be able to keep up with the payments owed to facilities.
- Patients who currently have private market coverage of these products also face a challenging situation as this proposal, in effect, shifts their coverage to Medicare and set a new precedent of establishing routine drug coverage as an automatic benefit under Medicare Part B. Given that many of these patients are participating in retiree or employer plans that minimize copayments, it is possible that the new copayment amount under their mandatory Medicare coverage could significantly exceed their current financial responsibility.
- Similarly, the few patients who currently do not have prescription drug coverage from an insurance source will essentially be given coverage under Medicare Part B with a 20 percent coinsurance obligation. Some of these patients may be receiving assistance with prescription drugs through a patient assistance program, in which case the required Part B coverage may result in an increased coinsurance responsibility which they may or may not be able to meet.
- Patients who are dually-eligible for both Medicare and Medicaid would also see an increase in their coinsurance liability, as minimal prescription drug copayment amounts are replaced with the 20 percent coinsurance requirement under the PPS. In practice, this cost-sharing is typically covered by the beneficiary's Medicaid benefit, but facilities anticipate difficulties in recovering this amount from State

programs due to claims processing complications posed by the new bundle. Left unresolved, this issue will become a source of anxiety for patients who worry about access to services and financial burden on facilities that are underpaid in the PPS by 20 percent when they are unable to collect coinsurance amounts.

Based upon the cursory discussion in the Proposed Rule, it is unclear whether CMS considered the direct beneficiary impact that will necessarily follow implementation of the oral drug proposal. Clearly, the proposed treatment of oral drugs could dramatically change the financial responsibility for many dialysis patients and could ultimately threaten their continued access to appropriate, high-quality ESRD treatment. As such, CMS should proceed down this path with caution and refrain from finalizing its current proposal until these issues are fully analyzed, understood, and can be fully addressed.

iii. Dialysis Facilities Face Significant Legal and Administrative Barriers to Furnishing Oral Drugs Dispensed by Pharmacies

In addition to the direct impact on quality of care and beneficiaries, dialysis facilities may face significant legal and practical barriers to acquiring and dispensing these drugs that could ultimately have an adverse impact on beneficiary access to these products. If CMS were to move forward with the Proposed Rule given these barriers, the end result would be significant disruptions in patient care and other unintended and undesirable consequences for beneficiaries. Complex delivery issues exist for facilities at both the local and State level, and dialysis clinics do not furnish oral drugs for home use today. Significantly, many dialysis clinics are not currently in compliance with State and local requirements for dispensing pharmaceuticals and would need to make additional investments to do so. For example, to meet State pharmacy licensure requirements, dialysis clinics would need to have a licensed pharmacist on staff whenever medications are dispensed, as well as would also need to meet State pharmacy requirements for inventory, storage, recordkeeping, and patient education. Likewise, furnishing these drugs "under arrangements" could also be a significant burden for many facilities. Prospective contracting for these drugs based on payment under the bundle will be extremely difficult and, if the bundled payment rate is not calibrated appropriately with respect to these drugs, will result in facilities bearing significant financial risk creating an unsustainable financial environment that could impact the quality of patient care furnished by these facilities. Even if the bundled payment rate were properly calibrated, needing to contract with pharmacies would be a new task and could be difficult to manage as dialysis clinics would need to develop new infrastructure and dedicate staff time to this new responsibility.

3. CMS Must Address Issues Critical to Patient Care Before It Can Consider Including Oral Drugs without an IV Equivalent in the Bundle

While it is clear that the current CMS proposal on oral drugs should not be finalized due to the outstanding issues set forth in this letter, KCP believes it is important that the Agency develop a better understanding of the implementation issues that would need to be addressed if it intends to propose changes to the treatment of oral drugs in the future and ensure that its policy meets the existing Medicare requirements for care of ESRD patients.

i. CMS Continues to Be Bound By the Fundamental Medicare Obligations to ESRD Patients in the Social Security Act, which are not met under the Current Proposal

The fundamental framework for Medicare's obligation to patients with ESRD is detailed in the Social Security Act in language that was not altered by the MIPPA provisions related to establishment of a new PPS for dialysis services. In fact, the Act sets forth three core requirements for Medicare coverage of ESRD. First, the statute requires that CMS furnish beneficiaries who qualify for Medicare coverage as a result of their ESRD status with benefits that are of the same "type, duration and scope" of benefits available to beneficiaries who qualify due to their age status.[18] Second, CMS is required to set payment for such services based upon a "cost-related basis or other economical and equitable basis."[19] Finally, the statute limits Medicare coverage to expenses for items and services that are "reasonable and necessary" for the treatment of ESRD.[20] Notably, none of these requirements are altered by the payment system changes included in MIPPA, and, as such, CMS must continue to fulfill these obligations when considering policies under the new PPS.

Taking into consideration these legal obligations that CMS must adhere to under the Act, CMS' existing proposal to include oral drugs without an injectable equivalent is not appropriate at this time. Under the proposed policy, CMS explains that the new PPS for dialysis services will include these drugs in the payment bundle but assigns an inadequate payment amount to compensate facilities for the costs of those drugs due to flawed data sources. However, once a benefit has been deemed to be reasonable and necessary for the treatment of ESRD, partial payment is prohibited under the Act. In fact, CMS has only two options when considering whether to include such item or service as a covered benefit: fully fund it or exclude it. To do otherwise would violate the Act's requirement for equitable payment, resulting in a benefit that is by definition inconsistent to those provided to non-ESRD beneficiaries. Yet by proposing to fund only a fraction of the cost of oral drugs, this is precisely the path that the Proposed Rule follows. Furthermore, the proposal fails to address critical implementation issues related to beneficiary cost-sharing, pharmacy distribution and claims processing that could ultimately result in limitations on benefits furnished to ESRD beneficiaries and unreasonable reimbursement for those treatments. Therefore, these shortcomings ultimately compromise CMS' ability to comply with its Medicare coverage obligations in the Act. Accordingly, until CMS addresses these fundamental shortcomings, KCP believes that it is prohibited by statute from moving forward with its current proposal for including oral drugs with no injectable equivalent.

ii. CMS Must Develop and Evaluate Appropriate Data to Determine the Use and Cost of Oral Drugs

KCP believes that CMS does not currently have appropriate data available for determining the use and cost of kidney-related oral drugs and is significantly underestimating the expenditures associated with these medications. For the Part B items included in the bundle, CMS has years of per patient utilization data for which it analyzed the stability of those data in constructing the bundle and case-mix adjustors. In contrast, for these oral drugs, CMS is relying on Part D data that are not

[18] 42 U.S.C. § 1395rr(a).
[19] 42 U.S.C. § 1395rr(b)(2)(B).
[20] 42 U.S.C. § 1395y(a)(1)(A).

transparent to the public, data that CMS acknowledges represents only a subset of Medicare dialysis patients, and data that may not be stable nor accurately reflect drug utilization by dialysis beneficiaries because it is from a new program with a benefit structure that greatly differs from Part B. As such, CMS must develop a method for collecting and accurately evaluating necessary data in order to determine an appropriate reimbursement rate and must be willing to fund that rate once it is determined. One possible approach to doing this would be to implement a pilot that could provide data for later consideration of a permanent policy. In any case, CMS should delay implementation of any proposal to include these oral drugs in the bundled payment until it has the data needed for proper implementation of the policy.

a. CMS Should Account for all Medicare Costs Associated with Including Oral Drugs in the Payment Bundle

The Proposed Rule allocates $12.48 per treatment in 2007 dollars for oral drugs included in the bundle.[21] However, as mentioned previously, KCP members' analyses indicate that the actual amount is significantly higher at approximately $45 to $100 per treatment. This broad discrepancy will create adverse, unintended consequences for patients and is largely attributable to the Proposed Rule's methodological choices for calculating the oral drug payment, described in more detail below.

(1) MIPPA Does Not Artificially Limit Payment for Oral Drugs

In calculating the component of the bundled payment associated with oral drugs, CMS proposes to include the 2007 Part D-related spending on these items as well as Medicare payments under the Retiree Drug Subsidy (RDS).[22] As its rationale, CMS suggests that it is prohibited from accounting for the Medicare costs associated with providing oral drugs to all Medicare Part B-enrolled beneficiaries who will be entitled to such drugs in 2011, citing Section 1881(b)(14)(A)(ii) of the Social Security Act, which requires that the "total amount of payments" in 2011 be equal to "98 percent of the estimated total amount of payments for renal dialysis services … in 2011 if such system had not been implemented."[23] This reasoning reflects a fundamental misinterpretation of this provision. MIPPA does not prohibit payment for these costs associated with "renal dialysis services." Rather, MIPPA requires it.

By its plain language, Section 1881(b)(14)(A)(ii) requires CMS to undertake the following steps. First, it must define what is included in "renal dialysis services." Second, it must determine the amount of payments that would be paid in 2011 for such services, assuming the bundled payment system had not been implemented. In other words, it must price such services under the current system, but at 2011 levels. Finally, it must multiply this amount by 98 percent.

It is noteworthy what this section does not do. First, it does not permit CMS to distinguish between beneficiaries' source of drug coverage. To do so would be to discriminate against ESRD patients under the new payment system based on their current means of obtaining oral drugs. In other words, such a reading would infer an intent by Congress to bar certain ESRD beneficiaries

[21] 74 Fed. Reg. at 49945.
[22] 74 Fed. Reg. at 49941 – 49942.
[23] Id.

from access to oral drugs under a bundled system because of how they choose to obtain drugs under a completely different payment regime. While it is certainly true that Congress intended to take a two percent efficiency adjustment from facilities, it is unlikely that it also intended to discriminate against a subset of patients in such a manner.

Second, this section does not equate the new bundled payment system with the passage of MIPPA itself. That is, Section 1881(b)(14)(A)(ii) requires CMS to make the calculation of payments assuming all of the various requirements of MIPPA are in effect *other than* the implementation of the bundled system. As a result, once it makes the determination that oral drugs should be included in the definition of "renal dialysis services," CMS must determine the price of such drugs under the current system, albeit with 2011 pricing. Only then may CMS make the requisite two percent adjustment; and such adjustment is the only adjustment that MIPPA permits.[24]

(2) The Proposed Rule Bypasses MIPPA's "Per Patient" Utilization Directive When Calculating the Oral Drug Payment

As noted above, Section 1881(b)(14)(A)(ii) requires CMS to calculate the "total amount of payments" for "renal dialysis services." The second sentence of the section requires use of "*per patient* utilization data from 2007, 2008, or 2009" (whichever is lowest) in making the "total amount of payments" estimation. This requirement amounts to more than simply using utilization data for 2007-2009, the choice made by CMS, as described in the Proposed Rule. Rather, it also requires that the analysis be based on per patient, rather than aggregate, spending. Otherwise, Congress would have had no reason to include the words "per patient." Taken together, the statute requires an estimation of the average enrolled beneficiary's utilization of "renal dialysis services" and an application of 98 percent of the associated payment amounts as a new single payment for all future enrolled beneficiaries.

With regard to oral drugs, however, the Proposed Rule contravenes this directive. Instead, it calculates aggregate Medicare spending on relevant oral drugs for Medicare Part D enrollees in 2007 (plus, potentially, applicable Medicare spending on the Retiree Drug Subsidy) divided by the total number of beneficiaries eligible to receive these drugs in 2011.[25] To reach CMS' conclusion of a roughly $14 per treatment payment for oral drugs,[26] CMS appears to have inflated the denominator of the "per patient utilization" equation to include all beneficiaries eligible to receive oral drugs in 2011 (rather than existing Part D enrollees) without a corresponding increase in the numerator to include all eligible beneficiaries' utilization of these drugs (as opposed to merely including Part D enrollees). To accurately calculate per patient utilization in accordance with Section 1881(b)(14)(A)(ii) of the Social Security Act, however, inclusion of the pool of patients in the numerator and their utilization of oral drugs in the denominator must be congruent. Accordingly, CMS should calculate per patient utilization of these oral drugs for patients actually enrolled in Part D, multiply that number by the expected inflationary increase in the price of these drugs for 2011, and then apply that figure to the per treatment payment for renal dialysis services.

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[24] The 98 percent adjustment in the same section was thoroughly debated in the Congress and designed to capture any efficiency gains that might be achieved in a bundled payment system, so the "had not been implemented" proviso was necessary to prevent CMS from making additional cuts to the bundled payment rate.

[25] 74 Fed. Reg. at 49939 – 49942.

[26] 74 Fed. Reg. at 49945.

Elsewhere in other calculations it undertakes, the Proposed Rule confirms the "per patient" application of Section 1881(b)(14)(A)(ii). In all other cases, the Proposed Rule estimates per patient utilization by dividing total Medicare utilization of renal dialysis services by the number of enrolled beneficiaries receiving them, and then inflating associated costs to 2011. Only in the context of Part D oral drugs does CMS estimate actual utilization divided by potential future enrolled beneficiaries. By failing to "use per patient utilization from 2007, 2008, or 2009" – and instead using a numerator of spending based on actual utilization and a denominator inflated by including all eligible beneficiaries – the Proposed Rule fails to comply with MIPPA's clear directive.

Notably, CMS appears to acknowledge the shortcoming of its calculation with respect to oral drugs. Specifically, the Proposed Rule concedes the incongruity of not including data for the one-third of ESRD beneficiaries who do not have Part D coverage given that "ESRD facilities would be responsible for providing ESRD-related oral drugs covered under Part D to [all of] their patients" once the ESRD PPS is implemented.[27] In an unsuccessful attempt to resolve this disconnect, CMS resorts to the aforementioned RDS proxy. The inherent irony of this argument is that it belies the fundamental flaw in CMS' calculation: the failure to focus on per patient utilization. Had CMS instead divided actual Part D benefit payments by actual Part D beneficiaries, as mandated by MIPPA, CMS' perceived dilemma would have been resolved.

KCP encourages CMS to calculate per patient utilization of included oral drugs in 2007, 2008, or 2009 and multiply that rate by the expected 2011 costs of such drugs to yield the per patient payment amount for 2011 (minus two percent). This is the only way to be in perfect compliance with the statute.

(3) CMS Interpretation Contradicts Longstanding Rules of Statutory Construction

By assuming that Congress intended an unfunded mandate on facilities to deliver oral drugs but only pay for a fraction of those costs, CMS violates two rules of statutory construction.

First, in interpreting statutes, CMS should assume "the legislature did not intend an absurd or manifestly unjust result."[28] Expanding the Medicare Part B entitlement to cover oral drugs but artificially deflating payments to such an extreme degree is a "manifestly unjust" result. As outlined above, it requires a circuitous reading of MIPPA and interpretation of Congress's intent to reach this conclusion. A rational and just result that is consistent with a straightforward reading of MIPPA would be to cover all renal dialysis services and funding their associated costs on a per patient basis.

Second, CMS should apply the rule of construction that states: "When the statute has not removed agency discretion by compelling a particular disposition of the matter at issue, courts defer to any reasonable agency interpretation."[29] Congress neither debated nor legislated an unfunded mandate for renal dialysis services, including oral drugs, and clearly did not compel CMS to implement one. The applicable statutory provisions most likely require full funding of these services

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[27] 74 Fed. Reg. at 49942.

[28] Green v. Bock Laundry Machine Co., 490 U.S. 504 (1989).

[29] Chevron U.S.A. v. Natural Resources Defense Council, 467 U.S. 837 (1984); CRS Report to Congress, "Statutory Interpretation: Principles and Recent Trends," p. 23 (August 31, 2008).

on a per patient basis, but at least should be interpreted as authorizing CMS to achieve this "reasonable" outcome.

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iii. CMS Must Establish a Tracking System and Relevant Metrics to Ensure Patients Receive Their Drugs in the Correct Frequency and Duration

It is important that before making a change to coverage for oral drugs that could impact patient access to the drugs, CMS establish a tracking system to understand use of these drugs and implications on patient outcomes, as well as relevant quality metrics to ensure that patients are protected against adverse outcomes. For example, the nature of disease progression for bone mineral metabolism disease can result in consequences that are serious and irreversible, including parathyroidectomies, cardiovascular calcification, treatment for fractures, hospitalization for cardiovascular disease, hospitalization for hypophosphatemia, hypocalcemia, hypercalcemia, and bone pain.

CMS is not currently tracking outcomes, and, as such, does not have baseline data that would allow the Agency to track changes in clinical outcomes. Moreover, in the proposed rule CMS does not include any specific measures related to oral drug use in the QIP program initially, nor does CMS discuss collection of baseline data on outcomes in this area. This lack of data for both utilization and outcomes for oral drugs, coupled with an inadequate proposed payment, could worsen quality and ultimately harm patients. Baseline data that accurately assesses utilization and patient outcomes, as well as mechanisms to track outcomes going forward, are critical pre-cursors before changing the payment paradigm for orals drugs from the current pharmacy benefit. This issue is discussed in more detail in Section XI of our comments, which addresses quality of care considerations and improvements.

iv. At a Minimum, CMS Must Delay Inclusion of Oral Drugs in the Payment Bundle To Ensure Orderly Implementation of the Proposed Rule

As noted above, KCP questions CMS' authority to include oral drugs without an injectable equivalent in the ESRD payment bundle. Nonetheless, if CMS insists on moving ahead with its proposed policy regarding oral drugs, the Agency must not do so until it is able to implement such a policy in full accord with Section 1881(b)(14)(B) of the Act.

KCP believes that CMS not only has the discretion to defer the inclusion of oral drugs in the payment bundle, it has a statutory obligation to do so under the relevant statutory language on implementation found at Section 1881(b)(14). For example, Section 1881(b)(14)(A)(ii) requires CMS to determine the total amount of payments for renal dialysis services. If the Agency cannot make such a determination as to specific items and services, it would be improper to include those items and services in the definition of renal dialysis services until it is able to do so. Given that CMS readily admits to the lack of data on oral drugs for at least one-third of beneficiaries with ESRD, inclusion of these products now in the payment bundle would not allow CMS to implement 1881(b)(14)(A)(ii) properly. Likewise, the Agency lacks the tracking ability needed to ensure that quality of care would be maintained with regard to the use of these oral drugs. We note also that Section 1881(b)(14)(B) does not time limit CMS' discretion to define "renal dialysis services" for

purposes of the ESRD PPS. Accordingly, CMS may define renal dialysis services without including oral drugs initially while maintaining authority to define these services as including oral drugs in a subsequent year when it can appropriately implement all aspects of the statute. KCP urges CMS to defer such inclusion until then.

Moreover, implicit in CMS' interpretation of the transition period under Section 1881(b)(14)(E) is the Agency's authority to delay inclusion of oral drugs in the new bundled payment system. Section 1881(b)(14)(E)(i) requires a "four-year phase-in (in equal increments) of the payment amount" associated with the new ESRD PPS. In establishing coverage and payment for the "increment" of the transition payments associated with the basic case-mix adjusted composite rate system, CMS proposes to include oral drugs entirely, along with the full proposed payment of $14 per treatment, in the first year of the transition period.[30] By the same logic, CMS could implement inclusion of oral drugs in the ESRD PPS in the fourth year of the transition period and still comply with the "equal increments" requirement of Section 1881(b)(14)(E)(i).

As discussed in this letter, inclusion of oral drugs in the payment bundle raises many significant concerns for patients and facilities alike. Layered on top of these is the transition period described above, which is intended to allow facilities to adjust to the new payment system and allow CMS to address implementation issues along the way. Given the inevitable complexity of issues for many facilities during this four-year transition period, KCP believes that CMS should delay inclusion of Part D oral drugs in the bundle until all implementation issues are addressed, which may not be feasible until the conclusion of the transition period.

B. Diagnostic Laboratory Tests and Other Items and Services

KCP believes that the Proposed Rule understates the proper reimbursement rate for diagnostic laboratory tests by factoring in a 20 percent beneficiary coinsurance amount in contravention of the MIPPA statute and when coinsurance does not exist for laboratory services received by all other Medicare beneficiaries. KCP is also concerned that the Agency's proposed definition of diagnostic laboratory tests for the purpose of inclusion in the ESRD PPS bundle impermissibly expands beyond those "furnished for the treatment of ESRD,"[31] exceeding the authority granted in MIPPA and threatening to create significant clinical and financial hardships for patients and facilities. The best way to ensure accurate and appropriate reimbursement consistent with clinical practice patterns is for CMS to include a defined list of ESRD-related laboratory tests, and we urge CMS to determine the reimbursement rate for these tests through a process that accurately reflects the MIPPA statute.

1. CMS Understates the Proper Reimbursement for Laboratory Tests in the Bundle and Should Adopt a Defined List of ESRD Related Diagnostic Tests

KCP believes that in the Proposed Rule, CMS understates the proper reimbursement for diagnostic laboratory tests in two significant ways. First, CMS appears to fund the costs of laboratory services at 80 percent assuming that the remaining 20 percent will be covered by

[30] 75 Fed. Reg. at 49945.
[31] 42 U.S.C. § 1395rr(b)(14)(iv).

coinsurance paid by beneficiaries and/or secondary insurers. Pursuant to Section 1833(a)(2)(D)(ii) of the Act, however, Medicare pays for laboratory services at 100 percent of the fee schedule rate.[32] Unlike other renal dialysis services, laboratory services are not subject to beneficiary coinsurance and the deductible is waived.[33] MIPPA does not change this longstanding policy for laboratory services but instead makes clear that payments under the bundle must "equal 98 percent of the estimated total amount of payments that would have been made … if such system had not been implemented."[34] As such, and subject only to MIPPA's two percent reduction,[35] CMS must ensure that the portion of the bundled payment attributable to diagnostic laboratory services includes the total cost of providing these services, and is not understated based on the improper premise that facilities will collect a 20 percent coinsurance amount for laboratory services.

Second, the significant uncertainty as to the precise laboratory services that are included in the Agency's calculations, and the lack of underlying data identifying tests by ordering physician, makes it impossible to determine the accuracy and validity of the reimbursement amount established in the Proposed Rule. However, as set forth in the Technical Appendix, KCP's analysis strongly suggests that including the universe of laboratory tests ordered by MCPs has caused CMS to significantly understate the per-treatment costs associated with laboratory costs by as much as one-half the proper amount.

2. The Agency's Proposed Definition Impermissibly Expands beyond Laboratory Tests "Furnished for the Treatment of ESRD"

KCP supports the inclusion of laboratory tests "furnished for the treatment of ESRD" as specifically provided for in MIPPA.[36] In defining laboratory tests for this purpose, CMS proposes to include all tests ordered by a physician who receives monthly capitation payments (MCPs) for treating ESRD patients.[37] MCP practitioners, however, often serve in a dual role as an ESRD patient's primary care physician or general practitioner in addition to managing the patient's ESRD. In this capacity, MCPs frequently order laboratory tests entirely unrelated to the management of ESRD but necessary to meet the needs of Medicare beneficiaries who often face multiple co-morbid medical conditions.

In addition to exceeding the authority granted in MIPPA, which directed CMS to include only those laboratory tests related to the treatment of ESRD, including unrelated laboratory tests ordered by MCPs will create significant clinical and financial complications. If dialysis facilities are responsible for all laboratory tests ordered by MCP practitioners for ESRD patients, MCPs will be constrained in their ability to contract with independent laboratories to meet the unrelated needs of their ESRD patients due to uncertainty about payment from the facility. For the same reason, independent laboratories may not be willing to contract with dialysis facilities to cover unrelated laboratories ordered by MCPs, such as cholesterol or oncology screenings, based on concern that these unrelated laboratory tests may not be reimbursed. MCP physicians will therefore have to refer patients to other providers for necessary diagnostics, imposing an unnecessary burden on patients

[32] 42 U.S.C. § 1395l(a)(2)(D)(ii).
[33] Id.
[34] 42 U.S.C. § 1395rr(b)(14)(ii) (emphasis added).
[35] 42 U.S.C. § 1395rr(b)(14)(ii).
[36] Id.
[37] 74 Fed. Reg. at 49929.

and interfering with the patient-physician relationship, the MCP's ability to practice medicine, and the effective coordination of care. In the end, the proposed policy is likely to result in less efficient delivery of care, which is detrimental to patients as well as the Medicare program as a whole.

Given the above considerations, KCP strongly urges CMS to replace its current proposal with use of a defined list of laboratory services that are commonly used for the treatment of ESRD. An actual list of those tests directly related to the treatment of ESRD will provide certainty to patients and facilities and will enable CMS to more accurately and completely capture laboratory costs under the bundle. It will furthermore bring the Agency's proposal in conformity with statutory intent and important clinical practice patterns. CMS currently has access to proposed tests to be included on such a list, and such a policy would remove any question or ambiguity as to whether a test is ordered in conjunction with care for ESRD, as intended by the MIPPA statute, or for some other purpose.

KCP would be pleased to work with CMS and the kidney care community in this effort to provide certain, accurate and clinically sensible reimbursement for furnishing laboratory services to ESRD beneficiaries.

C. Home Dialysis

1. CMS Should Maintain Home Dialysis Training Services Outside of the Bundle or Create a Separate Payment Recognizing the Incremental Costs of Training Services

KCP applauds CMS' stated goal of encouraging home dialysis. Assignment of a single base rate for adult beneficiaries, regardless of modality is supportive of home therapy. However, we believe the inclusion of training in the routine bundle of services is not consistent with this goal. Training for home therapy represents a significant clinical activity and expense on the part of the dialysis facility. CMS and the Medicare Payment Advisory Commission (MedPAC) have repeatedly recognized the additional expenses driven by this non-routine episode of care, utilized by only a small percentage of the dialysis population. In the 2008 Report to Congress, CMS acknowledged that the payment amount materially does not cover the actual costs of providing training, and that the payment amount had not been updated since 1983. Moreover, the recent Conditions for Coverage have more specifically outlined discrete, necessary activities under RN administration that constitute home dialysis training services. CMS does indicate that the four month adjustor could in part compensate for training activity; however, it is our experience that the clear minority of patients (only 15 percent of HHD, <50 percent of PD) initiate training during their initial four months on dialysis.

The Proposed Rule eliminates discrete compensation for training, a critical and necessary investment, and first step to home dialysis. Adequate home training is essential to Medicare beneficiaries going home with dialysis safely. Instead of helping clinics to offer appropriate home dialysis training, the Proposed Rule compensates clinics that choose not to offer this type of training. KCP urges CMS to maintain training services outside of the base bundle or to create a separate payment recognizing the incremental costs of home dialysis training services. Because historical payment for this service has been identified as inadequate, we urge CMS to create a

payment for home patient training using best available information on actual resource requirements.

II. KCP Supports CMS' Decision to Implement a Per Treatment Unit of Payment As it is Consistent with Statute and Avoids Adverse Beneficiary Impacts and Operational Difficulties

A. The Per Treatment Unit of Payment is Consistent with the Plain Meaning of the Statute

As noted in the Proposed Rule, MIPPA states that the Secretary "may provide for payment on the basis of services furnished during a week or month or such other appropriate unit of payment as the Secretary specifies."[38] CMS proposes establishing an ESRD PPS that relies on a per treatment unit of payment. CMS also proposes to maintain the current payment standard that allows dialysis facilities to be paid for up to three treatments per week, unless medical necessity requires more.[39]

It is a fundamental principle of statutory interpretation that in determining the meaning of a statute, one must first look to the text of the statute. If the meaning of the words is clear, this plain meaning governs.[40] MIPPA grants CMS broad authority to determine the appropriate unit of payment. Indeed, the statute allows the Secretary to provide payment based on any "appropriate unit of payment."[41] Given the plain meaning of the statute, CMS has the statutory authority to utilize a per treatment unit of payment.

B. Patients will Have Greater Flexibility Under a Per Treatment Unit of Payment

A per treatment unit of payment will also benefit ESRD beneficiaries by providing increased flexibility and freedom to receive treatments in more than one facility when necessary. For example, a per treatment unit of payment preserves access to transient dialysis for work-related travel and for patients who travel for family reasons. As CMS notes, approximately 19 percent of outpatient dialysis patients incur an interruption of service or receive their treatments at more than one facility during a month.[42] The per treatment unit of payment will ensure these patients are able to receive necessary treatment at appropriate locations without unnecessary burden or restriction.

C. A Per Treatment Unit of Payment Avoids a Number of Operational Difficulties and Provides Proper Incentives for Care

In addition to patient concerns, a unit of payment other than per treatment would be administratively complex. A per treatment unit of payment avoids the administrative complexity caused by interruptions of service that would occur if another unit of payment, such as per month, were adopted. For example, if a per monthly treatment were selected, a facility would have to monitor events causing an interruption of service, as well as the days associated with these events, so that a pro rata reduction to the monthly payment amount could be determined. A per treatment

[38] 42 U.S.C. § 1395rr (b)(14)(C).
[39] 74 Fed. Reg. at 49931.
[40] Caminetti v. U.S., 242 U.S. 470 (1917).
[41] 42 U.S.C. § 1395rr(b)(14)(C).
[42] 74 Fed. Reg. at 49932.

payment avoids these complexities. As CMS has noted, a large unit of payment, such as a monthly payment, would also be administratively complex due to the phase-in of the payment system.[43]

A per treatment unit of payment also provides the proper incentives to encourage facilities to help their patients comply with their plan of care and receive all recommended treatments. While KCP maintains that facilities are committed to ensuring their patients receive proper care in any payment system, a per treatment unit of payment aligns incentives correctly.

Finally, KCP appreciates and supports CMS' proposal to allow more than three treatments per week if justified by medical necessity. The ability to deliver medically necessary additional treatments is an appropriate recognition of the need to tailor the medical treatment to fit the clinical needs of the patients. This has been part of Medicare policy for some time and has been appropriately utilized. It is appropriate and appreciated that CMS maintains the ability for patients to receive additional treatments where medically indicated.

III. KCP is Concerned with Several Aspects of the Bundled ESRD Base Rate Calculation and the Resulting Impact on Beneficiaries' Access to Medically Appropriate Care

CMS calculates the bundled ESRD base rate in a multi-step procedure whereby the Agency calculates total Medicare Allowable Payments (MAP) per treatment based on 2007 claims data, updates the unadjusted per treatment base rate to 2011, and subsequently applies a standardization adjustment, outlier adjustment and payment adjustment to arrive at the 2011 ESRD PPS per treatment base rate.[44] CMS further states that the Final Rule will implement MIPPA's requirement to select from 2007, 2008 or 2009 the base year lowest "per-patient utilization."[45]

KCP is concerned with the Agency's methodology and legal authority with regard to several elements of the base rate calculation that may result in an inappropriate reduction in the base rate, negatively impacting facilities' ability to operate and beneficiaries' access to necessary medical care.

A. CMS Should Clarify its Methodology for Selecting the Base Year for Determining Spending and Establishing the Base Rate and Outlier Payments

MIPPA specifies that the Secretary shall select from 2007, 2008 and 2009 the year with the lowest "per patient utilization" when projecting the overall ESRD payment envelope and bundled payment rates.[46] The term "per patient utilization," however, is not defined in the statute and can be operationalized in multiple ways. While the Agency plans to calculate the lowest average payment amount per treatment, CMS does not specify what it is including in its definition of average payment per treatment. KCP is concerned that this generic term could equally encompass, for example, per patient utilization based on volume of services or based on payments for services. As such, KCP requests that the Agency clarify its definition of "per patient utilization" and its corresponding methodology for selecting the base year.

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[43] 74 Fed. Reg. at 49931-32.
[44] 74 Fed. Reg. at 49939-49947.
[45] 74 Fed. Reg. at 49939.
[46] 42 U.S.C. § 1395rr(b)(14)(A)(ii).

As stated in the Proposed Rule, CMS will be comparing per-patient utilization for 2007, 2008 and 2009 and setting forth the Agency's determination in the Final Rule. KCP is also concerned that promulgation of this decision in the Final Rule will not allow the public to address concerns regarding unresolved matters of methodology and calculation, especially as the community lacks access to any partial year data for 2009. KCP urges CMS to outline specifically how it will provide an opportunity for appropriate public review of the base year decision in the Final Rule. Given the importance of the choice of base year to the base rate, and in light of the benefits of this approach in several areas addressed in this comment letter, KCP encourages CMS to release an Interim Final Rule with a comment period and updated rate setting file before finalizing rates for 2011.

B. CMS Lacks Legal Authority and an Empirical Basis for Excluding Actual Claims Data When Calculating the Unadjusted Rate per Treatment and Should Restore the Excluded Values

KCP believes that CMS exceeds its authority under the statute and acts contrary to congressional intent when the Agency excludes actual paid claims from the payment envelope. Without any basis in MIPPA or other statute or regulation, CMS caps Hemodialysis-equivalent sessions at twenty (20) per-patient, per-month and caps Epogen® utilization at 30,000 units per treatment when calculating total MAP per treatment.[47] The Agency also excludes actual paid claims from facilities missing a valid county-code, and patients without a valid date of birth, from the MAP calculation.[48] CMS' explanation of how it trims and excludes paid claims from base rate and 98 percent budget calculations is furthermore not specific enough to replicate its calculations.

MIPPA states that CMS "shall ensure" that total estimated payments under the bundled payment system in 2011 "shall equal 98 percent of the estimated total amount of payments…that would have been made under this title…if such system had not been implemented."[49] In the Proposed Rule, the Agency excludes actual payments based upon newly imposed caps on utilization and remediable coding errors. Excluding these actual payments that would otherwise have been made in 2011 is inconsistent with the plain meaning of the statute (emphasis added). Accordingly, KCP urges CMS to restore these excluded values to the ESRD projected base rate calculations. KCP further encourages CMS to clarify its methodology in excluding these claims and payments and to make available the Agency's data sets.

1. CMS Lacks the Authority to Cap Hemodialysis (HD)-Equivalent Sessions and Epogen® Utilization

The 98 percent budget calculation is intended to cap total estimated payments under the bundle based on total estimated payments under the current payment system. As a budgetary requirement, this limit is necessarily based on a comparison of what payments are in fact, not what the Agency determines payment should be. KCP believes the Agency's retroactive adjustments to utilization are also inconsistent with other provisions of the statute. In making the payment estimation, MIPPA directs CMS to use data from 2007, 2008 or 2009 based on which set has the

[47] 74 Fed. Reg. at 49940.
[48] Id.
[49] 42 U.S.C. § 1395rr(b)(14)(A)(ii). (emphasis added).

"lowest per-patient utilization."[50] The fact that the statute expressly provides a mechanism for addressing utilization further demonstrates that Congress did not intend for CMS to exclude actual claims data based on utilization.

KCP is also concerned that CMS imposes a blanket cap on HD-equivalent treatments and Epogen® utilization without a transparent analytical process, and without regard to variation in individual medical necessity. CMS states that utilization above these capped levels is "clinically implausible," "inappropriate" or "clinically suspect,"[51] but does not substantiate this determination nor address the incidence of medically-appropriate deviations from these thresholds.

With respect to Epogen® utilization, CMS also displaces an existing and current regulatory regime which specifically addresses the parameters for Epogen® utilization. Under the Agency's standing ESA Monitoring Policy "Monitoring of Erythropoietin Stimulating Agents for Beneficiaries with End Stage Renal Disease" effective January 1, 2008, "The medically unbelievable edit (MUE) threshold for Epogen® [was] reduced to 400,000 units from 500,000 and to 1200 micrograms from 1500 micrograms for Aranesp®." A cap of 30,000 units per treatment is a lower cap than the 400,000 units per month cap on Epogen® and does not apply to Aranesp®. An additional cap on ESA payments was implemented in 2009, based on HCT/HGB values, but the Epogen® cap used in the Proposed Rule would not necessarily capture the impact of the regulatory caps under the ESA Monitoring Policy. KCP is concerned that this dual – and inconsistent – regulation of Epogen® undermines the Agency's existing ESA Monitoring Policy and creates unnecessary confusion.

We also question the Agency's underlying determination as to the propriety of a cap at 30,000 units per treatment. KCP emphasizes that all dialysis patients are different and that reducing the threshold could disproportionately impact minority patients and exacerbate patients' anemia. The Agency's methodology for calculating per treatment utilization, which is to divide monthly Epogen® utilization by the number of treatments, is of further concern. For example, a beneficiary who was hospitalized for part of the month and upon return for dialysis required higher doses of Epogen® may have had doses of Epogen® higher than 30,000 units and fewer treatments on the claim. Under the Agency's methodology, such instances of clinically appropriate utilization may be eliminated from the rate setting.

While KCP supports the Agency's efforts to achieve appropriate utilization of ESRD services, we urge CMS to apply the ESA monitoring policies in place through 2011 to re-calibrate payments for Epogen® and to rescind the 30,000 unit cap as inconsistent with these policies.

2. CMS Should Restore Payment for Facilities and Beneficiaries Excluded Due to Remediable Coding Errors

KCP believes that the exclusion of facility and beneficiary claims data from the payment envelope and base rate calculation is inconsistent with the statutory intent to estimate total payments and with the Agency's past practice. KCP encourages CMS to restore these facilities and their claims into the ESRD projected base rate calculations.

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[50] Id.
[51] 74 Fed. Reg. at 49941, 49948.

Excluding payments for any facilities based on lack of a county code and the associated match to CBSA and wage index is problematic as these facilities continue to deliver and to be paid for ESRD services and, pursuant to MIPPA, should not be excluded from the estimate of total costs under the current payment system. KCP notes that historic ESRD and other PPS Rules specify how wage index values will be assigned for facilities lacking these designations.

KCP is also concerned with the Agency's basis for eliminating patients with "no valid date of birth." Since available data on the Standard Analytical File (SAF) includes some age designation for all patients and dialysis facilities record age on claims forms because it is a current case-mix adjustment, we do not believe it is appropriate to eliminate these patients or their claims from the calculation of treatments or payments.

3. CMS Should Be Explicit as to What Claims and Payments are Excluded from the MAP Calculation and Make Available the Agency's Data Sets

Being able to replicate and understand the Agency's calculations is essential to developing a bundled payment system where the kidney care community can be confident and assured that the needs of beneficiaries and facilities will be appropriately met. However, CMS' current explanation of how it trims and excludes paid claims from base rate and 98 percent budget calculations is not detailed enough to replicate its calculations.

Specifically, KCP found that the Agency's actual exclusion of facilities based on the lack of a county code does not correspond to the number of facilities lacking that designation. Our analysis of the SAF claims for 2007 and KCP's rate setting file both indicate more paid treatments than the Agency indicates. As the number of paid claims and the number of treatments provides the very basis for the base rate calculation, KCP urges CMS to make available all appropriate underlying data and to be explicit about what the Agency includes and excludes from these calculations at each step through a claims accounting document.

C. KCP Generally Supports Update Factors for the 98 Percent Budget Calculation but Remains Concerned with Agency's Method for Updating Drug Prices

KCP generally appreciates the Agency's efforts to update the 2007 Medicare Allowable Payments per treatment to 2011.[52] However, we are concerned with the Agency's use of 2009 ASP for the first two quarters as a proxy for 2011 prices.[53] This approach effectively assumes that drug prices will not change between 2009 and 2011. KCP urges the Agency to use the CMS Office of the Actuary generated PPI for prescription drugs to increase these payments. This is the value used in the market basket for ESRD drugs included in the composite rate, and we believe that the Agency's methodology should be consistent.

[52] 74 Fed. Reg. at 49942-49944.
[53] 74 Fed. Reg. at 49943.

D. KCP is Concerned with the Agency's Methodology in Establishing the Standardization Factor for 2011 and in Future Years and Requests that CMS Release a Flagged Beneficiary Level Rate Setting File for Validation

KCP has serious concerns with regard to the Agency's methodology for standardizing the base rate to remove the effect of case mix and facility adjustors and CMS' ultimate calculation of a standardization factor of 0.7827 and a reduction of 21.73 percent.[54] We are concerned that the proposed standardization factor for the case-mix adjustors is based on questionable data, is drawn from multiple data sources not available to facilities for their own patients, and is outdated (with data from as early as 2000). In addition, the data are not available for public review and comment.

In the preamble, CMS is also unclear as to how its proposed standardization would be applied in future years after 2011 and how the Agency will provide relief for errors, if at all. As such, we request that CMS specifically address how it will standardize rates for case-mix in the future. In order for the community to determine the impact of the application of the individual case-mix adjustors, KCP further requests that CMS provide a beneficiary level rate setting file including a unique flag for each specific case-mix or other patient adjustor assigned by CMS as the basis for rate setting.

E. CMS Should Apply the Outlier Adjustment to the Base Rate After the Two Percent Payment Adjustment is Applied

In the Proposed Rule, CMS applies the one percent outlier adjustment to the base rate after standardization but before the Agency applies the two percent discount mandated by MIPPA.[55] As the Agency explains, it adopts a one percent outlier adjustment to account for the one percent of "aggregate ESRD PPS payments estimated to be made as outlier payments."[56] Because the outlier payments are intended to be paid out, it appears that they should be included in the 98 percent of the adjusted 2011 base rate. As such, KCP believes that the outlier adjustment logically should be made after the two percent payment adjustment is applied and requests the Agency to clarify its position and revise this sequence as appropriate.

IV. Other Proposed Adjustments

A. Eligibility for Outlier Payment

CMS proposes to reduce the base rate by one percent to provide payment for outliers.[57] We believe CMS' methodology is generally consistent with the MIPPA statute and the proposed policy represents a minimal impact on the base rate relative to other reductive features of the Proposed Rule.[58] However, KCP asks CMS to remove laboratory tests from the calculation of the outlier payment. Because laboratory tests would have minimal impact on the ultimate distribution of outlier payments, there is no justification for inclusion at this time. Removing these tests may also provide

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[54] 74 Fed. Reg. at 49944.
[55] Id.
[56] Id.
[57] Id.
[58] 74 Fed. Reg. at 49987-49994.

some reporting relief for facilities, especially when CMS resolves all the issues surrounding the inclusion of laboratory tests, as noted below.

In the outlier calculations, CMS uses Average Sales Price (ASP) data to determine prices for separately billable drugs, but does not specify an actual value that will be imputed into the outlier calculations. KCP urges that in the Final Rule, CMS clarify the specific payment rate assigned to separately billable drugs within the outlier adjustment. Currently, CMS reimburses separately billable drugs in the ESRD program at ASP+6 percent. KCP asks that this methodology continue to be used as this is a reasonable approximation of average acquisition, preparation, and handling costs for these products.

Additionally, if CMS determines that oral drugs without an injectable equivalent are included in the ESRD payment bundle at this time, the Agency will need to specify a reimbursement methodology for valuing the costs of those drugs for purposes of calculating outlier eligibility. Given that these drugs are currently furnished in the Part D program and cost data is readily available in Part D data files, KCP encourages CMS to rely on the current Part D drug pricing information, if necessary, to determine eligibility for an outlier payment.

At this time, KCP is unclear as to whether other items and services, such as blood, blood products and blood transfusion procedures are included in the calculation of the outlier adjustment. Blood transfusion procedures are expensive, especially when the cost of blood or blood products and staffing time are taken into account. Although blood transfusions are life-saving procedures, they are not considered the standard of care for all beneficiaries. The Proposed Rule does not provide details as to how blood transfusion procedures are reflected or calculated in the new payment system. KCP suggests that because of the high cost of blood transfusions and their unpredictable rate of use, blood transfusion procedures be categorized as an outlier service.

V. Transition Payment Adjustment

A. The Secretary Does Not Have Legal Authority to Apply an Additional Adjustment to Payments Made During the Transition Period

In the Proposed Rule, CMS explains that it intends to make two separate adjustments to payments made to dialysis facilities during the years of the transition period. The first of these adjustments is an add-on fee intended to compensate facilities for the inclusion of certain oral drugs in the new payment bundle, which as previously discussed is inadequate and which does not provide a true transition period for oral drugs. The second adjustment is a payment reduction that CMS claims is necessary under the language of the MIPPA statute.[59] However, a review of the statutory language enacting the new ESRD PPS indicates that, while the first adjustment is applicable under Section 1881(b)(14)(A)(ii) of the Act, CMS does not have authority to make the second adjustment. Moreover, the methodology and assumptions used in formulating the transition adjustment in the Proposed Rule are fundamentally flawed.

1. The Plain Language of the Statute Does Not Require an Additional Transition Payment Adjustment

[59] 42 U.S.C. § 1395rr(b)(14)(A)(ii)

When enacting a new Medicare PPS for dialysis related services, Congress sought to control expenditures under the PPS by setting an overall budget target for payments made under the new system. MIPPA directs the Secretary to "ensure that the estimated total of payments under this title for 2011 for renal dialysis services shall equal 98 percent of the estimated total amounts of payments for renal dialysis services…that would have been made under this title with respect to services furnished in 2011 if such system had not been implemented."[60] The second sentence of this section requires CMS to "use per patient utilization" in making this estimation. In the most basic of terms, this directive authorizes the Secretary to determine the 2011 payment amounts under the new PPS by calculating the per patient amount that would have been spent in 2011 for the components of the new bundle under the previous composite rate system and then reducing that amount by two percent.

Recognizing that such a reduction could pose a hardship for some facilities if implemented all at once, Congress also included a phase-in period for new payment amounts under the PPS, directing the Secretary to transition payments in equal amounts over a four-year period.[61] Providers or facilities that furnish dialysis services are also given the ability to make a one-time, irrevocable election to be excluded from the blended payments offered during the phase-in period, meaning that they would begin receiving payments based upon 100 percent of the new PPS rates in 2011.[62]

During this phase-in period, referred to as the "transition" period in the Proposed Rule, CMS indicates that MIPPA requires the Agency to make an additional adjustment to payment rates.[63] Citing Section 1881(b)(14)(E)(iii) of the Act, CMS explains that it will make an additional three percent reduction to payment amounts made to all facilities in 2011, to be followed by similar adjustments in 2012 and 2013.[64] This reduction is made pursuant to the Agency's interpretation that this provision requires it to ensure that "the estimated total amount of payments under the ESRD PPS, including payments under the transition, equals the estimated amount of payments that would otherwise occur without such a transition." [65] However, the Agency's interpretation is incorrect under both the plain meaning of the statutory language as well as pursuant to other longstanding principles of statutory construction. As such, CMS should not implement the proposed three percent transition reduction.

In pertinent part, MIPPA provides that the Secretary "shall make an adjustment to the payments made under this paragraph for years during which the phase-in under clause (i) is applicable so that the estimated total amount of payments under this paragraph, including payments under this subparagraph, shall equal the estimated amount of payments that would otherwise occur under this paragraph without such phase-in."[66] CMS contends that this provision requires the Agency to address "the overall effect of the ESRD facilities' decision to be paid under the transition versus being paid under the ESRD PPS" and that without the adjustment, the total amount of

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[60] Id.
[61] 42 U.S.C. § 1395rr(b)(14)(E)(i).
[62] 42 U.S.C. § 1395rr(b)(14)(E)(ii).
[63] 74 Fed. Reg. at 50003.
[64] 74 Fed. Reg. at 49946.
[65] 74 Fed. Reg. at 49945.
[66] 42 U.S.C. § 1395rr(b)(14)(E)(iii).

payments under the transition would be higher than the amount of payments under a 100 percent PPS rate.[67]

As stated, this proposal is premised upon an incorrect interpretation of the statute. It is a basic tenant of statutory construction that statutes should be interpreted using the plain meaning of the language.[68] The logical, plain language reading of the provision found at Section 1881(b)(14)(E)(iii) applies the 98 percent budget requirement found in Section 1881(b)(14)(A)(ii) to select payments made during the phase-in period. As evidenced by the use of the language "payments under this paragraph, including payments under this subparagraph," Congress inserted this provision to ensure that the payments made during the transition period are subject to other payment adjustments found in the statute related to the ESRD bundle, such as the 98 percent adjustment and the market basket updates. To interpret the statute as requiring an additional adjustment is illogical, and would defeat both the plain language meaning of the statute and Congress' purpose in authorizing a phase-in payment period in the first place.

Furthermore, the proposed transition adjustment accounts for behavioral changes that are already accounted for in the new PPS. The 98 percent budget requirement that applies to the PPS in its entirety is premised upon expected efficiencies in the new payment bundle, and these efficiencies are driven, in part, by anticipated changes in dialysis facility behavior. In fact, the behavioral changes that CMS states that it must address with the additional three percent payment reduction are already factored into the payment threshold applicable to the PPS and are, therefore, redundant. Because Congress already included accommodation of these changes in the 98 percent budget requirement applicable to the entire PPS, CMS' proposal to make another adjustment to address the same issue is unnecessary and inappropriate under the MIPPA statute.

2. CMS' Interpretation of MIPPA Defeats the Congressional Intent of Enacting a Payment Transition Period

Not only is CMS' interpretation requiring an additional transition payment adjustment inconsistent with the plain language meaning of the statute, it also renders meaningless the portions of the statute authorizing a phase-in payment period. It is a longstanding principle of statutory construction that a statute should not be interpreted to contradict another portion of the statute.[69] In this case, Congress explicitly directed the Secretary to provide a four-year phase-in period offering facilities a payment rate that blends rates under the current composite rate system with the new rates under the PPS in equal increments.[70] Congress understood that dialysis facilities need time to adjust to a new payment rate and offered the blended payment rate option in order to ease that transition. To interpret Section 1881(b)(14)(E)(iii) as requiring a payment reduction to specifically offset the cost of this blended payment option would essentially render the purpose of the phase-in accommodation useless, penalizing all facilities for the delayed implementation of the PPS system.

This interpretation not only contradicts the provisions set forth at Section 1881(b)(14)(E)(i) and (ii), but it also produces an absurd result. Courts have repeatedly held that when interpreting a

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[67] 74 Fed. Reg. at 49946.
[68] Caminetti v. U.S., U242 U.S. 470 (1974).
[69] Foley Bros. v. Filardo, 336 U.S. 281 (1949); Markham v. Cabell, 326 U.S. 404 (1945); Litchfield Securities Corp. v. U.S. 325 F.2d 667 (2nd Cir. 1963).
[70] 42 U.S.C. § 1395rr(b)(14)(E)(i)-(ii).

statute, language should not be construed to produce an absurd result.[71] In this instance, it would be incongruous for Congress to specifically offer a phase-in period to ease transition into a new payment system and simultaneously direct the Secretary to make an additional payment adjustment removing any financial benefit associated with that phase-in period.[72] As such, the statute should not be interpreted to require an additional payment adjustment during the transition years, and CMS should refrain from finalizing its proposed three percent payment reduction in 2011.

Finally, the proposed CMS interpretation would also create a disincentive for facilities to opt-in to the transition, which is certainly not what Congress intended. In the Proposed Rule, CMS explicitly states that it believes that ". . . the transition budget neutrality adjustment should not change facilities' incentives with respect to whether or not to opt out of the transition."[73]. However, the proposed policy does just that by inadequately informing facilities of the terms of participating in the transition period over the four-year period and inaccurately measuring anticipated facility behavior during that same period. In creating the transition option for facilities, Congress intended to offer a helpful tool that was properly implemented so that they could make an informed decision based upon a full set of facts and knowledge of their individual circumstances. The policy set forth by CMS does not accomplish this, but rather places facilities at a disadvantage should they choose to take advantage of the blended transition payment. As this was not the result that Congress (or CMS by its own explanation) intended, the Agency should refrain from finalizing its proposal to implement a transition payment adjustment in 2011.

B. The Proposed Payment Adjustment is Highly Speculative and Should Not be Made in 2011

In addition to the legal issues raised above, CMS' proposal to implement a three percent reduction in payment amounts for 2011 is unnecessary and predicated upon a flawed methodology. Section1881(b)(14)(E)(iii), cited by CMS as the justification for the 2011 reduction, does not require CMS to address phase-in years on an individual basis nor does it require CMS to make an adjustment in 2011. Rather, the statute directs the Secretary to make an adjustment for "years during which the phase-in under clause (i) is applicable."[74] CMS misconstrues this language to require an adjustment in each individual year of the phase-in, proposing a three percent payment reduction in 2011 and indicating that it will calculate a similar adjustment for 2012 and 2013 in the future.[75] However, the statutory language does not require an adjustment in each individual year, but rather requires that the adjustment be made for the "years" during which the phase-in payment is available.[76]

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[71] American Tobacco Co. v. Patterson, 456 U.S. 63 (1982); Rosado v. Wyman, 397 U.S. 397 (1970); C.I.R. v. Brown, 380 U.S. 563 (1965).

[72] In fact, members of Congress have previously opposed CMS efforts to impose proposed reductions premised on providers' behavioral reaction to payment system changes. See, e.g., June 19, 2007 Letter to Leslie Norwalk from Senators Baucus and Grassley criticizing CMS proposal to apply a payment reduction to the Hospital Inpatient Prospective Payment System based upon projected provider response to changes in the MS-DRG payment system.

[73] 74 Fed. Reg. at 49945.

[74] 42 U.S.C. § 1395rr(b)(14)(E)(iii).

[75] 74 Fed. Reg. at 49946.

[76] 42 U.S.C. § 1395rr(b)(14)(E)(iii).

It is a well-recognized rule of statutory construction that in the case of ambiguity or question, the language of a statutory provision should be read in the context of surrounding provisions.[77] In this case, Congress included language regarding cost control in other provisions of this statute and that language did, in fact, specify budget requirements for individual years. For instance, the 98 percent budget directive found at Section 1881(b)(14)(A)(ii) specifies that the ESRD spending target applies specifically to year 2011. As such, if Congress had intended to require the Secretary to implement a payment adjustment in 2011 with regard to the phase-in, it would have included the same specific language found elsewhere in the paragraph.

KCP further believes that CMS has a strong basis for making any adjustment in the future, after the results of the facility elections are known. In other words, there is no reason for CMS to base its calculations on guesswork, especially since it will soon know which facilities opt in and which do not. To best implement statutory language and intent, CMS should pursue an approach that makes an adjustment over multiple years and should delay implementation of such an adjustment until a later date whereupon it has the necessary data. Given that the election to participate in the phase-in is a one-time, irreversible election that must be made prior to 2011, a delayed adjustment would allow CMS to make an accurate determination of the payments that will be made during the phase-in period. Similarly, CMS could also ensure accuracy by conducting a retroactive review of its prospective assumptions to reconcile any excess spending or savings at the end of the phase-in period. Either approach would obviate the need to prospectively speculate about facility behavior and furnish a data-centered foundation for calculating the adjustment that CMS believes it is required to make.

C. The CMS Methodology Used to Determine the Transition Adjustment Amount is Inaccurate

Finally, if CMS determines to move forward with a phase-in adjustment despite the lack of legal authority to do so, the methodology detailed in the Proposed Rule is fatally flawed and should be abandoned.

In order to fulfill the directive found in Section 1881(b)(14)(E)(iii) (as interpreted by CMS), the Agency explains that it must calculate a payment adjustment based upon its prediction of whether dialysis facilities will exercise the opt-out option furnished under Section 1881(b)(14)(E)(ii) of the statute.[78] CMS further explains that it must, therefore, prospectively predict facility behavior with regard to this option and proposes to use an oversimplified and rudimentary analysis to do so.[79] Specifically, the Proposed Rule indicates that CMS will use a basic calculation of whether a facility receives a higher aggregated payment under the existing composite rate-based payment system or the new bundled payment system to determine whether the facility will elect to take advantage of the blended rate offered during the phase-in period.[80] First and foremost, the preamble of the Proposed Rule contains no detail as to how this calculation was made or what factors were considered in

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[77] Gustafson v. Alloyd Co., Inc., 513 U.S. 561 (1995); U.S. Nat. Bank of Oregon v. Independent Ins. Agents of America, Inc., 508 U.S. 439 (1993); Smith v. US, 508 U.S. 223, (1993)(overruling on other grounds recognized by, U.S. v. Regans, 125 F.3d 685 (8thCir. 1997)); In re Public Nat Bank of New York, 278 U.S. 101, 49 S. Ct. 7, 73 L. Ed. 503 (1928).
[78] 74 Fed. Reg. at 49946.
[79] Id.
[80] Id.

determining the aggregate payment amount. As such, there is no information available to conduct an independent evaluation of the actual projections set forth in the proposal.

Additionally, the proposed CMS assessment appears to look only at a facility's payment performance in 2011, rather than over the entire four year phase-in period.[81] Given that the election to participate in the phase-in is a permanent, one-time decision, it is most likely that a facility will base its decision on the impact of the phase-in in its entirety, rather than in a one-year snapshot as assumed by CMS. This oversight in the methodology is likely to lead to mistaken behavioral assumptions and result in seriously flawed budgetary projections. For instance, a facility that appears to be minimally profitable under the blended rate in 2011 would elect to participate in the phase-in under the CMS analysis. However, if that same facility was not profitable under the blended rate in 2012 and 2013, they may not participate given the overall impact and would be incorrectly categorized by CMS for purposes of calculating the phase-in adjustment.

Based upon the brief description provided in the Proposed Rule, it also appears that CMS failed to consider any other factors besides the aggregate 2011 payment rate when trying to predict facility behavior[82] and, as such, the Agency ignores very common considerations contemplated by facilities. For instance, a facility that was slightly profitable under the blended payment option may determine that it is undesirable to participate in the phase-in for ease of administration and predictability. Individual facilities may also be influenced by overall operations decisions made by dialysis facility organizations, meaning that a chain may determine to use the blended rates for all of its facilities despite the fact that some individual facilities may not benefit under that approach.

These are just a few examples of common considerations in facility behavior that are overlooked by CMS' rudimentary analysis, which will likely produce an inaccurate projection of payments made during the phase-in period. If CMS is going to move forward with the proposed payment adjustment, despite its lack of authority to do so, it should, at the very least, use an alternative methodology that more accurately reflects the considerations of facilities when determining whether they will opt-out of the phase-in period.

Finally, CMS fails to indicate in the Proposed Rule how or if it will attempt to reconcile the actual decisions of facilities to opt-out of the phase-in period to ensure that the predicted spending levels are, in fact, equal to the actual payment amounts during this period. Such a reconciliation is required if the Agency is going to ensure that it meets the budget requirements that it claims are required under Section 1881(b)(14)(E)(iii). While KCP does not believe that CMS has authority to implement the proposed three percent payment reduction in 2011, if the Agency is determined to move forward with such an adjustment, it should at least consider delaying the adjustment until actual data is available to accurately determine the adjustment amount or institute a reconciliation process to ensure that payment reductions do not needlessly harm facilities in violation of the bundled payment statute.

[81] Id.
[82] Id.

VI. CMS Should Implement Race and Sex Case-Mix Adjustors While Working With the ESRD Community to Develop Further Appropriate Case-Mix Adjustors in the Future

KCP is appreciative of CMS for continuing inclusion of existing case-mix adjustors, such as age, body mass index (BMI), and body surface area (BSA). These adjustments are familiar to facilities and eligible patients can be identified using information that is currently available to dialysis facility staff. Nonetheless, while we are pleased that CMS heeded its own advice to continue to use age, BMI and BSA as adjustors at this time, we remain concerned about the proposed case-mix system outlined in the Proposed Rule.

KCP supports CMS' effort to include relevant case-mix adjustors in the ESRD PPS, but we believe the case-mix adjustors should be simple, based on available data and predictive of resource use.[83] Because they are the only proposed adjustors that meet this test, KCP supports the creation of only the race and sex case-mix adjustors at this time.

The purpose of a case-mix adjustment is to make higher payments to ESRD facilities when they treat resource-intensive patients, according to objective criteria.[84] However, if the case-mix adjustor process becomes burdensome because the data required are overly complex or not readily available, facilities will be disadvantaged in obtaining reimbursement for patients who are legitimately more expensive to treat. In addition, if the adjustors are not predictive of resource use, there will be payment inefficiencies and unintended consequences. The Agency should keep the case-mix adjustors list simple, based on available data and predictive to ensure that the adjustors reflect dialysis center costs and do not inappropriately burden facilities.

A. CMS Should Implement a Case-Mix Adjustor for Race Because of the Strong Correlation Between Race and Costs, Medicare's Significant Existing Race Data, and the Significant Burden Faced by the Facilities in the Absence of a Race Adjustor

MIPPA requires that the ESRD PPS include a payment adjustment for case mix that may include a patient's race.[85] KCP believes that a race case-mix adjustor should be included in the ESRD PPS given the strong correlation between race and costs and payments. As CMS notes in the Rule, there is a "statistically significant relationship" between race and costs.[86] CMS further notes the "demonstrated significance that race has on provider costs and drug utilization."[87] Indeed, race may explain cost variability in patients more effectively than other adjustors. Accordingly, it is critical that race be included as a case-mix adjustor.

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[83] 74 Fed. Reg. at 49927.
[84] 74 Fed. Reg. at 49925-26.
[85] 42 U.S.C. § 1395rr(b)(14)(D).
[86] 74 Fed. Reg. at 49962.
[87] Id.

1. The Medicare Data Surrounding Race is No Less Reliable Than the Data Used to Implement Other Case-Mix Adjustors

In the Proposed Rule, CMS states its concern that "race/ethnicity is not objectively measured" because it is "commonly based on self-reported information."[88] It then states its belief that the patient's underlying clinical conditions are "more measurable indicators of cost and payment." KCP disputes the assertion that self-identified race data are less reliable than clinical condition data. Clinical condition data are often self-reported by a patient who details his or her medical history prior to treatment. In other instances, information about clinical conditions from the diagnosing physician is not available to the dialysis center. KCP is concerned that CMS has questioned the quality of race data while not addressing the significant existing concerns with other data sets.

KCP believes that CMS should develop criteria to verify race in such a way that race data could be collected with reasonable reliability. For example, CMS could require that patients who are unwilling or unable to identify race be defaulted to the "other" or "unknown" category. In such cases, the patients would not be eligible for an adjustor. Such an approach would improve accuracy of race identifications and payments.

It is also important to note the strengths in the current Medicare database. The Agency already has a great deal of information surrounding race. Researchers have noted the usefulness of Medicare data on enrollment and utilization in enhancing understanding of the Medicare population and its health, health care utilization, and quality of care.[89] In the Proposed Rule, CMS relies on two data sets: the Medicare Enrollment Database (EDB) and the Renal Management Information System (REMIS).[90] EDB contains enrollment information on all individuals ever entitled to Medicare. REMIS includes race data from a substantial number of Medical Evidence Report Forms. These two data sources provide a significant amount of data to inform decisions regarding race. In addition to sheer volumes of data, CMS has attempted over a number of years to improve the quality of that data. These efforts have included a survey of beneficiaries with an unknown race/ethnicity, annual file updates from the NUMIDENT system, and work with the Indian Health Service to record beneficiaries' race as American Indian or Alaskan native.[91] These efforts have led to substantial improvements in Medicare data on race.[92]

Because of existing, verifiable data, CMS already has the means to implement a case-mix adjustor based on race.

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[88] Id.
[89] A. Marshall McBean, Improving Medicare Data on Race and Ethnicity, National Academy of Social Insurance, October 2006. See also Marian E. Gornick, Paul W. Eggers, Thomas W. Reilly, Renee M. Mentnech, Leslye K. Fitterman, Lawrence E. Kucken, and Bruce C. Vladeck, Effects of Race and Income on Mortality and Use of Services among Medicare Beneficiaries, New England Journal of Medicine, 335(11): 791-9, 1996.
[90] 74 Fed. Reg. at 49962.
[91] 74 Fed. Reg. at 49963.
[92] A. Marshall McBean, Improving Medicare Data on Race and Ethnicity, National Academy of Social Insurance, October 2006.

2. Failure to Include a Race Adjustor Could Have Negative Effects on Access to Care Since it Will Have a Dramatic Negative Impact on Facilities that Treat a High Number of Minority Beneficiaries

KCP is concerned that facilities that serve a predominantly minority population will be greatly harmed if CMS does not include a race case-mix adjustor, leading to a potential access problem in some areas. ESRD treatments for any particular racial group are not spread out evenly across the country. Rather, they are often concentrated in specific areas. Dialysis facilities in these areas treat more minority patients than other facilities. For example, in 2007, 687 facilities had greater than 75 percent of their treatments for African American patients. CMS has noted the higher spending on separately billable drugs for African American patients. In the past, a facility would have been paid for these higher drug costs separately. Under the new PPS, however, these drugs will be included in the bundle that will not adequately account for the high proportion of minority patients in the facility. Accordingly, facilities that treat a large number of African American patients will be at great financial risk under the new payment system. [See Technical Appendix]

There are also a number of facilities that are dependent on Medicare payments to remain in operation. Ten States have more than 50 percent of their African American patient treatments in facilities that have more than 80 percent Medicare treatments. [See Technical Appendix] Because of this high percentage of Medicare treatments, these facilities have very few other payers to make up for low Medicare reimbursement. If CMS reimbursement to cover the cost of high-cost racial minorities is inadequate, it will have devastating effects on these facilities and will likely negatively affect access to care.

B. Beneficiary Sex Should Be Included as a Case-Mix Adjustor Due to its Relation to Costs and the Availability of Patient Data on Sex

Patient sex should also be included as a case-mix adjustor because of its strong connection to dialysis treatment costs and because patient sex is objectively determined through available data. KCP agrees with CMS that "patient sex is a strong predictor of variation in payments for ESRD patients."[93] As CMS notes, data show that female patients are generally more costly to treat than male patients. CMS should implement a patient sex case-mix adjustor to account for these higher costs.

In addition, patient sex is an "objective measure and data on patient sex are readily available."[94] Facilities will be able to obtain reliable data on patient sex without undue burden. Given the predictive power of sex with regards to cost, and the ease of collecting this data, CMS should include patient sex as a case-mix adjustor.

[93] 74 Fed. Reg. at 49950.
[94] Id.

C. Other Case-Mix Adjustors Should Not Be Included At This Time Because They Lack Predictive Power, Require Unavailable Data, and Would Impose Difficult Coding Requirements. CMS Should Work with the Dialysis Community to Identify Appropriate Case-Mix Adjustors in the Future

1. Many of the Proposed Case-Mix Adjustors Do Not Accurately Predict Dialysis Costs because They Are Not Independent Variables or Accurately Reflect Cost of Care

To accurately implement case-mix adjustors, the costs associated with these variables must not duplicate costs associated with other variables. That is, each case mix-adjustor must stand on its own as an independent variable. The independence of these variables should be based on clinical expertise and be based on evidence. CMS has not discussed its efforts to assure the independence of the variables. In fact, CMS reports different results from different regression models, and different results when a race adjustor is added to its analysis. These differences suggest that the variables treated by CMS as independent for purposes of the analysis are not actually independent with respect to distinct resource use. If the variables selected by CMS are not, in fact, independent, the values of the adjustors would be overstated.

CMS uses cost report data in its analysis to estimate the patient-level case-mix adjustors. However, cost reports provide no link between facility costs and individual characteristics of patients. There is little basis to assume that conditions of patients that occur with low frequency would have a noticeable impact on differences in overall facility costs. Other factors, such as occupational mix and facility group purchasing practices, are likely to have a greater impact on facility costs than patient-level characteristics. Until CMS modifies cost reporting in some way to more accurately connect costs with individual patient characteristics, it should exclude cost report data from its adjustment methodology.

2. Many of the Proposed Case-Mix Adjustors, Particularly the Co-Morbidities Adjustors, Are Not Predictive of Dialysis Costs because They May Involve Medical Conditions that are not Relevant to the Current Dialysis Treatment

Based upon a review of data furnished by members of the kidney care community with expertise in tracking the clinical impact of patients' co-morbidities, KCP believes that there is little relevance of many of the proposed case-mix adjustors to cost, especially when a significant period of time has passed between the condition and the onset of dialysis. For example, the case-mix adjustor CMS proposes for patients with substance abuse problems requires that a patient meet three of seven possible criteria. In practice, almost any ESRD patient who consumes beer or wine could meet these criteria, and clinical literature has highlighted the unreliability of such criteria. This results in an adjustor that is unreliable in predicting a patient's needs during dialysis treatment and inappropriately establishes a payment mechanism that could be subject to abuse. Absent a strong connection to clinical variance and dialysis costs, CMS should refrain from implementing such adjustors.

3. Much of the Co-Morbidity Case-Mix Adjustment Data Requested by CMS are Not Readily Available

KCP is concerned that the data required for determining co-morbidity adjustments are not readily available. For example, one of the co-morbidity categories is HIV/AIDS. Although it is clear that HIV/AIDS patients are more costly to treat overall, obtaining this data to qualify for the case-mix adjustment will be difficult in practice, in part due to strict patient confidentiality regulations and State law. The treatment of HIV/AIDS is often a sensitive clinical area in which great confidentiality is necessary. Reporting data on HIV/AIDS patients runs counter to this reality. In addition, as CMS notes in the Rule, facilities are often "required by State law to maintain patient confidentiality."[95] Finally, as CMS also notes, facilities "may not be aware of [a] patients' HIV/AIDS status."[96] Moreover, due to differences in State law, data availability may differ across States, thus creating disadvantages with regard to a specific HIV/AIDS adjustor.

The co-morbidity category of alcohol/drug dependence also raises data availability concerns. It is unclear how an MCP physician or a dialysis facility staff member would determine whether a patient had such a condition. Patients are often not likely to describe their alcohol or drug dependence history. If a patient does disclose this history, they are not likely to describe it in terms of a specific diagnosis that would match with one of the proposed ICD-9 codes. Furthermore, an MCP physician may not be qualified to make a specific diagnosis, or code it properly, even if he or she is aware of past alcohol or drug abuse.

Because the data required to qualify for the case-mix adjustors (with the exception of race and sex) are not readily available, CMS should not implement any of the eleven proposed case-mix adjustors at this time.

4. Because the Information Needed to Code Co-Morbidities for Payment Adjustors will not be Consistently Available to Dialysis Facilities, CMS Should Not Implement Co-Morbidity Adjustors

To document the co-morbidity case-mix adjustor for payment purposes, CMS will likely require facilities to place ICD-9 codes on all claims. However, in many instances the dialysis facility will not have access to the diagnoses required to accurately use an ICD-9 code. For example, if the patient is being treated by multiple physicians, the MCP physician may not have access to the diagnoses relevant for ICD-9 coding purposes. Patients coming to dialysis facilities from hospitals would not usually have the diagnosis information at the ICD-9 five-digit code level, and hospitals do not generally provide this information to dialysis facilities. Because there is no existing mechanism for dialysis facilities to receive the ICD-9 level diagnoses necessary to claim a co-morbidity adjustor on a claim, it would be near impossible for facilities to accurately capture these data. Requiring a facility to obtain these data would impose additional burdens on facility staff, patients, and physicians.

5. CMS Should Not Implement the New Patient Adjustor because New Patient Costs are Already Captured through Other Adjustors, There are Few Current Issues with New Patients Obtaining Access to Care, and the Adjustor Misaligns Incentives

[95] 74 Fed. Reg. at 49954.
[96] Id.

CMS correctly notes that patients in their first "months of dialysis have higher costs."[97] Based on this finding, CMS proposes to implement a "new patient adjustment" for patients for their first 120 days of dialysis. KCP believes this new patient adjustor should not be implemented because new patient costs are already captured with other adjustors and more would be accurately captured with the race adjustor.

KCP maintains that the first 120 days of treatment are not independent of all other adjustor variables. In other words, the inclusion of the new patient adjustor is duplicative of other adjustors that more accurately predict treatment costs. Much of the costs for new patients are associated with hospitalizations and race. These costs are better handled through mechanisms other than a new patient adjustor. As noted above, a race adjustor would account for costs accrued within the first 120 days. Furthermore, there are little data proving higher labor costs with the commencement of dialysis.

In addition, the costs associated with the initial months of dialysis have not prevented new patients from gaining access to dialysis.[98] One of the purposes of a case-mix adjustment system is to erase any disincentive to treat costly patients. Since there appears to be no disincentive currently, the new patient adjustment is not necessary. Rather, furnishing an adjustment for new patients may actually create incentives for undesirable behaviors such as the steering of certain patients from one treatment setting to another based upon payment considerations.

Finally, while KCP supports CMS' effort to support facilities that furnish home dialysis training to their patients, we believe that reimbursement for this activity is improperly included in the 120 day adjustor because an overwhelming majority of patients receiving such training do not receive it in their first 120 days of care. Rather, most patients who receive training for home dialysis initiate this activity further along into their dialysis treatment because, due to a number of clinical or lifestyle reasons, they may not be ready for such services when they first come to a facility for care. While we encourage CMS to continue to improve support for such training, we urge the Agency to do so in a more appropriate manner.

6. Numerous Data and Analytical Gaps in the Area of Case-Mix Adjustors Raise Questions as to the Credibility and Accuracy of CMS' Case-Mix Calculations

In the Proposed Rule, CMS proposes a "standardization factor" of 21.73 percent that would be applied to the base rate to account for the effect of case mix and facility adjustors.[99] Although CMS assigned case-mix adjustors to patients and facilities in the 2007 claims, the impact file released with the Proposed Rule does not include the case-mix adjustors. This data gap makes it impossible to estimate the incidence rates for the conditions associated with the application of the case-mix adjustors. Accordingly, it is extremely challenging to accurately estimate the impact of any change to the adjustors.

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[97] 74 Fed. Reg. at 49952.
[98] Medicare Payment Advisory (MedPAC), Report to the Congress: Medicare Payment Policy (March 2009).
[99] 74 Fed. Reg. at 49944.

KCP renews the request it made in a previous communication to the Agency that patient-level data should be provided and should include a unique flag for each specific case-mix or other patient adjustor assigned by CMS as the basis for rate setting.[100] If the Agency is unwilling to issue such data, the Agency's impact analysis should at least be expanded to provide an accounting of the number of treatments at each facility to which each case adjustor is applied.

Although CMS describes in some detail its process for setting the standardization factor for the Proposed Rule's initial rate setting, the Agency does not describe how it will apply the standardization in future years.[101] This omission could have a significant effect if, for example, the actual mix of adjustors for the 2011 patient population is materially different from the base year that was used to set the rates. KCP requests that CMS disclose how it will standardize rates for case mix in future years. As part of this effort, CMS should consider reconciling the standardization factor to actual experience in future years. Such reconciliation would prevent leakage from the budget-neutral payment system.

VII. Low-Volume Facility Adjustor

KCP is pleased that CMS proposes to include a low-volume adjustor at the facility level but we are concerned that the current proposal includes criteria and data that are problematic. As a result, the policy included in the Proposed Rule could ultimately result in an inappropriate selection of facilities subject to the adjustor as well as incorrect payment incentives for facilities.

The Kidney Care Council (KCC) is submitting a more detailed analysis of the low-volume facility adjustor in its comments to CMS, and KCP supports that analysis and encourages CMS to consider those comments when finalizing its policy in this area. KCP identified similar data issues that it agrees will cause facilities deserving of this adjustment to be excluded from eligibility and potentially assist facilities that would not be eligible under a more accurate formula. Given the importance of low-volume facilities in communities across the country, we urge CMS to give serious thought to the KCC recommendations and modify its proposal as appropriate.

VIII. Pediatric Patients

A. CMS Should Develop a More Appropriate Single Category Case-Mix Adjustor for All Pediatric Patients Regardless of Age or Modality, and the Agency Should Consider Postponing the Application of the Bundled Payment to Pediatric Patients Until More Accurate Data Can Be Collected and Analyzed

KCP appreciates that CMS specifically invited comments about the proposed case-mix adjustor for pediatric patients and is happy to respond. Pediatric patients less than 18-years old comprise a very small portion of the dialysis population, accounting for just less than 0.6 percent of prevalent dialysis patients and only 0.2 percent of dialysis Medicare beneficiaries. The vast majority of these children are dialyzed in about 50 pediatric dialysis units (case mix >50 percent patients <18 years old), who provide pediatric focused services to this small vulnerable population. In these

[100] Letter from Kent Thiry and Michael Klein to Jonathan Blum, Director, Center for Medicare Management, September 29, 2009.
[101] 74 Fed. Reg. at 49944.

units, specially trained pediatric personnel are essential to care for the smallest children, but also the teenagers, who have unique behavioral adjustments in this last developmental stage of childhood, which lead to difficulty tolerating dialysis procedures, adhering to dietary restrictions and medications, and maintaining school performance. Pediatric patients range in size from 3 kg newborns to 90 kg teenagers, which requires access to a wide variety of specialized dialyzers, blood lines, and other supplies, most of which are expensive and only made by one or at most two vendors.

We are concerned that CMS' proposed reduction in the pediatric (<18 years old) case-mix adjustor from 1.62 to 1.199 or below has underestimated the costs of dialyzing children and will have an unintended consequence of pediatric patients losing access to specialized pediatric dialysis care. The proposed pediatric case-mix adjustor is based on a statistical regression model developed for the much larger adult population, but is flawed when applied to the small number of pediatric patients (only 600 patients in the analysis) and made worse by the missing or incomplete cost data from pediatric dialysis units. The proposed case-mix adjustor does not analyze actual data from cost reports of pediatric units. The analysis is further distorted by cost data for pediatric patients dialyzed in adult units, whose facility costs represent the adult costs in those units and not pediatric-specific services. In the past, CMS has repeatedly recognized the increased cost of dialyzing children, both in the granting of pediatric dialysis facility exceptions to reimbursement and in the provision of the temporary pediatric case-mix adjustor of 1.62 in 2005. Pediatric dialysis units that applied successfully for exception for reimbursement were granted higher facility rates for pediatric services based on the actual costs in their Medicare cost reports, including higher personnel staffing, higher costs of pediatric-specific dialysis disposable equipment, and higher costs of support for home care of children and their caregiver families. Also of concern is that a pediatric case-mix adjustor of 1.199 or less would be a disincentive for those adult units that must adapt their services to meet the special needs of children who are geographically unable to be cared for at a pediatric dialysis center.

In addition, CMS has proposed multiple payment categories for pediatric patients to adjust for factors such as age and modality, a method that unnecessarily complicates the pediatric case-mix adjustor.[102] KCP believes assigning a single pediatric case-mix adjustor regardless of pediatric age group or modality will allow pediatric nephrologists and families to choose the right dialysis modality for each child. The proposed pediatric rates are the lowest for the youngest patients (<13 years old), which is contrary to the known technical complexity and high cost of staffing and specialized supplies involved in dialyzing this group of children. The extra effort required for technical support of parent caregivers and adolescent self-care patients for the 50 percent of pediatric patients managed on home modalities is not recognized by the proposed modifiers. The acceptable co-morbidities stated in the ESRD PPS, including diabetes and alcohol/drug dependence, among others, are relevant for adults and do not often apply to children. However, pediatric ESRD co-morbidities, including developmental delay, failure to thrive, seizure disorder, deafness, pulmonary hypoplasia, congenital heart disease and renal osteodystrophy of growing bones are not addressed. Most pediatric dialysis patients would not be classified as having co-morbidities from the proposed ESRD PPS list.

[102] 74 Fed. Reg. at 49987.

Given these concerns, while KCP appreciates CMS' effort to provide an adjustment for young patients, we strongly encourage CMS to reassess the pediatric case-mix adjustor methodology and provide a more appropriate single category case-mix adjustor for all pediatric patients regardless of age or modality. The reassessment should include analysis of actual Medicare cost reports of pediatric dialysis units, where the majority of pediatric patients are dialyzed and receive truly pediatric-focused services, and should also include pediatric-specific co-morbidities as outlined above. As noted previously in our comments, many of the case-mix adjustors CMS proposes in the Rule, including this adjustor, are flawed and do not accurately reflect the clinical needs and costs of care for patients with the targeted conditions or characteristics. CMS may also want to consider postponing the application of the bundled payment to pediatrics until more accurate data can be collected and analyzed to prevent the small, but vulnerable pediatric population from losing access to vital pediatric-specific care.

IX. The Proposed Rule Imposes a Significant Administrative Burden on Both Patients and Facilities

KCP understands and supports the Agency's intent to reduce administrative burden on beneficiaries and facilities in the ESRD PPS; however, we believe that some aspects of the Proposed Rule, if implemented, will create additional barriers to provide coordinated, high quality care. As noted above, case-mix adjustments were created to measure costs associated with caring for certain types of beneficiaries. Many of the co-morbidity adjustors proposed (i.e., substance abuse, HIV/AIDs, etc.) create an additional burden because these data and claims describing beneficiaries' past medical history are not accessible by dialysis facilities. To obtain these data, a survey instrument would have to be created and additional staff time would be needed to obtain this information from each beneficiary treated in their facilities. The demands required would be costly and negate the purpose of co-morbidity adjustors.

A. Including Oral Drugs and Laboratory Tests in the Bundle will Impose Burdensome Cost-sharing Amounts for Items and Services for which there is Currently No Cost-sharing Obligation and Increase Contracting Requirements for Facilities

Moreover, as described throughout this comment letter, KCP has a number of concerns that under the Proposed Rule beneficiaries would be forced to pay more for items and services than what they pay currently. If finalized, beneficiaries would be held responsible for coinsurance on laboratory tests, as well as, duplicative or increased coinsurance on oral drugs, placing yet another burden on this vulnerable population.

The burden will be especially severe for Medicaid dual eligible patients. Drugs for Medicaid dual eligibles are currently provided by Part D. Part D limits the amount that prescription drug plans can charge dual eligibles for copayments. As stated previously, with the inclusion of oral drugs in the bundle, dual eligibles will be responsible for 20 percent of a bundle that includes the full cost of the drug. Although this coinsurance amount is typically paid by State Medicaid programs, it is questionable whether such programs will immediately recognize this obligation under the new PPS. This may ultimately result in increased anxiety over access issues for dually-eligible beneficiaries and leave providers with no means of recovering this 20 percent payment.

This is especially concerning because there has been no indication from the States that they will assist with the increased costs to dual eligibles once the ESRD PPS is implemented. Dual eligibles are generally poorer and sicker than the typical Medicare or Medicaid beneficiaries. Accordingly, prescription drug use is higher among dual eligibles than other Medicare beneficiaries. Therefore, policies that increase costs will be especially damaging to this population. CMS must ensure that the new payment system does not inappropriately burden vulnerable Medicaid beneficiaries who have extremely limited resources and who face questionable support with increased costs from State Medicaid programs.

Beneficiaries are also certain to face increased cost-sharing requirements because of the inclusion of laboratory tests in the payment bundle. As stated previously, ESRD patients have no coinsurance obligations for laboratory tests.[103] Under the proposed PPS, laboratory tests would be included within the payment bundle. Accordingly, the cost of the laboratory tests will be included in the 20 percent coinsurance amount owed by the beneficiary.

B. Increased Contracting Requirements Lead to Additional Burdens on Facilities

Furthermore, dialysis facilities will need to contract with outside pharmacies and laboratories in order to fulfill consolidated billing requirements. Facilities will have to set up arrangements with a potentially large number of outside suppliers and pay them directly, thereby, increasing burdens to ensure beneficiaries receive all the items and services needed to ensure proper care. This increased burden on facilities, particularly for small dialysis facilities, may create an unintentional need for additional resources to make changes to billing systems, to prepare appropriate contractual arrangements for services, and to educate facility staffs and suppliers with which facilities are contracting, and, in many cases, the States that pay for some of these services for low income beneficiaries

Also, facilities must deal with increasing demands to document care processes and conduct pre-authorizations, ongoing utilization review, and follow-up reviews. Increasing these responsibilities for facilities may increase costs and further complicate the management of patients. With a growing emphasis on outcome measurement and cost reduction as facilities must survive with fewer available resources, and the addition of documentation and consolidated billing requirements, KCP asks that CMS be cautious when implementing requirements that may force facilities to use resources for additional paperwork, rather than focusing on patient management and care.

X. CMS Must Provide Details on Longer Term Operation of PPS and the Process for Reevaluation of the ESRD PPS in Subsequent Years

KCP is concerned that Proposed Rule outlines a number of specific policies related to the PPS that are specifically linked to the 2011 payment year but provides little detail on how those policies will be treated in future years. In fact, the Proposed Rule includes little to no information on how CMS intends to handle items and services within the bundle after 2011. This is

[103] 42 U.S.C. § 1395l(a)(2)(D)(ii).

unacceptable and leaves patients and facilities with no real means of anticipating future years under the new PPS, which ultimately inhibits their ability to develop the best treatment plan and regimen for ESRD patients. CMS must take steps to provide additional information on the payment bundle beyond 2011, and it should provide the kidney care community with the opportunity to comment once that information is available.

Similarly, the Proposed Rule includes policy determinations related to a number of specific items and services, and reimbursement for such items and services, under the new PPS based upon the current clinical practice for treatment of ESRD patients. Presuming that the bundled payment system will be utilized over the long term— in fact, the current payment system has been used for decades— it is essential that CMS specify an appropriate process for updating policies under the PPS as clinical treatments evolve. For instance, if CMS is going to specify the types of pharmaceuticals and lab services included in the bundled payment, it should establish a periodic review process to add or remove items and services included on those lists as well as update the reimbursement allocated to those treatments within the bundle as market conditions change. This is critically important to allow practitioners in the Medicare system to utilize the most current clinical practices for treating ESRD patients. Additionally, CMS should also establish a review process for evaluating the impact of the new PPS on patients and providers alike to ensure that the changes in the payment system have not resulted in clinical practice changes that adversely impact the quality of care furnished to patients.

Finally, given the number of possible policy changes that should be addressed before implementation of the new dialysis PPS, KCP strongly encourages CMS to issue its next public notice as an Interim Final Rule with an additional opportunity for public comments rather than a Final Rule. The critical importance of the issues at stake and the number of details missing from the Proposed Rule dictate the need for more consideration and caution before finalizing potentially dangerous policy changes.

XI. Quality Incentives in the ESRD Program

Section 1881(h) of the Act,[104] as added by Section 153(c) of MIPPA[105] requires the Secretary to implement a Quality Incentive Program (QIP) that will result in the reduction of payments to providers of services and dialysis facilities that do not meet or exceed a total performance score based on performance standards (i.e., benchmarks) for specified performance measures. Further, CMS has noted that the QIP is intended to help ensure the quality of services implemented under the new bundled payment system—specifically to "minimize risks of unintended consequences related to a bundled payment system."[106] In Section XV of the Proposed Rule,[107] CMS sets forth its conceptual model for the QIP and proposes that three specific measures be used for the calendar year 2012 payment reduction. KCP appreciates the opportunity to comment on CMS' early conceptual model and further appreciates that CMS "understand[s] the importance of giving

[104] 42 USC 1395rr.
[105] Id.
[106] CMS, Open Door Forum End Stage Renal Disease Prospective Payment System (ESRD PPS) Proposed Rule, http://www.cms.hhs.gov/ESRDPayment (last visited November 16, 2009).
[107] 74 Fed. Reg. at 50009-50016.

providers and facilities time to prepare for the implementation of this new quality incentive program and to assess how the new program will affect them."[108]

KCP members have a longstanding history of a progressive, forwarding looking approach to quality improvement and accountability. As CMS notes, quality has been integral to the ESRD program since the late 1970s, and the community has been an active partner and participant in a broad array of CMS and ESRD Network initiatives and programs to ensure quality of care for dialysis patients. In fact, KCP has gone well beyond the government's initiatives in addressing quality of care issues. In 2005, KCP voluntarily established the Kidney Care Quality Alliance and funded the development and testing of measures to assess the quality of dialysis care; five of these measures were submitted to and endorsed by the National Quality Forum (NQF). Unique among healthcare sectors, the community did so in a proactive manner and without government funding. Most recently, KCP launched the Performance Excellence and Accountability in Kidney Care (PEAK) Campaign in June 2009. This voluntary national campaign has established the goal of reducing mortality of first-year dialysis patients by 20 percent by the end of 2012. We look forward to working with CMS as it develops the QIP and appreciate the opportunity to provide comment on the proposal to date.

A. Proposed Anemia Management and Dialysis Adequacy Measures

In the QIP's initial year, CMS proposes to adopt three performance measures that it currently uses for Dialysis Facility Compare (DFC):

- Percent of patients with hemoglobin <10 g/dL—time-limited NQF-endorsed, and was published in April 2008 Federal Register notice listing clinical performance measures (CPMs) (though with a different measurement timeframe in the specifications);
- Percent of patients with hemoglobin >12 g/dL—neither NQF-endorsed nor published in the Federal Register; and
- Percent of hemodialysis patients whose urea reduction ratio (URR) is 65 percent or greater—endorsed by NQF (until Kt/V measure available) and published in the Federal Register.

KCP supports using an anemia management measure of hemoglobin <10 g/dL, but opposes using the hemoglobin >12g/dL for the QIP. KCP also has concerns about the URR dialysis adequacy measure.

1. KCP Supports Using an Anemia Management Measure of Hemoglobin <10 g/dL, but has Concerns about the DFC Specifications and Recommends Changes in this Regard.

Numerous observational research studies have documented associations between low hemoglobin levels and poor outcomes, such as hospitalizations, mortality, and higher likelihood of transfusions; avoiding low hemoglobin levels is an important treatment goal. Accordingly, KCP supports using a performance measure that assesses patients with hemoglobin levels <10 g/dL. We have concerns, however, about CMS' proposal to use the DFC specifications. In particular, KCP has concerns about utilizing a yearly average for the hemoglobin level and recommends that CMS

[108] 74 Fed. Reg. at 50011.

calculate a three-month average and then average these over a 12-month period (i.e., utilize patient quarters as the unit). KCP notes that utilizing a three-month average more closely resembles the CPM endorsed by NQF, recognizes the clinical consequences such as transfusions that can occur even when patients have transiently low hemoglobin levels, and provides a more robust clinical assessment of the quality of care by further averaging these over a 12-month period, while also not penalizing a facility for a random higher hemoglobin value for which there is no evidence of associated harm. KCP also recommends CMS use the CPM specifications related to number of claims, minimum period on dialysis, high/low values, etc. KCP also strongly recommends that the claims form clearly instruct that pre-treatment hemoglobin values are to be reported, so as to standardize the methodology and ensure a level playing field. Finally, KCP recommends that CMS collect data that would permit the Agency to apply the measure to all patients, irrespective of erythropoesis-stimulating agent (ESA) use, as the CPM specifies (in contrast to the DFC specifications).

2. KCP Strongly Opposes Using an Anemia Management Measure of Hemoglobin >12 g/dL for the QIP. KCP Recommends that CMS Use a Measure of Hemoglobin of 10-12 g/dL.

KCP acknowledges that Section 1881(h)(2)(A)(i) of the Act provides that the anemia management measures must reflect the labeling approved by the U.S. Food and Drug Administration (FDA) for such management.[109] The current FDA label released November 8, 2007, for the administration of ESAs to patients with chronic kidney disease on dialysis states, "Individualize to achieve and maintain hemoglobin levels between 10 g/dL to 12 g/dL."[110] KCP disagrees with CMS' interpretation that using a measure of hemoglobin >12 g/dL and the separate measure of hemoglobin <10 g/dL reflect the FDA labeling. KCP believes that to promote achievement of more patients with hemoglobin levels in the 10-12 g/dL range, a quality measure for the percent of patients with hemoglobin levels between 10-12 g/dL should be used in conjunction with a measure for patients with hemoglobin levels <10 g/dL.

CMS appears to be assuming that minimizing <10 g/dL and >12 g/dL will yield more individuals between 10-12 g/dL; however, given the hemoglobin distribution curve the three measures may not move synchronously. As CMS is aware, due to the general poor health status of a typical dialysis patient and the natural variability in patient hemoglobin levels, it is difficult to consistently maintain hemoglobin within a narrow band, such as between 10 and 12 g/dL. Consequently, patients targeted to hemoglobin levels between 10 and 12 g/dL will at various times have achieved hemoglobin concentrations that are above and below the target at various times. However, worse patient outcomes have been shown to be associated with even transiently low hemoglobin levels in dialysis patients compared with transient excursions above 12 g/dL. Thus, we believe an anemia measure for the percent of patients with hemoglobin levels 10-12 g/dL in concert with an anemia measure for the percent of patients with hemoglobin levels <10 g/dL is most appropriate.

CMS indicates in the Proposed Rule that it can use available data to calculate hemoglobin levels of 10-12 g/dL. Although KCP members continue to oppose such a measure of "targeted

[109] 42 USC 1395rr.
[110] 74 Fed. Reg. at 50011.

care," and continue to believe CMS should use measures endorsed by the NQF, on balance using a measure of 10-12 g/dL in the QIP, which we further acknowledge was published as a CPM, is preferable to using the measure of >12 g/dL. As with the measure of hemoglobin <10 g/dL, we recommend the performance period be based on patient quarters. Further, as with the measure of hemoglobin <10 g/dL, CMS should look to the CPM specifications and not the DFC specifications with regards to number of claims, time on dialysis, extreme values, and reporting of pre-treatment values. Finally, KCP strongly believes the measure should be applied to all dialysis patients, not just patients receiving ESAs.

3. KCP has Concerns about the URR Measure—Both as an Indicator of Quality, as Well as the Manner in Which Data are Collected for DFC and How Performance is Calculated. KCP Recommends Specific Changes in this Regard.

KCP recognizes that CMS is proposing the URR measure because of its limited data source availability, but we have issues with URR as a valid measure of quality. Additionally, we note that claims reporting uses ranges of URRs and does not require the number of treatment sessions. KCP recommends that CMS require reporting the specific URR value and the number of treatments so that CMS can appropriately include only patients with values based on three treatments per week; including patients with more frequent treatments unfairly penalizes facilities who have higher numbers of these patients, especially (but not limited to) home hemodialysis patients. We note that KCP is not suggesting that an "adjusted URR" be calculated. Rather we merely propose that only the appropriate individuals' results be encompassed by the performance calculation. KCP also proposes that, as with anemia management, the basis be patient quarters and not a 12-month average.

Furthermore, CMS refers to using the URR measure from DFC for the QIP (which we understood in 2007 included patients on home hemodialysis [or other patients] with more than three treatments per week), but in a separate section of the Proposed Rule,[111] CMS states that the dialysis adequacy measure will apply only to in-center hemodialysis patients and not home hemodialysis or peritoneal dialysis patients. We note that the 2009 Dialysis Facility Compare Guide, issued in September 2009, excludes patients receiving five or more treatments per week. We seek clarification on this conflicting information and a clear presentation of the specifications that will be used, in particular as relates to the baseline year data that CMS will be using and the 2008 data that CMS only recently released on November 30, 2009.

The concern about unfairly penalizing facilities with higher numbers of patients who receive more than three treatments per week becomes even more acute as CMS moves from public reporting to pay for performance under the QIP. KCP's analyses of the 2007 DFC data indicate that facilities that do not offer home hemodialysis receive an average of 10.92 points on the URR measure compared to 9.85 for facilities that do offer home hemodialysis (using the national scoring rules and 12-point maximum score).

[111] 74 Fed. Reg. at 50013.

4. KCP Recommends that CMS Adopt Vascular Access as a Third Measurement Area for the Initial Year of the QIP for Hemodialysis Patients.

KCP members note that facilities report arterial venous fistula (AVF) and catheter data to the ESRD Networks on a monthly basis. Given these data are provided by facilities contemporaneously and the clear evidence about poor outcomes associated with catheter use, KCP recommends that the initial year of the QIP should include separate measures of AVF and catheter use. This recommendation is consistent with Section 1881(h)(2)(A)(iii),[112] which states that the measurement areas encompassed by the QIP shall include, to the extent feasible, other measures as the Secretary specifies, including measures on iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula).[113]

5. KCP Looks Forward to Working with CMS to Implement a More Robust QIP.

In addition to anemia management and dialysis adequacy, Section 1881(h)(2)(A)(iii) [114] states that the measures shall include, to the extent feasible, other measures as the Secretary specifies including measures on iron management, bone mineral metabolism, vascular access (including for maximizing the placement of arterial venous fistula), and patient satisfaction. Congress clearly envisioned a more comprehensive QIP, but as set forth in the Proposed Rule only two of six areas outlined in the Act are contemplated. Moreover, KCP concurs with CMS that dialysis adequacy is not addressed for peritoneal dialysis patients and that pediatric patients are not encompassed by the current measurement specifications. While the proposed QIP does not present a robust assessment of dialysis quality, KCP looks forward to working with CMS on implementing a more complete program. Additionally, KCP looks forward to working with CMS to develop valid measures in the area of bone mineral metabolism.

B. Performance Standards for the ESRD QIP Measures

The Proposed Rule sets forth CMS' interpretation of how the performance standards for the specific measures will be established. In particular CMS describes the "Special Rule," centered on facility-specific performance rates in the initial year of the QIP, in addition to a model with a national performance standard, which CMS proposes be the national average for all three measures. CMS states that it does not propose performance standard levels of achievement or improvement because it does not believe that Section 1881(h)(4)(E) requires their inclusion at this time. Finally, CMS indicates that it interprets the term "initially" to apply only to the performance period applicable for payment consequence year 2012.

[112] 42 USC 1395rr.
[113] 74 Fed. Reg. at 50012.
[114] 42 USC 1395rr.

1. KCP Generally Concurs with CMS' Presentation of the Special Rule, but Strongly Recommends that the Forthcoming Rule on the QIP Articulate how CMS Intends to Handle Improvement.

KCP is troubled by the apparent signal that CMS does not intend to address in the forthcoming rule how improvement will be specifically handled after the initial year of the QIP. Improvement is a core element of MIPPA. KCP strongly urges CMS to address how it intends to mitigate payment reduction for facilities that improve when it releases the forthcoming rule that further delineates the parameters of the QIP. CMS itself notes in this Proposed Rule that it "understand[s] the importance of giving providers and facilities time to prepare for the implementation of this new quality incentive program and to assess how the new program will affect them."[115] KCP notes that its concern is heightened given the CMS position that facilities will not be awarded the bonus points unless performance exceeds the national average, even if performance has improved.

2. KCP Strongly Encourages CMS to Articulate at Least a Two-Year Vision for the QIP in the Forthcoming Rule Devoted to the QIP, as Well as to Articulate the Approach CMS Intends to Use to Expand the Program.

Throughout this Proposed Rule, CMS makes reference to forthcoming rulemaking, which will provide additional details of the QIP. While KCP greatly appreciates the opportunity to comment on the conceptual model, we are troubled by the many inferences that the QIP will rapidly evolve and the lack of details provided on key components such as improvement, achievement, and expansion of the program. We are concerned that such details will be lacking in the next rule.

With concurrent implementation of the bundled payment system, new (and incomplete) QIP, and CROWNWeb, as well as the new Conditions for Coverage within the last year, many changes are in play and planning and stability is essential. We recommend in the strongest possible terms that the forthcoming rule related to the QIP delineate matters such as how improvement and achievement will be handled in the second year of the program and that this information, as well as information about additional measures and other changes to the program, be provided on an ongoing basis with similar two-year notice. We further recommend that CMS indicate in detail how it intends to add measures in the future – be that in the second year or beyond.

3. KCP Seeks Clarification on CMS' Intent Regarding the Adoption of the "Special Rule," Only in the Initial Year.

CMS indicates that the facility-specific performance rates shall apply only in the first year of the QIP. KCP's position, however, is that the Congress clearly contemplated that a more comprehensive QIP be initially adopted. Given the limited scope of the program being proposed by CMS for the first year, KCP requests that the Special Rule apply when CMS adopts any new performance measure for the QIP and that the forthcoming rulemaking address this matter. The addition of any new measures, in essence, constitutes a new program—even leaving aside the issue of how new measures and measurement areas may be weighted. Application of the Special Rule to

[115] 74 Fed. Reg. at 50011.

new measures going forward also will meet CMS' goal of allowing facilities adequate time to assess how the program will affect them.

Applying the Special Rule to new measures also addresses concerns about transparency and KCP's ability to independently review the data underlying CMS rulemaking on any new measures. CMS itself admits that it does not currently have the data systems in place to support newer measures such as the CPMs. Accordingly, KCP does not have access to such data to itself analyze the impact of any new measures. Committing to the Special Rule for new measures will, to an extent, mitigate transparency concerns.

4. KCP Concurs with Adopting a National Standard in the First Year of the QIP that is Equal to the Average Performance of all Dialysis Providers and Facilities. KCP Believes Strongly that CMS Must Use the Same Year for Both the Quality Baseline Data for the QIP and the Baseline Payment Data for the Bundle.

CMS states that it is considering adopting a standard for each of the three performance measures that is equal to the average performance of all dialysis providers and facilities based on 2008 data.[116] KCP concurs with using the average performance in the initial year of the QIP. Since CMS only made the 2008 data for review available on November 30, 2009, however, KCP cannot comment on the specific use of 2008 data. As a general principle, KCP believes that CMS should use data that reflects current clinical practice and quality. However, most importantly, KCP believes strongly that CMS must align the quality baseline data year for the QIP with the baseline payment year data for the bundle.

C. Performance Period for the ESRD QIP Measures

CMS states that it is considering all or portions of 2010 as the potential performance period, but that it is also contemplating other periods. [117]

1. KCP has No Specific Comment on the Potential Performance Period. We Again Note that, as a General Principle, the Performance Period Adopted Should be one that Reflects Current Clinical Practice and Quality.

D. Methodology for Calculating the Total Performance Score for the ESRD QIP Measures

CMS notes that Section 1881(h)(3)(A)(i) of the Act requires the Secretary to develop a methodology for assessing the total performance of each provider and facility based on the performance standards with respect to the measures selected for a performance period. It further states that Section 1881(h)(3)(A)(iii) states that the methodology must also include a process to weight the performance scores with respect to individual measures to reflect priorities for quality improvement. CMS proposes to use 10 points for each of the three measures identified in the Proposed Rule and to use a scoring methodology that subtracts two points for each two percentage

[116] 74 Fed. Reg. at 50012.
[117] Id.

point increment range that the provider or facility's performance falls from the set performance standard (be under the facility-specific or national approach).

1. KCP Objects to CMS' Proposal to Assign 10 Points per Measure, Thereby Weighting the Total Performance Score as 2/3 Anemia Management and 1/3 Dialysis Adequacy. KCP Recommends that each Measurement/Quality *Area* be Assigned Equal Weight, but Only if the Quality and Payment Data Baseline Years are Aligned.

KCP believes that the areas of anemia management and dialysis adequacy are both important quality areas and that one should not be weighted more heavily in the total performance score merely because there are two measures for the former area and one measure for the latter. Accordingly, KCP recommends 15 points be assigned to each area if the 30-point system is retained.

2. KCP Objects to CMS' Proposal to Assign Equal Weight to the Two Hemoglobin Measures Proposed for Anemia Management. KCP Recommends the Measure of Hemoglobin <10 g/dL be Assigned Significantly Greater Weight, but Only if the Quality and Payment Data Baseline Years are Aligned.

Within the area of anemia management, CMS proposes to assign equal weight to each measure. Earlier in this letter, KCP expressed its opposition to the use of the hemoglobin >12 g/dL measure and instead has recommended a measure of hemoglobin 10-12 g/dL. Regardless of the use of either measure, KCP objects to the proposal to assign the same number of points to either the hemoglobin >12 g/dL or the 10-12 g/dL measure as is assigned to the measure of hemoglobin <10 g/dL. Hemoglobin <10 g/dL is a valid, evidence-based indicator: Numerous observational research studies have documented associations between low hemoglobin levels and poor outcomes, such as hospitalizations, mortality, and higher likelihood of transfusions. If the quality and payment baseline years are aligned, KCP recommends that CMS give significantly greater weight (i.e., points) to the measure of hemoglobin <10 g/dL given well-documented adverse consequences of low hemoglobin. KCP strongly disagrees with the CMS suggestion that because there is less opportunity to improve based on the 2007 data, less weight should be given to this measure. The hemoglobin <10 g/dL measure, in contrast to the URR or other hemoglobin measure, represents a true quality indicator.

3. KCP Recommends that CMS Adopt a One-Point per One Percentage Increment Approach in Assigning Points for the Three Performance Measures.

CMS proposes that for each two percent that a facility falls from the benchmark/performance standard, the facility score would be deducted two points. Given the limited scope of the proposed QIP, KCP recommends using a one-point increment to provide a finer distribution for the initial QIP. This finer distinction should be coupled with a one-point based payment distribution, as we detail elsewhere in this letter.

4. KCP Requests that CMS Clarify in the Forthcoming Rule How it Intends to Address the Issue of "Small Numbers." KCP also Requests that CMS Provide Details on the "Rounding Rules" it will Use.

KCP appreciates the opportunity to comment on CMS' conceptual model, but several details not presented are important to the community. We request that the forthcoming rule on the QIP articulate precisely how CMS intends to address the issue of cell size/small numbers in calculating performance scores for individual measures, as well as for the total performance score if an individual measure score is suppressed because of the small numbers issue. As CMS is aware, this issue has been important to public reporting on DFC; with performance now tied to payment, it becomes even more so. Additionally, the forthcoming rule should detail the rounding rules that CMS will use in calculating performance rates for specific measures.

E. Application of Payment Reductions Using the Total Performance Score

CMS proposes to implement a sliding scale of payment reductions up to the full two percent. Under the 30-point system, the payments in 2012 will be reduced as follows:

28-30 points	0% reduction
24-26 points	0.25% reduction
20-22 points	0.5% reduction
16-18 points	0.75% reduction
12-14 points	1.0% reduction
8-10 points	1.25% reduction
4-6 points	1.50% reduction
2 points	1.75% reduction
0 points	2.0% reduction

CMS also is considering proposing that for any measure for which a provider or facility receives four points or less, the provider or facility would receive a 0.25 percent reduction even if its total performance score is 28 points.

1. KCP Strongly Objects to the CMS Proposal to Implement the Full Two Percent Reduction. KCP Recommends that the Maximum Payment Reduction be Significantly Less than Two Percent, Commensurate with the Scope of the QIP being Proposed.

The QIP proposed by CMS encompasses three measures (one of which KCP objects to) in two quality areas: anemia management and dialysis adequacy. Congress clearly envisioned something more comprehensive when it authorized a quality incentive program that provided for up to a two percent reduction. Section 1881(h)(2)(A)(iii)[118] states that the measures shall include, to the extent feasible, other measures as the Secretary specifies including measures on iron management, bone mineral metabolism, vascular access (including for maximizing the placement of arterial venous fistula), and patient satisfaction. The Proposed Rule addresses only two of six areas noted in MIPPA.

[118] 42 USC 1395rr.

We acknowledge that CMS lacks the data systems that would provide additional measures to address some of the other quality areas that the CPMs clearly include. However, if CMS had deployed CROWNWeb as scheduled – an event within the Agency's control – the data system would have been in place to implement the CPMs as part of a far more robust QIP under which the two percent reduction might be more appropriate.

Given the limited scope of the QIP proposed, however, KCP strongly objects to the CMS proposal to apply the full two percent payment reduction. To penalize providers and facilities the full two percent under a QIP that does not accurately reflect a comprehensive assessment of quality, and that further stems from the Agency's delay in deploying CROWNWeb, is inappropriate. KCP recommends that CMS reduce the maximum payment reduction of two percent to a level commensurate with the scope of the QIP being proposed.

2. KCP Recommends that CMS Adopt a Payment Reduction System Based on, at Most, a One-Point Sliding Scale Distribution.

CMS proposes to implement a sliding scale of payment reductions based on a two-point sliding scale distribution. Again, given the limited scope of the proposed QIP, KCP's position is that using, at most, a one-point increment will provide a more equitable distribution at this time. We further emphasize that this distribution should be coupled with a maximum payment reduction that is less than the proposed two percent.

3. KCP Supports the Principle Underlying the CMS Proposal of a Reduction for Facilities that May Perform well Overall, yet Still Perform very Poorly on one of the Measures.

Although we have noted elsewhere that we recommend increments of 0.125 percent payment reductions and that we oppose implementation of the full two percent payment reduction, KCP supports the principle underlying the CMS proposal of a 0.25 percent reduction (under the proposed system using the full two percent reduction) if a provider or facility receives four points or less on any individual measure, even if its total performance score is 28 of 30 points. That is, KCP agrees that very poor performance on a single measure, even while performing well on others, should result in some level of payment reduction. We propose that it be proportionate to the final increment used, noting that KCP recommends payment reduction increments of 0.125 percent, not 0.25 percent.

F. Public Reporting of Measures

CMS invites comment on how to implement the statutory requirements for public reporting of dialysis facility performance.

1. KCP Notes that the New System Must Reflect Accurate, Current Quality and in this Regard Must Significantly Improve upon DFC, which We Consider to be Woefully Inadequate. DFC is Updated Only Annually and, Although 2009 was Drawing to a Close, 2007 Data were Reported. Dated Data are Misleading and Unfair to Patients, Providers, and Facilities.

G. Impact of the Bundle on Quality

Although not specifically stated within Section XV of the Proposed Rule, CMS has noted elsewhere that the QIP is intended to help ensure the quality of services implemented under the new bundled payment system – specifically to "minimize risks of unintended consequences related to a bundled payment system."[119] KCP concurs strongly with this view.

1. KCP Members are Concerned about Unintended Consequences that the Bundled Payment System May Have on the Quality of Care. As Such, We Believe it is Incumbent on CMS to Begin Collecting Data Immediately to Establish Benchmarks so that Such Consequences Can be Monitored.

Implementation of the bundled payment system has the potential to result in unintended consequences that adversely affect the quality of care for dialysis patients. Such an impact will not be readily apparent unless CMS begins data collection now; however, the Proposed Rule is silent as to how CMS intends to measure and assess the aspects of care that may be affected.

KCP believes that, at minimum, CMS should begin collecting data to track trends in the following areas:

Outcomes related to bone and mineral metabolism disease. CMS should begin to track trends in the following areas: parathyroidectomies, cardiovascular calcification, treatment for fractures, hospitalization for cardiovascular disease, hospitalizations for hypophosphatemia, hypocalcemia and hypercalcemia, and bone pain;

Outcomes related to anemia care such as transfusions across all care settings, panel reactive antibody levels, and changes in transplantation rates for graft success;

Vascular access, particularly AVF and catheter use;

Mortality, generally;

Hospitalizations, generally; and

Disproportionate impact on minority populations, especially with regard to anemia and bone and mineral metabolism disease. As discussed elsewhere in this comment letter, it is documented that African American patients require more ESAs to achieve the same hemoglobin outcomes as white patients, as well as have higher parathyroid hormone levels and use more vitamin D analogs and calcimimetics than Caucasians. Thus, the incentives

[119] CMS, Open Door Forum End Stage Renal Disease Prospective Payment System (ESRD PPS) Proposed Rule, http://www.cms.hhs.gov/ESRDPayment (last visited November 16, 2009).

under a bundled payment system could have a disproportionate impact on African Americans, as well as other minority populations.

Sincerely,

Kent Thiry
Chairman
Kidney Care Partners

Affymax
AMAG Pharmaceuticals
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Diagnostic and Interventional Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Genzyme
Kidney Care Council
National Association of Nephrology Technicians and Technologists
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Renal Advantage Inc.
Renal Physicians Association
Renal Support Network
Renal Ventures Management, LLC
Satellite Healthcare
U.S. Renal Care
Watson Pharma, Inc.

XII. Technical Appendix

All analyses referenced in this technical appendix were performed by The Moran Company (TMC) under contract to KCP.

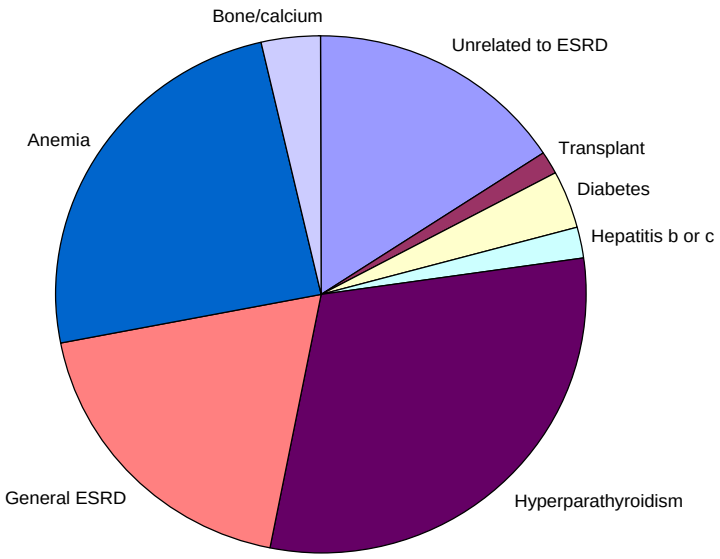
A. Diagnostic Laboratory Tests

We were unable to simulate the CMS process of identifying lab tests performed for ESRD patients based on an order by the MCP physician, because the physician identifier in the Standard Analytic Files (SAFs) is encrypted, and because we do not have access to lists of MCP providers that are linked in time to the claims files. To demonstrate that lab tests ordered for ESRD patients go well beyond tests closely related to ESRD, we performed an analysis of all dialysis patients with treatments in the 5 percent sample SAF files for 2005-2006, and profiled these tests based on the ICD-9 codes on the line with the code for the lab test. The ICD-9 code were grouped into larger diagnostic categories and the results showed that about 15 percent of lab tests performed for dialysis patients in a year have nothing to do with the management of ESRD[120]. See Exhibit 1.

[120] These tests included those ordered through dialysis facilities, hospitals, and from any physicians, not just MCPs.

Exhibit 1. Diagnostic Profile of Lab Tests for ESRD Patients

Laboratory Tests for ESRD Patients Receiving Dialysis for 4 Consecutive Calendar Quarters 2005-2006 By Diagnostic Category Based on Payments



The Moran Company Analysis of 2005 & 2006 Medicare 5% Beneficiary Sample Standard Analytic Files

Accuracy in Valuing the Lab Portion of the Bundle cannot be Validated using MCP Method

To estimate the correct value for lab tests associated with ESRD, we performed a number of different analyses using the 2005 through 2007 five percent beneficiary sample SAFs. We identified all patients with dialysis treatments using the outpatient hospital SAF 72x bill type claims. We then identified all paid lab tests based on several different selection methods including:

- All lab tests (HCPCS codes in 8xxxxx series, G-codes, and panel test codes) in a year.
- A narrow selection of lab tests closely associated with ESRD chosen by the KCC Lab Work Group before the release of the Proposed Rule.
- A broader selection of lab tests developed by the KCC Lab Work Group after the release of the rule, and included with this comment letter.

We calculated the total payments for each group of lab tests and divided the payments by the number of treatments for the patient, to arrive at an average payment per treatment. Lab fee schedule rates did not change during this period of time so we did not apply an inflation factor. We then took the total paid claims in the 2007 final ESRD rate setting file, and extracted payments for all lab tests for all facilities and divided that amount by the total number of dialysis (and hemo-equivalent) treatments to arrive at an average payment per treatment. We added the average payments per treatment together for each file to calculate a total average payment per treatment. The tests and payments in the two files are mutually exclusive.

The estimated values for different defined lab test bundles are shown in Exhibit 2. All of our estimates are significantly higher than CMS' estimate based upon its MCP methodology. CMS' use of the MCP identifier on claims requires that all MCPs be identified that might link to any claims for patients in that year. For the Proposed Rule, CMS used a 2006 list of MCPs with 2007 claims. CMS does not explain the origin of the list, so it is not clear whether an updated list would be all inclusive for the year or a point in time list. Any list that is not all-inclusive and perfectly corresponds to the full year of claims analyzed will understate the value of the lab tests to be included in the bundle. A prescribed list of lab tests provides an administratively simple and verifiable mechanism to accurately value the lab bundle.

B. ESA Monitoring Policy and the "Epo" Cap

We performed a simulation of the 2008 ESA monitoring policy cap on Epogen® and Aranesp® payments for 2007 drug payments. We found that the cap reduced payments by $15.5 million, or slightly less than 1 percent of Epogen® and Aranesp® payments. CMS references capping Epogen® payments at 30,000 units per treatment. This is a lower cap than the 2008 cap of 400,000 units per month on Epogen® and does not apply any cap to Aranesp®. The 30,000 unit Epogen® cap results in a reduction in payments of approximately $27 million, about 1.4 percent of payments for Epogen® in the SAF data. An additional $4.5 million in Epogen® payments were made for claims without any treatments. We do not know if CMS included or excluded the latter payments for Epogen® without treatments on the claim, since without treatments, CMS could not apply the cap. In 2007, providers were not required to record ESAs by line item date of service, so many 2007 claims include a rolled up volume of Epogen® for the month. In such cases, we assume that CMS would divide the total amount by the number of treatments and exclude payments for amounts over 30,000 units on average per treatment. This methodology results in trimming payments for Epogen® that are consistent with current ESA monitoring policy. Such trims will impact outlier payments.

CMS does not indicate whether either this trim or current ESA monitoring policies were incorporated into the regression analysis. Applying the ESA monitoring policy cap would dampen some of the variation in separately billed payments and could affect the adjustor values.

Exhibit 2. Estimates of Value of Lab Test Portion of the Bundle in 2007 Dollars

	Average Per Treatment Payment Based on 2006-2007 5% Carrier SAF--All Patients with Dialysis Treatment Claims	Average Per Treatment Payment Based on 2007 Final 100% ESRD Rate Setting File	Total Estimated Average Per Treatment Payment 2007
CMS Estimate of 2007 Value of Lab Tests Based on MCP Method of Identification (2006 MCP List applied to 2007 Claims)			8.74
TMC Estimate of 2007 Value of All Lab Tests Based on Analysis of 5% SAF Carrier File Lab Claims for ESRD Patients + Lab Tests in Dialysis Claims	15.83	0.63	16.46
TMC Estimate of 2007 Value of KCC Recommended List of Lab Tests Used to Manage ESRD Based on Analysis of 5% SAF Carrier File Lab Claims for ESRD Patients + Lab Tests in Dialysis Claims	10.69	0.63	11.32

C. Base Rate Calculations

To the extent that CMS' adjustments to the base rate result in undervaluation of what would otherwise have been spent in 2011 without implementation of the bundled payment system beyond the two percent statutory cut, these adjustments cause "leakage." Sources of likely leakage are discussed in this section.

Undervaluation and possible bias in CMS' calculation based on 2007 claims

Using the 2007 outpatient hospital 100 percent SAF, we identified all patients with 72x bill type claims for dialysis services. We also examined the 2007 final ESRD rate setting file. We used these two sets of data to attempt to replicate CMS' payments and treatments reported in Table 8 in the Proposed Rule. We attempted to replicate the trimming procedures described by CMS in the Proposed Rule. Throughout this process we found numerous discrepancies that lead to two types of questions:

1) Did CMS evaluate whether its various trimming and exclusion procedures introduced bias into the calculation of the 2007 MAP?
2) Did CMS' methods result in undervaluation of the 2007 MAP and the resulting base rate for 2011?

We found the following problems in attempting to benchmark 2007 data from our Medicare data files to CMS' description of its calculations resulting in Table 8 in the Proposed Rule:

Based on CMS' Table 2 before it had excluded and trimmed facilities for various reasons, we found 7 more facilities with paid claims in 2007 than CMS. The Proposed Rule shows 4921 facilities in the impact analysis. Based on CMS' report of 4955 facilities with paid claims, it appears CMS excluded 34 facilities and their claims from the estimation of Medicare Allowable

Payments (MAP) shown in Table 8 of the Proposed Rule. The only explanation for exclusion of facilities is that some did not have a valid county code to map to a CBSA designation that matched to the wage index.

When we attempted to replicate CMS' exclusion of facilities lacking CBSA designations, we identified 448 facilities that could have been excluded based on the explanation in the rule. These facilities accounted for 150,000 claims. It does not appear from the tables in the rule, however, that CMS would have excluded all of these facilities or the payments for these facilities in its calculations. Nowhere in the rule does CMS say exactly how many facilities and payments were excluded from its calculations.

CMS reports raw 2007 claims data only trimmed for more than 20 treatments per claim as including 36,667,669 treatments. In Table 8 CMS shows it has trimmed out 143,878 treatments. No additional explanation is provided for exclusion of these treatments unless their payments were included in the facilities that were excluded or they were for patients without valid dates of birth. Our 2007 SAF claims show 37,183,371 treatments untrimmed, indicating paid treatments in our data of 529,708 more treatments than shown in CMS' Table 8. Our rate setting files that include some of CMS' trims show 469,877 more treatments paid in 2007 than Table 8. We see between 1.3 and 1.45 percent more paid treatments than are included in the MAP calculations. We cannot determine whether or not the payments associated with these treatments have also been excluded from the MAP calculations. Our data is understated for lack of payments and treatment information for Method II home patients included in CMS' Table 8 treatment volume.

While CMS reported trimming out more than 20 treatments per month, we see that home hemodialysis patients are often paid based upon 4, 5, or 6 treatments per week, which leads to payments in excess of 20 treatments per month. The assumption underlying this trimming decision is not based on current practice.

Our comparison data are shown on Exhibit 3.

1. Inflation of IV Drug Payments to 2011

CMS provides an inflation rationale to bring all 2007 payments to estimated 2011 levels, with the exception of IV drug payments. CMS freezes these payments at 2009 levels using the most recent available ASP+6 percent as its valuation method. Elsewhere, CMS proposes using the PPI to inflate its 2007 estimate of oral drugs, and the PPI is used as the standard index for inflating drug values in the ESRD and other Market Basket projections. Based on the CMS Office of the Actuary projected PPI for 2010 and 2011, the drug payments would increase by 10.87 percent. The use of the PPI would be consistent with other procedures to estimate future drug costs, and makes a material difference in the valuation of drugs in the unadjusted base rate. See Exhibit 4.

2. Standardization Adjustment

The accuracy of the standardization adjustment depends upon: 1) an accurate estimation of the frequency/prevalence of the various patient level adjustors in the dialysis population; 2) an accurate designation of low-volume facility adjustors; 3) an accurate assignment of wage index adjustors to facilities; and 4) the assumption that the assignment of adjustors to 2007 claims will be consistent with 2011 patient and facility characteristics. For reasons described in the body of the comment letter and in subsequent sections of this technical appendix, we find that:

The assignment of patient level adjustors to 2007 claims will be materially different than facility assignment of patient adjustors in 2011, and that CMS' estimates will overstate the value of the standardization adjustment, because facilities will never have the information to claim most of the co-morbidity adjustors included in CMS' calculations.

The assignment of the low-volume facility adjustors will result in identification of a different group of low-volume facilities in 2011.

Significant differences in the prevalence of patient level adjustors and different facilities and facility adjustors will result in a different and, most likely lower, value for the standardization adjustor. If the value represented by the actual 2011 claims is substantially lower than that projected based on 2007 claims (or other base year), the standardization adjustment will have reduced the base rate below what would have been spent in 2011 without the implementation of the bundled payment system.

Exhibit 3. Benchmarking CMS' Table 8 to 2007 Rate Setting (RS) and SAF data (TMC is The Moran Company)

Categories from Table 8, ESRD Proposed Rule	ESRD Proposed Rule CMS Values (Actual MAP for 2007, as reported on claims[1])	TMC Estimated Totals		Pct. TMC Values Differ from CMS' Tabular Values	
		RS File	SAF Files	RS to CMS	SAF to CMS
Total Medicare Allowable Payments by service category					
Outpatient dialysis and other composite rate services^	$ 5,705,412,338	$ 5,767,776,383	$ 5,772,809,692	1.09%	1.18%
Dialysis support services^	$ 1,447,484	$ 1,542,056	$ 1,550,215		7.10%
Part B drugs and biologicals^					
Epogen*	$ 1,846,771,009	$ 1,891,713,626	$ 1,908,962,299	2.43%	3.37%
Darbepoetin	$ 167,776,951	$ 169,813,975	$ 172,266,296	1.21%	2.68%
Vitamin D	$ 402,447,416	$ 405,728,710	$ 405,955,589	0.82%	0.87%
Calcitriol	$ 3,116,590	$ 3,149,614	$ 3,153,958	1.06%	1.20%
Doxercalciferol	$ 76,770,839	$ 77,486,146	$ 77,543,640	0.93%	1.01%
Paricalcitol	$ 322,559,988	$ 325,092,950	$ 325,257,991	0.79%	0.84%
Iron	$ 234,031,283	$ 236,072,203	$ 236,253,200	0.87%	0.95%
Iron Sucrose	$ 165,992,904	$ 167,449,778	$ 167,556,598	0.88%	0.94%
NA Ferric Gluconate	$ 68,038,379	$ 68,622,426	$ 68,696,601	0.86%	0.97%
Levocarnitine	$ 5,025,914	$ 5,085,431	$ 5,090,636	1.18%	1.29%
Alteplase	$ 26,682,197	$ 26,920,315	$ 26,952,598	0.89%	1.01%
Vancomycin	$ 3,578,996	$ 3,622,136	$ 3,625,625	1.21%	1.30%
Daptomycin	$ 1,234,405	$ 1,240,174	$ 1,240,308	0.47%	0.48%
Other injectables	$ 7,467,546	$ 7,774,429	$ 7,796,025	4.11%	4.40%
Laboratory tests billed by dialysis facilities or ordered by physicians receiving monthly capitation payments for treating ESRD patients**	$319,165,724				
DME Supplies and Equipment					
DME supplies	$15,039,695	N/A	N/A	N/A	N/A
DME equipment	$3,358,535	N/A	N/A	N/A	N/A
Supplies and other services billed by dialysis facilities^, [1TMC]	$44,864,130	$ 48,749,724	N/A	8.66%	N/A
Part D drugs	$455,683,740	N/A	N/A	N/A	N/A
Total Medicare Allowable Payments for Composite Rate (CR) and Separately Billable (SB) Services	$9,239,987,362	N/A	N/A	N/A	N/A
Total Medicare Hemodialysis-equivalent sessions***	36,523,791	36,993,768	37,053,500	1.29%	1.45%
Average Medicare Allowable Payment per Session for CR and SB services	$252.99	N/A	N/A	N/A	N/A

FOOTNOTES FROM TMC:

[1TMC:] The value for 'Supplies and other services" was calculated with the following groupings and dollar estimates: 1) Supply $40,252,009; 2) Blood Product $1,971,841; 3) Dialysis training $5,705,400; 4) Other procedures paid $820,473

FOOTNOTES FROM ESRD PROPOSED RULE:

[1]Based on payment amounts reported on Medicare claims for 2007. Excludes facilities without a valid county code for determining the CBSA wage index and patients with an unknown birthdate.

^Billed by dialysis facilities.

*Monthly payments for EPO were capped to reflect no more than 30,000 units per session.

**Includes lab tests billed by dialysis facilities on outpatient institutional claims and lab tests ordered by physicians receiving monthly capitation payment (MCP) amounts and billed on carrier claims. Labs ordered by physicians receiving MCP amounts were determined using a list of MCP physicians from 2006. The estimates for total lab payments will be updated when the list of MCP physicians for 2007 is available.

**Hemodialysis-equivalent sessions were capped at 20 per patient per month and include both sessions reported based on the average number of sessions per month reported for Method I peritoneal dialysis patients (12.5 in 2007) and an estimate for Method II patients.

Exhibit 4. Use of the PPI to Inflate IV Drugs to 2011 Values Compared

Drugs and biologicals Price Updates	2007 MAPs as published in proposed rule	Update Factor from 2007 to 2009 as proposed by CMS	Update Factor from 2009 to 2011 using PPI	Potential 2007-2011 Update Factor	2011 Projected MAPs as used by CMS in proposed rule	2011 Revised Projected MAPs using PPI	Difference Made by Fixing the Drug Update after 2009 using PPI to 2011	Difference on a per treatment basis
Total	***$ 2,695,015,718***				***$ 2,723,989,897***	***$ 3,020,087,599***	***$ 296,097,702***	***$ 8.11***
EPO	$ 1,846,771,009	1.7%	10.87%	12.75%	$ 1,878,166,116	$ 2,082,322,773	$ 204,156,657	$ 5.59
Paricalcitol	$ 322,559,988	-2.8%	10.87%	7.77%	$ 313,528,308	$ 347,608,835	$ 34,080,527	$ 0.93
Sodium_ferric_glut	$ 68,038,379	-0.5%	10.87%	10.32%	$ 67,698,187	$ 75,056,980	$ 7,358,793	$ 0.20
Iron_sucrose	$ 165,992,904	4.8%	10.87%	16.19%	$ 173,960,563	$ 192,870,077	$ 18,909,513	$ 0.52
Levocarnitine	$ 5,025,914	-19.0%	10.87%	-10.20%	$ 4,070,990	$ 4,513,507	$ 442,517	$ 0.01
Doxercalciferol	$ 76,770,839	17.8%	10.87%	30.60%	$ 90,436,048	$ 100,266,447	$ 9,830,398	$ 0.27
Calcitriol	$ 3,116,590	-14.1%	10.87%	-4.76%	$ 2,677,151	$ 2,968,157	$ 291,006	$ 0.01
Vancomycin	$ 3,578,996	-11.1%	10.87%	-1.44%	$ 3,181,727	$ 3,527,581	$ 345,854	$ 0.01
Alteplase	$ 26,682,197	2.3%	10.87%	13.42%	$ 27,295,888	$ 30,262,951	$ 2,967,063	$ 0.08
Aranesp	$ 167,776,951	-8.2%	10.87%	1.78%	$ 154,019,241	$ 170,761,133	$ 16,741,891	$ 0.46
Daptomycin	$ 1,234,405	13.9%	10.87%	26.28%	$ 1,405,987	$ 1,558,818	$ 152,831	$ 0.00
Other injectables	$ 7,467,546	1.1%	10.87%	12.09%	$ 7,549,689	$ 8,370,340	$ 820,651	$ 0.02

D. Transition Payment Adjustment—Accuracy of Calculation

Using CMS' impact analysis for each facility included as released with the Proposed Rule, we examined several alternative hypotheses about how facilities would actually decide whether or not to opt out of the transition. Exhibit 5 illustrates how alternative decision rules would affect the value of the transition adjustor. Key hypotheses include:

1) Decisions will be made by chains for their facilities, not by individual facilities commonly owned without regard for the financial performance of the chain; and
2) Different threshold levels of profit or loss would make it worthwhile for a facility or chain to deal with the operational issues associated with the transition.

The decision rule that determines facilities opting out of the transition when a threshold hypothesis is in force is that the facility or chain would need to exceed the threshold to opt out of the transition and into the 100 percent PPS.

Another hypothesis is that chains and independent facilities will choose the transition if faced with significant uncertainty about payments through the entire transition. Under the situation posed by the Proposed Rule, with no information provided about future payments after 2011, chain and facility decisions would likely approximate scenario #4, a situation which yields half the size transition adjustor compared to what CMS proposes.

Exhibit 5 Alternative Scenarios, Associated Transition Adjustor Values, and Potential "Leakage"

Scenario #	Scenario Description	Transition Adjustor Using CMS' Calculations	CMS Assumes Scenario 1 BUT Scenario X OCCURS then . . leakage =	Per Tx Leakage, Assuming CMS' Total Tx = 36,523,791
1	CMS' FACILITY-level Revenue Maximizing decision	3.00%	N/A	N/A
2	CHAIN-LEVEL Revenue Maximizing Decision, Assuming if you are not a chain, then you stick with CMS' Decision	2.52%	$ 48,447,672	$ 1.33
3	Everyone Opts 100% INTO the PPS, OUT of the transition	0.00%	$ 283,264,130	$ 7.76
4	Everyone Opts 100% Out of the PPS and INTO the transition	1.50%	$ 144,573,104	$ 3.96
5	At the FACILITY-Level, Requiring decision to OPT IN VS OUT to be an absolute difference of Greater than 10%	1.98%	$ 99,751,789	$ 2.73
6	At the FACILITY-Level, Requiring decision to OPT IN VS OUT to be an absolute difference of Greater than 5%	2.54%	$ 46,934,447	$ 1.29
7	At the CHAIN-Level, Requiring decision to OPT IN VS OUT to be an absolute difference of Greater than 10% Assuming if you are not a chain, then you decide same as scenario 5	1.90%	$ 107,487,662	$ 2.94
8	At the CHAIN-Level, Requiring decision to OPT IN VS OUT to be an absolute difference of Greater than 5% Assuming if you are not a chain, then you decide same as scenario 6	2.27%	$ 72,800,790	$ 1.99

E. Case-Mix Adjustor—Race

In our analyses of the differences in historical payments based on the race of patients, we find that race, in particular African American race (black is the variable in the EDB data), is strongly associated with variation in payment. See Exhibit 9. We cannot replicate the regression analysis performed by UM-KECC, but we find that both outliers and higher payments during the first 120 days of dialysis are associated with hospitalization and/or African American (black) race. We use the race variable in the Medicare Standard Analytic File Denominator File (equivalent to the EDB data referred to in the rule) that shows what the patient reported for race when applying for Medicare.

The main point in understanding the impact of higher costs associated with a particular racial group, is that they are not distributed evenly or randomly across the population: they are, rather, often concentrated in population centers whose demographics are dominated by one group. As a result, many facilities serve communities of color. Where higher costs are associated with a racial group, such as costs for ESAs associated with hypo-responsive patients, and were historically paid separately, the bundling of those costs with payment at a population mean will have a very

significant negative impact on facilities whose patients are mostly in the high cost racial group. Lack of a race adjustor of some sort will disadvantage a significant number of facilities, potentially negatively affecting access to care in a significant number of communities.

Our examination of dialysis facilities in the 2007 claims demonstrates the problem:

In 2007, 687 facilities had >75 percent of their treatments for African American patients. Given the consistently documented higher costs of historically separately billed drugs for African American patients as documented at comparable levels by both CMS' and Moran Company analyses, these facilities would appear to be at significantly higher financial risk under the new payment system.[121]

Ten (10) States have more than 50 percent of their African American patient treatments in facilities that have >80 percent Medicare treatments. Facilities with >80 percent Medicare treatments have limited private pay revenues to offset losses when Medicare payments do not cover the costs of care for a patient population that has generally higher costs. We refer to facilities with >80% Medicare treatments as Medicare dependent in this discussion. More than 95 percent of the African American patient treatments in the District of Columbia are in these facilities.

Our analysis of increased payments by racial group demonstrates significantly higher payments (mostly for drugs) for African American patients (Exhibit 6). White patients have somewhat higher costs compared to Native American, Hispanic and Asian patients.

Incorporating a race/ethnicity adjustor will provide some relief for facilities that serve predominantly African American communities, particularly in rural areas, thereby avoiding potential loss of services in these areas. Such an adjustor also serves to reinforce facilities in more multi-ethnic communities in providing services regardless of race-associated hypo-responsiveness to ESAs.

We start our analysis of the situation by examining the distribution of patients by race/ethnicity across facilities. Exhibit 7 shows the counts and percentages of facilities that are majority (>50 percent) one racial group, and those that are >75 percent and >90 percent one racial group. More than half of all facilities have >50 percent treatments for white patients, 30.5 percent of facilities have >50 percent treatments for black patients, and 1 percent have >50 percent treatments for Native American patients. Since the highest race/ethnicity adjustor from both CMS' and our estimates is for" black" patients, we will focus our discussion on the expected impact of an adjustor on facilities serving black communities in the US. Nearly 14 percent of facilities had >75 percent of treatments for black patients, and 5.1 percent had >90 percent. Concentrations of race/ethnicity treatments in facilities are not likely to vary much from year to year due to their basis in the demographics of the communities in which facilities are located.

[121] All percent of treatments refer to Medicare treatments. We have no information on the race/ethnicity of non-Medicare patients. Later when we discuss payer mix, we use cost report data to characterize the proportion of the facility's treatments that are for Medicare patients.

Exhibit 6. Comparison of Payments by Race Based on 2007 SAF Dialysis Claims

Race	Total Treatment Units	Total Composite Rate Payments	Total ESA Payments	Total Other Drug Payments	Composite Rate Payments Per Treatment	ESA Payments Per Treatment	Other Drug Payments Per Treatment
Unknown	129,225	$ 21,470,044	$ 6,502,640	$ 2,145,162	$ 166.14	$ 50.32	$ 16.60
White	18,385,209	$ 2,839,790,372	$ 982,413,885	$ 290,715,848	$ 154.46	$ 53.44	$ 15.81
Black	13,915,477	$ 2,193,242,446	$ 856,164,252	$ 318,622,290	$ 157.61	$ 61.53	$ 22.90
Other	897,200	$ 140,579,651	$ 43,028,964	$ 13,857,976	$ 156.69	$ 47.96	$ 15.45
Asian	1,099,664	$ 174,467,839	$ 49,847,064	$ 14,997,953	$ 158.66	$ 45.33	$ 13.64
Hispanic	2,156,786	$ 333,584,141	$ 100,892,677	$ 34,974,163	$ 154.67	$ 46.78	$ 16.22
Native American	545,930	$ 81,620,119	$ 24,751,723	$ 7,976,838	$ 149.51	$ 45.34	$ 14.61
TOTAL	37,129,490	$ 5,784,754,613	$ 2,063,601,204	$ 683,290,232	$ 155.80	$ 55.58	$ 18.40

NOTE1: These values are created using the simulated ESA cap logic for all available ESRD patients in 2007 SAF data. No other data trimming is performed thus these data are more inclusive than the data presented in the ESRD 2011 Proposed Rule.
NOTE2: Race is defined using the same categories as the Denominator file race categories.

Exhibit 7. Overview of facilities based on proportion of treatments for patients by race/ethnicity

Distribution of ESRD Facilities (Number and Percent) Serving Patient Populations that Exceed 50%, 75%, or 90% Per Racial Category

	Number of Facilities			Percent of Facilities		
Race Category	Over 50%	Over 75%	Over 90%	Over 50%	Over 75%	Over 90%
Unknown	5	3	2	0.1%	0.1%	0.0%
White	2,689	1,429	671	54.3%	28.9%	13.6%
Black	1,508	687	252	30.5%	13.9%	5.1%
Hispanic	12	-	-	0.2%	0.0%	0.0%
Asian	25	2	-	0.5%	0.0%	0.0%
Native American	50	32	26	1.0%	0.6%	0.5%
Other	4	-	-	0.1%	0.0%	0.0%
Total Number of Facilities	4,948	4,948	4,948	100.0%	100.0%	100.0%

Majority racial group facilities are shown by State in Exhibit 8. The rural and urban status of facilities treating majority racial groups is shown in Exhibit 9. We also looked at the payer mix for facilities in 2007 based on the race of patients. Exhibit 10 shows by State, the proportion of treatments by patient racial group in facilities that have more than 80 percent Medicare treatments. We cannot see Medicaid status in our claims files, but these facilities may also be at risk for greater bad debt associated with difficulty in collecting copayments for economically disadvantaged patients and are likely to have higher Medicaid caseloads, which may also result in increased bad debt under the proposed payment system.

A distribution of facilities with treatments of greater than 75 percent for a single racial group is shown in Exhibit 11. The ownership type for facilities with greater than 75 percent treatments for

black and Native American racial groups is shown in Exhibit 12. Finally, a detailed distribution of facilities by race and payer mix is shown in Exhibit 13 for facilities with majority, 75 percent, and 90 percent treatments for a single racial group.

Exhibit 8. Distribution of Majority Race Facilities by State

State-By-State Distribution of Facilities Serving Patient Populations Greater than 50% Per Race Category														
	Count of Facilities Serving Patient Populations Greater than 50% Per Racial Category							Percent of Facilities Serving Patient Populations Greater than 50% Per Racial Category						
State	Unknown	White	Black	Hispanic	Asian	Native American	Other	Unknown	White	Black	Hispanic	Asian	Native American	Other
Unknown	-	246	104	5	11	2	1		9%	7%	42%	44%	4%	25%
AK	-	3	-	-	-	-	-		0%					
AL	-	31	71	-	-	-	-		1%	5%				
AR	-	25	31	-	-	-	-		1%	2%				
AZ	-	60	-	1	-	16	-		2%		8%		32%	
CA	-	160	25	4	7	-	-		6%	2%	33%	28%		
CO	-	32	2	-	1	1	-		1%	0%		4%	2%	
CT	-	22	3	-	-	-	-		1%	0%				
DC	-	-	18	-	-	-	-			1%				
DE	-	7	7	-	-	-	1		0%	0%				25%
FL	1	146	68	-	-	-	-	20%	5%	5%				
GA	-	38	170	-	-	-	-		1%	11%				
HI	-	-	-	-	3	-	-					12%		
IA	-	55	-	-	-	-	-		2%					
ID	-	11	-	-	-	-	-		0%					
IL	-	110	52	-	-	-	-		4%	3%				
IN	-	69	17	-	-	-	-		3%	1%				
KS	-	35	5	-	-	-	-		1%	0%				
KY	-	59	9	-	-	-	-		2%	1%				
LA	-	26	98	-	-	-	-		1%	6%				
MA	-	60	7	-	1	-	-		2%	0%		4%		
MD	-	27	72	-	-	-	-		1%	5%				
ME	-	17	-	-	-	-	-		1%					
MI	1	91	46	-	-	-	-	20%	3%	3%				
MN	-	66	2	-	-	2	-		2%	0%			4%	
MO	-	73	33	-	-	-	-		3%	2%				
MS	-	8	56	-	-	1	-		0%	4%			2%	
MT	-	9	-	-	-	4	-		0%				8%	
NC	-	28	109	-	-	1	-		1%	7%			2%	
ND	-	10	-	-	-	3	-		0%				6%	
NE	-	27	3	-	-	1	-		1%	0%			2%	
NH	-	10	-	-	-	-	-		0%					
NJ	-	60	37	1	-	-	-		2%	2%	8%			
NM	-	19	-	-	-	7	-		1%				14%	
NV	-	10	1	-	-	-	-		0%	0%				
NY	2	106	64	-	2	-	-	40%	4%	4%		8%		
OH	-	137	50	-	-	-	-		5%	3%				
OK	-	42	2	-	-	4	-		2%	0%			8%	
OR	1	39	1	-	-	-	-	20%	1%	0%				
PA	-	165	48	-	-	-	-		6%	3%				
RI	-	15	2	-	-	-	-		1%	0%				
SC	-	12	80	-	-	-	-		0%	5%				
SD	-	14	-	-	-	6	-		1%				12%	
TN	-	65	48	-	-	-	1		2%	3%				25%
TX	-	221	86	1	-	-	-		8%	6%	8%			
UT	-	20	-	-	-	1	-		1%				2%	
VA	-	35	65	-	-	-	1		1%	4%				25%
VT	-	5	-	-	-	-	-		0%					
WA	-	46	1	-	-	-	-		2%	0%				
WI	-	86	14	-	-	-	-		3%	1%				
WV	-	23	1	-	-	-	-		1%	0%				
WY	-	8	-	-	-	1	-		0%				2%	
Total Number of Facilities >50% one group	5	2,689	1,508	12	25	50	4	100%	100%	100%	100%	100%	100%	100%

Exhibit 9. Distribution of Facilities with Majority Racial Group by Rural / Urban Status

Count of Urban/Rural Facilities Serving Patient Populations Exceeding 50% Per Race Category			
Race	Number of Facilities "Unknown"	Number Facilities "Rural"	Number Facilities "Urban"
Unknown			5
White	249	628	1,812
Black	104	286	1,118
Hispanic	5	1	6
Asian	11	2	12
Native American	2	37	11
Other	1		3
TOTAL	372	954	2,967

Count of Urban/Rural Facilities Serving Patient Populations Exceeding 75% Per Race Category			
Race	Number of Facilities "Unknown"	Number Facilities "Rural"	Number Facilities "Urban"
Unknown			3
White	134	483	812
Black	41	145	501
Hispanic			
Asian			2
Native American		24	8
Other			
TOTAL	175	652	1,326

Count of Urban/Rural Facilities Serving Patient Populations Exceeding 90% Per Race Category			
Race	Number of Facilities "Unknown"	Number Facilities "Rural"	Number Facilities "Urban"
Unknown			2
White	83	318	270
Black	14	37	201
Hispanic			
Asian			
Native American		19	7
Other			
TOTAL	97	374	480

Exhibit 10. Distribution of Treatments by Patient Race/Ethnicity by State in Facilities with >80% Medicare Treatments (Medicare dependent)

Percent Race/Ethnicity Category for Facilities with 80% or more Medicare Treatment Share, by State, 2007							
	Race/ethnicity Categories						
State	*Unknown*	*White*	*Black*	*Hispanic*	*Asian*	*Native American*	*Other*
Unknown	0.37%	65.31%	25.47%	5.49%	0.92%	0.62%	1.82%
AK	0.21%	53.05%	11.27%	2.95%	12.94%	17.22%	2.36%
AL	0.15%	37.25%	61.77%	0.30%	0.17%	0.14%	0.21%
AR	0.27%	46.36%	50.39%	0.38%	0.61%	1.34%	0.65%
AZ	0.25%	44.31%	3.44%	13.65%	0.49%	37.15%	0.72%
CA	0.42%	56.71%	8.84%	19.72%	6.15%	3.24%	4.91%
CO	0.03%	69.19%	5.65%	14.24%	0.02%	8.69%	2.18%
CT	0.45%	68.79%	24.21%	3.94%	1.13%	0.00%	1.49%
DC	0.73%	0.74%	95.43%	2.83%	0.25%		0.02%
DE	0.34%	39.51%	49.85%	1.37%	0.27%		8.67%
FL	0.37%	61.28%	32.82%	2.80%	1.34%	0.23%	1.15%
GA	0.24%	29.55%	68.16%	0.62%	0.63%	0.02%	0.77%
IA	0.21%	84.54%	9.60%	1.44%	0.80%	2.30%	1.10%
ID		88.64%	0.11%	5.60%	0.28%	3.07%	2.29%
IL	0.35%	73.00%	22.21%	1.97%	1.10%	0.09%	1.28%
IN	0.26%	63.60%	33.49%	1.46%	0.44%	0.11%	0.64%
KS	0.37%	70.44%	19.94%	4.81%	1.24%	1.86%	1.34%
KY	0.32%	77.22%	21.84%	0.20%	0.03%	0.11%	0.28%
LA	0.51%	28.76%	69.55%	0.34%	0.16%	0.09%	0.58%
MA	0.16%	88.88%	6.61%	1.34%	1.03%	0.00%	1.97%
MD	0.43%	44.59%	52.04%	0.56%	1.28%	0.06%	1.03%
ME	0.24%	94.63%	2.66%	0.29%	0.57%	0.23%	1.37%
MI	0.21%	54.94%	41.40%	0.94%	0.65%	0.64%	1.23%
MN		90.50%	2.90%		0.84%	3.95%	1.81%
MO	0.20%	59.32%	38.17%	0.71%	0.39%	0.47%	0.74%
MS	0.11%	25.26%	72.51%	0.19%	0.24%	1.45%	0.23%
MT	0.52%	65.57%	1.68%	1.03%		30.81%	0.39%
NC	0.21%	27.86%	68.19%	0.83%	0.34%	1.54%	1.03%
NE		84.64%	8.08%	2.43%	0.64%	3.01%	1.19%
NH	0.54%	95.77%	1.08%		0.98%		1.63%
NJ	0.27%	55.07%	31.85%	6.09%	3.81%	0.01%	2.89%
NM	0.26%	45.82%	4.07%	14.45%	0.14%	32.12%	3.14%
NV		59.69%	15.61%	7.02%	3.26%	12.60%	1.82%
NY	0.38%	60.36%	27.93%	5.95%	1.19%	0.84%	3.35%
OH	0.28%	70.65%	27.21%	0.60%	0.35%	0.13%	0.78%
OK	0.16%	56.18%	17.44%	0.89%	0.34%	24.40%	0.60%
OR	0.57%	90.52%	1.21%	2.01%	1.16%	1.93%	2.60%
PA	0.01%	85.94%	9.59%	2.12%	0.63%	0.50%	1.22%
RI		92.27%	4.94%		0.18%	2.61%	
SC	0.23%	27.61%	71.03%	0.31%	0.30%	0.00%	0.52%
TN	0.30%	50.78%	48.05%	0.25%	0.27%	0.13%	0.23%
TX	0.30%	52.33%	26.51%	17.88%	0.74%	0.32%	1.91%
UT	0.89%	83.96%	1.10%	2.41%	1.56%	7.37%	2.71%
VA	0.20%	36.87%	59.62%	0.54%	1.55%	0.04%	1.17%
WA	0.40%	83.69%	4.08%	3.68%	1.78%	3.85%	2.51%
WI	0.22%	73.54%	21.05%	0.74%	1.34%	2.04%	1.08%
WV	0.15%	85.56%	13.07%	0.26%		0.15%	0.82%
WY		90.92%	2.22%	1.22%	2.10%	0.03%	3.51%

Exhibit 11. Facilities by State with >75% Treatments for Single Race/Ethnic Group

State-By-State Distribution of Facilities Serving Patient Populations Greater than 75% Per Race Category														
	Count of Facilities Serving Patient Populations Greater than 75% Per Racial Category							Percent of Facilities Serving Patient Populations Greater than 75% Per Racial Category						
State	Unknown	White	Black	Hispanic	Asian	Native American	Other	Unknown	White	Black	Hispanic	Asian	Native American	Other
Unknown	-	131	41	-	-	-	-		9%	6%				
AK	-	1	-	-	-	-	-		0%					
AL	-	13	40	-	-	-	-		1%	6%				
AR	-	11	16	-	-	-	-		1%	2%				
AZ	-	27	-	-	-	13	-		2%				41%	
CA	-	28	4	-	2	-	-		2%	1%		100%		
CO	-	19	-	-	-	-	-		1%					
CT	-	5	-	-	-	-	-		0%					
DC	-	-	16	-	-	-	-			2%				
DE	-	2	1	-	-	-	-		0%	0%				
FL	1	43	14	-	-	-	-	33%	3%	2%				
GA	-	10	102	-	-	-	-		1%	15%				
HI	-	-	-	-	-	-	-							
IA	-	48	-	-	-	-	-		3%					
ID	-	9	-	-	-	-	-		1%					
IL	-	69	31	-	-	-	-		5%	5%				
IN	-	52	8	-	-	-	-		4%	1%				
KS	-	21	1	-	-	-	-		1%	0%				
KY	-	41	3	-	-	-	-		3%	0%				
LA	-	2	49	-	-	-	-		0%	7%				
MA	-	43	1	-	-	-	-		3%	0%				
MD	-	11	42	-	-	-	-		1%	6%				
ME	-	16	-	-	-	-	-		1%					
MI	1	51	29	-	-	-	-	33%	4%	4%				
MN	-	58	-	-	-	2	-		4%				6%	
MO	-	61	17	-	-	-	-		4%	2%				
MS	-	-	36	-	-	-	-			5%				
MT	-	7	-	-	-	3	-		0%				9%	
NC	-	13	50	-	-	-	-		1%	7%				
ND	-	8	-	-	-	2	-		1%				6%	
NE	-	21	-	-	-	1	-		1%				3%	
NH	-	10	-	-	-	-	-		1%					
NJ	-	27	9	-	-	-	-		2%	1%				
NM	-	3	-	-	-	5	-		0%				16%	
NV	-	2	-	-	-	-	-		0%					
NY	1	58	17	-	-	-	-	33%	4%	2%				
OH	-	84	14	-	-	-	-		6%	2%				
OK	-	11	-	-	-	-	-		1%					
OR	-	29	-	-	-	-	-		2%					
PA	-	120	24	-	-	-	-		8%	3%				
RI	-	12	-	-	-	-	-		1%					
SC	-	-	48	-	-	-	-			7%				
SD	-	10	-	-	-	5	-		1%				16%	
TN	-	36	28	-	-	-	-		3%	4%				
TX	-	37	9	-	-	-	-		3%	1%				
UT	-	14	-	-	-	1	-		1%				3%	
VA	-	16	30	-	-	-	-		1%	4%				
VT	-	5	-	-	-	-	-		0%					
WA	-	27	-	-	-	-	-		2%					
WI	-	77	7	-	-	-	-		5%	1%				
WV	-	22	-	-	-	-	-		2%					
WY	-	8	-	-	-	-	-		1%					
Total Number of Facilities	3	1,429	687	-	2	32	-	100%	100%	100%		100%	100%	

Note: "Total Number of Facilities" means the total count of Facilties where the Race Category was over 75%.

Exhibit 12. Ownership of Facilities with >75% Black or Native American Patient

Ownership Status for Facilities with >75% Treatments for Black Race Category	Number of Facilities	Percent of Facilities with >75% Treatments for Black Race Category
LDO	491	71.50%
Regional	80	11.60%
Independent	75	10.90%
Hospital	34	4.90%
Unknown	7	1.00%
Total Number of Facilities with >75% Treatments for Black Race Category	687	100.00%

Ownership Status for Facilities with >75% Treatments for Native American Race Category	Number of Facilities	Percent of Facilities with >75% Treatments for Native American Race Category
LDO	16	50.00%
Regional	9	28.10%
Independent	3	9.40%
Hospital	4	12.50%
Unknown	-	0.00%
Total Number of Facilities with >75% Treatments for Native American Race Category	32	100.00%

Exhibit 13 Distribution of Facilities by Racial Group and Payer

Facilities With Patient Mix Exceeding 50% Per Race Category

Medicare Treatment Share Percentages	Black				Hispanic				Asian				Native American				Other			
	Freq.	Percent	Cumulative Freq.	Cum. %	Freq.	Percent	Cumulative Freq.	Cum. %	Freq.	Percent	Cumulative Freq.	Cum. %	Freq.	Percent	Cumulative Freq.	Cum. %	Freq.	Percent	Cumulative Freq.	Cum. %
0%-9%	105	7	105	7	4	33	4	33	4	16	4	16	14	28	14	28	1	25	1	25
10%-19%	6	0	111	7					1	4	5	20								
20%-29%	10	1	121	8																
30%-39%	14	1	135	9																
40%-49%	24	2	159	11									3	6	17	34				
50%-59%	92	6	251	17	3	25	7	58	7	28	12	48	1	2	18	36				
60%-69%	206	14	457	30	5	42	12	100	4	16	16	64	7	14	25	50	1	25	2	50
70%-79%	467	31	924	61					9	36	25	100	9	18	34	68				
80%-89%	492	33	1,416	94									13	26	47	94	2	50	4	100
90%-100%	91	6	1,507	100									3	6	50	100				
Over 100%	1	0	1,508	100																

Facilities With Patient Mix Exceeding 75% Per Race Category

Medicare Treatment Share Percentages	Black				Hispanic				Asian				Native American				Other			
	Freq.	Percent	Cumulative Freq.	Cum. %	Freq.	Percent	Cumulative Freq.	Cum. %	Freq.	Percent	Cumulative Freq.	Cum. %	Freq.	Percent	Cumulative Freq.	Cum. %	Freq.	Percent	Cumulative Freq.	Cum. %
0%-9%	50	7	50	7									9	28	9	28				
10%-19%	2	0	52	8																
20%-29%	2	0	54	8																
30%-39%	5	1	59	9																
40%-49%	6	1	65	9									3	9	12	38				
50%-59%	38	6	103	15									1	3	13	41				
60%-69%	81	12	184	27									4	13	17	53				
70%-79%	223	32	407	59					2	100	2	100	6	19	23	72				
80%-89%	232	34	639	93									8	25	31	97				
90%-100%	48	7	687	100									1	3	32	100				
Over 100%																				

Facilities With Patient Mix Exceeding 90% Per Race Category

Medicare Treatment Share Percentages	Black				Hispanic				Asian				Native American				Other			
	Freq.	Percent	Cumulative Freq.	Cum. %	Freq.	Percent	Cumulative Freq.	Cum. %	Freq.	Percent	Cumulative Freq.	Cum. %	Freq.	Percent	Cumulative Freq.	Cum. %	Freq.	Percent	Cumulative Freq.	Cum. %
0%-9%	20	8	20	8									8	31	8	31				
10%-19%	1	0	21	8																
20%-29%	2	1	23	9																
30%-39%	4	2	27	11																
40%-49%	2	1	29	12									2	8	10	38				
50%-59%	17	7	46	18																
60%-69%	35	14	81	32									4	15	14	54				
70%-79%	94	37	175	69									4	15	18	69				
80%-89%	67	27	242	96									7	27	25	96				
90%-100%	10	4	252	100									1	4	26	100				
Over 100%																				

F. Other Adjustors

We have a number of concerns regarding the methodology used to develop the patient level adjustors. These include:

Potential bias resulting from exclusion of hundreds of facilities from the regression analysis;
Lack of any relationship between cost report data and patient level characteristics; and
Inconsistent description of criteria for determination of adjustors between research method used to develop adjustor values and actual decisions in practice.

Together, these concerns as discussed in detail below, lead us to question the validity of the adjustor values in the Proposed Rule. We understand that CMS proposes to re-run the regression analysis using the same methodology, but with more recent claims and cost report data to re-value the patient level adjustors.

Potential Bias

CMS excluded hundreds of facilities from the regression analysis using 2004-2006 data, eliminating 15 percent of facilities with little explanation. About half of these facilities were eliminated because the research team was unable to match a cost report to claims data. We believe, based on our own efforts to match claims and cost reports, that these facilities would be hospital based. We do not know why the other half of facilities were excluded, but our experience suggests that many of these may also be hospital based facilities, as hospitals use different cost report forms which are more likely to be inconsistent with independent facility cost reports. If a significant proportion of patient claims are eliminated due to excluding hospital based facilities, we question whether the resulting adjustors would be biased. We are not aware of any detailed comparison of patients in hospital based dialysis centers and independent dialysis centers. The patients treated in different sites of care would have to be very similar for the adjustor values to accurately represent the dialysis population.

The facilities included in the regression analyses are referred to as a "sample", but we have found no discussion of the extent to which this sample is representative of the total universe of facilities. Apart from disproportional representation of hospital based units among those excluded, we would wonder whether other characteristics of those facilities excluded (e.g., geography, size, non-chain status, start-ups) might bias the sample, and the resulting adjustor values.

Cost Report Data

CMS acknowledges that cost report data do not include any references that can link cost to individual patient characteristics. Yet, these data are used in the regression analysis to determine the value of patient level adjustors. We would make the case that these data are not appropriate to use in the regression analysis for patient level adjustors.

We concur that cost report data cannot be interpreted as representing patient characteristics, and further point out that cost reports are submitted for the organization's fiscal year, and that while most chains have the same calendar fiscal year as represented by claims data, a few chains and some number of independent and hospital based facilities report data for a different fiscal period that only

overlaps in part with the claim year. We do not know if this lack of correspondence of the reporting period with the claims period was used as criteria to eliminate facilities from the regression analysis.

Cost reports also cap costs associated with Medical Director and certain administrative activities that may vary with patient mix. Cost reports do not include cost data representing the lab tests that are being added to the bundled payment system, nor do they include costs for formerly Part D drugs. These omissions distort the actual costs associated with delivery of care, and thereby also distort the variance in average cost per treatment.

Facility cost reports allocate overall operating costs to Medicare patients based upon allocation rules detailed in cost reporting instructions. As a result, the costs reported for Medicare patients are really average costs for all patients, and not reflective of costs for Medicare patients alone. Facilities have a wide range of payer mix, and differences in allocated average cost per treatment for Medicare patients may reflect a wide variety of differences in facility operations that have nothing to do with the co-morbidities of patients, with how many new patients are seen, or with any other patient characteristics. While regression analysis may yield statistically significant results when cost report data are used, we do not see any reason to assume that these results are validly linked to the conditions or characteristics of patients. We suggest that these results are more likely to be an artifact of varying features of facilities that are not measured or controlled for in the analysis.

Inconsistent Definitions and Criteria for Identifying an Adjustor

CMS uses ICD-9 codes to five digits to specify the co-morbidity adjustors in the Proposed Rule, both codes that qualify and codes that do not qualify. These codes are used to assign adjustors to claims. It is not clear how adjustors are identified in the regression analyses. References are made to both historical claims going back to 2000 and to the 2728 form completed for patients at admission to a facility. Criteria related to historical claims are shown in reports and in the Proposed Rule (e.g., presence of a diagnosis code in claims going back to 2000). The 2728 form includes generally described conditions to be checked off, and these data could not be used to apply any of the criteria that are described.

CMS also indicates that old diagnoses that no longer affect ESRD treatment should not qualify for adjustors, yet no explanation is provided as to how to make this determination in performing the regression analysis or in assigning adjustors to patients. We find no reference to analysis or statistical evaluation of the period of time in the past for which a condition is relevant to the costs of ESRD treatment. We conclude that the flagging of patients for each individual adjustor based on diagnostic criteria could be very different if codes were searched in claims for different time periods.

Varying features of the research used to flag patients for adjustor conditions would yield varying adjustor values, as some patients would lose adjustors if the number of years used to identify a condition was decreased, and more patients would gain adjustors if the number of years of data used were increased. Furthermore, since the availability of Medicare claims over an increased numbers of years will be present only for patients that are elderly or have been on dialysis for many years, patients starting dialysis with private insurance and younger patients will be under-represented among those with assigned adjustors both in calculating regression values and in the rate setting process.

Adjustor values may be biased toward older patients due to the lack of information for younger patients. Furthermore, adjustors for patients with long histories of Medicare claims may include more cases of out-dated adjustors no longer relevant to the treatment of ESRD. The inconsistent data base for assigning adjustors across patients may result in distorted adjustor values. All of the inconsistency in assigning adjustors to patients in claims used for the regression will call into question the predictive value of the adjustors that are produced. This predictive value is further decreased when different criteria are used to assign the adjustors to claims for rate setting: if claims going back to 2000 is used as a criteria for 2007 claims, and the same criteria is used in the regression based on 2004 to 2006 claims, then the time period for identifying the adjustor condition is different, and the prevalence will be different.

CMS likely expects the facilities to identify adjustor conditions and to record them on claims to qualify for payment adjustors. Yet CMS will have to develop criteria for facilities that are quite different from those used to cull claims for ICD-9 codes. Facilities have no access to historic claims for patients, nor will they be likely to have access to most of the diagnostic information required in the rule. Even if they could obtain most of this information, what historic period would apply? And how would that change from year to year. CMS' silence regarding the transition from a research project to find adjustors that statistically predict some amount of variance in cost based on separately billed services, to the operational reality of facilities putting information on claims to request a payment adjustor, leaves many questions as to the predictive validity and accuracy of the patient level adjustors.

Start-up Dialysis 120 Day Adjustor

We are unable to replicate this adjustor in our data without a date for the start-up of dialysis and dates of service. However, using estimation methods to identify services likely to be in the start-up period, we did find that separately billed payments were higher during start-up than they are after the start-up period. We examined payments during our estimated start-up period and found that higher payments are strongly associated with hospitalization and with race (black). Addition of a race adjustor would account for some portion of these elevated payments, and outlier payments would account for an additional portion.

None of our analyses suggest that the scale of the proposed adjustor can be justified. We have discussed our concerns about the use of cost report data in any patient adjustors, and we reiterate those concerns here.

G. Low-Volume Facility Adjustor

An in-depth review of CMS' discussion of its proposed low-volume policy yields a large number of concerns, both ambiguities and discrepancies. CMS' interpretation of the intent of the low-volume facility adjustor requirements is stated as: We believe the low-volume adjustment should encourage small ESRD facilities to continue to provide access to care to an ESRD patient population where providing that care would otherwise be problematic.[122] Several factors affect any definition of low-volume that would be consistent with this stated interpretation.

[122] 74 Fed. Reg. at 49969.

CMS refers to the number of treatments per year referring to cost reports as the source for the data. Among the list of facilities identified in the impact file as low-volume, we found at least 11 facilities with total treatments in cost report data for 2006 higher than 3000 (data for 2004, 2005, and 2006 were purportedly used to apply the criteria).[123] We cannot determine whether CMS is referring to Medicare treatments or to treatments for all payers. CMS does not, in fact, make this distinction anywhere in its discussion. Both of these data points are present in the cost report files. If Medicare treatments are used to determine which facilities fall below the threshold for low-volume, then the low-volume adjustor will reward facilities with lower Medicare share of payer mix and may, in fact, reward larger facilities with a low Medicare volume. That is, in fact, what we see in an examination of the impact file for a number of facilities.

CMS uses Medicare treatment counts in its discussion of facilities losing the low-volume adjustor: In the event an ESRD facility provides 3000 or more treatments during their payment year, that is, no longer eligible for the low volume adjustment; the ESRD facility would stop receiving the adjustment at the time they reach their 3000th treatment.[124] The only way CMS would be able to determine when a facility received a 3000th treatment would be using Medicare claims and that would only count Medicare treatments, not total treatments. Relying on cost reports would not yield information about exceeding the 3000th treatment until the cost report is submitted some 6 months or more after the end of the calendar year in which the payment adjustor was applied. Use of the cost report to identify facilities that lost eligibility for the payment adjustor would entail retrospective "claw back" of the dollars already paid out that are associated with that adjustor. CMS is clearly referring to facilities losing eligibility for the adjustor in real time, not retrospectively, and so must be referring to claims counts which would ignore the effect of payer mix.

UM-KECC used 89 low-volume facilities in the adjustor analysis but CMS lists 166 low-volume facilities in the Impacts File released with the Proposed Rule. CMS does not discuss this difference in the rule. CMS indicates that it used final cost reports to identify low-volume facilities with treatments lower than the threshold for three years. We cannot replicate what CMS did to get from 89 to 166 facilities. Among the 166 facilities we find:

- 6 facilities that closed in 2007 or 2008
- 11 facilities with >3000 treatments in 2006
- 2 facilities that were start-ups in 2007 (may have changed ownership)
- 30 facilities have zero workstations and most of these appear to be home dialysis programs

These discrepancies in the list of identified low-volume facilities to which CMS is assigning an adjustor lead us to question the sources of data used. We have looked at facility capacity by using the total treatments in the cost reports and the number of dialysis stations in the provider of service

[123] In fact in the impact file released with the rule, CMS flags 489 facilities as having fewer than 3000 treatments: "total" treatments, implying that these are not just Medicare treatments. The source for this information would have to be the cost report. But when we match cost reports to these facilities, we find quite a few that have >3000 total treatments in the 2006 and/or 2007 cost report. Other flags in the impact file identify even more facilities as having <3000 treatments and no information explains the discrepancies between these different measures.

[124] 74 Fed. Reg. at 49975.

files. We use the certification dates in cost reports to identify start-up dates, and we have data from KCC member companies on closures of facilities in 2007 and 2008. CMS indicates it does not think home programs should be given low-volume status, yet most of the 30 facilities with zero work stations on the impact file appear to be home programs.

It is not clear to us that the facilities with low-volume adjustors on the impact file are in need of the adjustor as proposed at 20.2 percent. The low-volume facilities listed were paid, on average, $0.27 more per composite rate treatment (not counting separately billed items) in 2007 than the facilities that were not low-volume (based on 2007 claims). We cannot replicate the analysis performed by UM-KECC or even evaluate it because we do not know which 89 facilities were identified as low-volume for that analysis. We question the validity of the regression analysis for this purpose when the underlying data have considerable error/extreme values in it, and the number of facilities is small.

We looked at the cost report data for the 166 flagged low-volume facilities, and found that using a weighted average of Medicare costs per treatment, the low-volume facilities on the impact file list had 34 percent higher cost per treatment than the facilities that were not low-volume. However, looking at the cost reports more closely, we found 20 facilities with >50 percent pediatric patients (pediatric facilities) in 2007, and these facilities have much higher costs per treatment than do independent facilities, tend to be hospital based, and tend to have lower Medicare payer mix. We found one children's hospital cost report with $ 877,000 in Medicare costs with zero Medicare revenues. We found another provider whose cost per treatment was >$6000. Removing just the latter two facilities reduced the average cost per treatment to 28 percent higher than for non low-volume facilities. We find numerous data problems in cost reports, suggesting that calculating average cost per treatment for a small number of facilities (such as this set of designated low-volume facilities) will likely result in distorted values. CMS provides no information to suggest that it required any trimming of extreme and obviously incorrect values used in the regression analysis, so we cannot determine how it came up with its 20.2 percent adjustor.

H. Pediatric Adjustors

We have a number of concerns with the pediatric rates and methodology used to develop those rates as described by CMS. There are two distinct situations that need to be addressed in setting rates for children as distinct from setting rates for adults: 1) most, but not all younger children are receiving care in pediatric facilities defined as those with more than 50 percent of their treatments for children; and 2) many older children/teenagers are receiving care in facilities that overwhelmingly treat adults. Pediatric facilities historically demonstrated higher costs to CMS to qualify for exception rates. CMS' regression results lack credibility when costs for pediatric facility are closely examined, as they are much higher than costs for adult facilities. The small number of facilities and patients along with the distribution of pediatric patients, and cost report data problems make the regression methodology used by CMS inappropriate.

When an adjustor is calculated for all children, the facility cost reports for facilities treating one or a few children will represent adult facility costs, not pediatric facility costs. Average cost per treatment in these facilities will wash out any special costs associated with treatment of the children, as the vast majority of costs are associated with adult care. Therefore, the costs of care for children

cared for in adult facilities will not be represented by the cost reports. See Exhibit 14 for a breakdown of the number of facilities treating children in 2007.

The pediatric facility cost reports to which we have access,[125] show much higher costs of care by several magnitudes compared to adult facility costs. Given that most of these facilities exceed the criteria of treating >50 percent children, the costs reflected in these cost reports will better represent the costs of care for children. However, there are few of these cost reports relative to the cost reports for adult facilities treating children. Also, given our difficulty in linking a cost report to every pediatric facility, we are not assured that CMS was able to find cost reports for all facilities treating children, particularly all pediatric facilities. The larger number of adult facilities treating the older children will yield a downward bias to the cost per treatment for children based on cost report data.

Exhibit 14. Distribution of Pediatric Patients (<age 19) among Facilities 2007 (SAF)

Percent of Treatments that were for Pediatric Patients	Number of Facilities
<5%	4,875
>0<5%	478
5-10%	21
10-15%	4
15-20%	1
20-25%	-
30-35%	-
40-45%	3
45-50%	-
50-55%	3
55-60%	2
60-65%	4
65-70%	4
70-75%	3
75-80%	2
80-85%	2
>90%	28

[125] We have not been able to match a cost report to all of the pediatric facilities.