



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 Statute 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

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

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.

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

