



THE KIDNEY CARE COUNCIL



April 19, 2010

Director, Regulations Management (00REG1)
Department of Veterans Affairs
810 Vermont Avenue, NW
Room 1068
Washington, DC 20420

RE: RIN 2900-AN37—Payment for Inpatient and Outpatient Health Care Professional Services at Non-Departmental Facilities and Medical Charges Associated with Non-VA Outpatient Care

Dear Director:

The Kidney Care Council (“KCC”) and Kidney Care Partners (“KCP”) are pleased to have this opportunity to submit its comments with regard to the *Payment for Inpatient and Outpatient Health Care Professional Services at Non-Departmental Facilities and Medical Charges Associated with Non-VA Outpatient Care* (the “Proposed Rule”).¹

The KCC is a coalition representing 14 of the leading renal care organizations that treat nearly 80 percent of the dialysis population in the United States. The KCC members operate more than 3,400 dialysis facilities in 47 states, Puerto Rico, and the District of Columbia, providing care to over 262,000 individuals with kidney failure. The members of the KCC include: American Renal Associates, Inc.; Atlantic Dialysis Management Services, LLC; Centers for Dialysis Care; DaVita, Inc.; Dialysis Corporation of America; DSI Renal, Inc.; Fresenius Medical Care North America; Liberty Dialysis, Inc., LLC; Northwest Kidney Centers; Renal Advantage Inc.; Renal Care Partners, Inc., Renal Ventures Management, LLC; Satellite Healthcare, Inc.; and U.S. Renal Care, Inc. As the primary providers of dialysis services across the country, KCC member companies are committed to improving clinical outcomes, patient safety, and quality of life measures.

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”). 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.

¹ 75 *Fed. Reg.* 7218 (Feb. 18, 2010).

Given both organizations' commitment to ensuring access to the provision of high quality dialysis care to those who need it, we wish to share our views on several of the policy proposals suggested in this historic rule. We have outlined below our specific concerns and recommendations regarding the various policies set forth in the Proposed Rule.

Any changes have to be viewed in terms of the impact on patients. Our members are concerned that the proposed policy will negatively affect veterans receiving dialysis treatments. More than 10,000 veterans receive dialysis treatments at non-VA facilities. The economics of dialysis facilities are extremely fragile and most facilities treat many patients at a loss. A reduction in the reimbursement rate for veterans could destabilize the current economic balance and create access to care problems. Veterans would be forced to change dialysis providers and perhaps travel greater distances to get to dialysis. All dialysis patients must receive treatments three times a week. Such treatments can be exhausting for patients. Having to change trusted providers or to travel greater distances would be a great hardship both personally and financially for these veterans. This could result in skipped treatments that would negatively impact their health outcomes. The Department should avoid implementing any policy that has the potential to cause such harm.

I. EXECUTIVE SUMMARY

The Proposed Rule contravenes the Department of Veterans Affairs ("VA") own statutory mandate to contract with private sector health care providers for non-departmental services. The Proposed Rule seeks to impose a mandatory cap, tied to Medicare payment rates in the absence of a Federal Acquisition Regulation contract, on the reimbursement of dialysis treatments provided to veterans outside of VA facilities without sufficient statutory authority to do so. Federal law and public policy require that VA use full and open competition both to award contracts and to determine the rates paid to providers under such contracts. The Proposed Rule violates this obligation when it pays for essential health care services outside of non-departmental facilities. Moreover, in proposing that rates for such services be tied to those of Medicare, the Proposed Rule fails to consider or comprehend the broad transformation that Medicare's own payment system for dialysis care will undergo in 2011. As such, the Proposed Rule dramatically oversimplifies what is one of Medicare's most complex payment and regulatory schemes. The Congressionally-mandated Medicare payment system change, discussed more fully below, requires significant clinical and operational resources from the payer that the VA likely cannot replicate. The new system also subjects providers to instability associated with new and uncertain payment rules. Furthermore, in its overall regulatory impact analysis, the VA fails in the Proposed Rule to fully evaluate the effect of extending Medicare rates on an already fragile economic system for dialysis providers that sustains provider function and ensures access to dialysis care only by cross subsidization from payer sources other than Medicare. VA's substitution of Medicare rates for its own privately contracted amounts disturbs this balance, and in turn jeopardizes dialysis facility capacity to serve veterans across the country.

II. KEY ISSUES

A. The Proposed Rule is Inconsistent with VA’s Statutory Authority.

Congress granted VA general authority to provide for health care services to veterans at non-VA facilities in 38 U.S.C. § 1703. This statute enables VA to contract with health care service providers, as is required for VA to contract with any vendor outside of the VA system. It grants VA specific authority to limit reimbursement rates in very limited instances, including certain emergency services providers. Importantly, it does not grant specific rate-setting authority to VA to limit reimbursement for maintenance dialysis services.

(1) VA Lacks Specific Statutory Authority to Limit Reimbursement for Non-Emergency Medical Services.

Pursuant to 38 U.S.C. § 1703(a), VA is authorized to provide for medical care for veterans in non-VA facilities when VA facilities are not capable of providing these services. The implementing regulation for this authority likewise describes VA’s authority to “contract with non-VA facilities for care”² Neither VA’s statutory authority, nor the regulation promulgated by the Secretary to exercise that authority, allows the Secretary to limit reimbursement for these contracted services.

The Proposed Rule notes that VA is authorized to provide payment for emergency care in a non-VA facility in limited situations, primarily where the care is needed for the treatment of a service-connected disability or related conditions aggravating a service connected disability.³ “Emergency treatment” is defined as “medical care or services furnished . . . when [VA] or other Federal facilities are not feasibly available and when an attempt to use them beforehand would not be reasonable; when such care or services are rendered in a medical emergency of such nature that a prudent layperson expects that delay in seeking care would be hazardous to life or health”⁴

We note that routine maintenance dialysis in a free-standing dialysis facility (as opposed to in-patient “acute” dialysis in a hospital setting) is not an emergency treatment under the statutory definition. VA’s own guidance also makes clear that dialysis care is provided on an “ongoing, long-term”⁵ rather than emergent basis, and to the extent that VA does pay for dialysis on an emergency basis, the Secretary is required to reimburse veterans for the “reasonable value of such care or services.”⁶

² 38 CFR § 17.52.

³ 38 U.S.C. § 1728.

⁴ 38 U.S.C. § 1725(f).

⁵ VHA Directive 2007-025, Sept. 12, 2007.

⁶ 38 CFR 17.120 (emphasis added).



No authority exists to impose limitations on reimbursement in either 38 U.S.C. 1703 or 1728, cited by the Proposed Rule as the foundation for VA to contract with private sector providers for dialysis services. In contrast, 38 U.S.C. § 1725, governing reimbursement for emergency treatment, contains a “limitations on reimbursements” clause at paragraph (c), authorizing the Secretary to “establish the maximum amount payable [for emergency treatment].”

The fact that Congress gave the Secretary explicit authority to limit reimbursement for veterans’ care only in the case of non-service-connected emergency care, and withheld such authority in the case of general hospital care or medical services⁷ or service-connected emergency care⁸ is objective proof that VA is required by law to negotiate the rates for health care services with private sector providers, and may not arbitrarily cap the rates for such services by establishing an administered pricing scheme tied to Medicare rates. This is a basic canon of statutory interpretation, long established in federal courts.⁹

In the absence of explicit authority, the Proposed Rule’s efforts to impose Medicare prices on providers of maintenance dialysis care at non-departmental facilities lacks the adequate statutory foundation to move forward.

(2) The Proposed Rule Violates VA’s Obligations Under Federal Procurement Law and Policies.

The Federal Acquisition Regulation (“FAR”),¹⁰ the Veterans Administration Acquisition Regulation (“VAAR”),¹¹ the Competition in Contracting Act¹² and other federal procurement laws and policies apply to all VA acquisitions made with appropriated funds unless explicitly exempted under Title 38. These laws and policies consistently favor negotiated contracts and support full and open competition as the method to deliver the best value to the federal government and the citizens it serves.

The responsibility of VA to use full and open competition and negotiated contracts to establish prices for health care professional services is also statutorily mandated by 38 U.S.C. § 8153, governing the sharing of health-care resources.

⁷ 38 U.S.C. § 1703.

⁸ 38 U.S.C. § 1728.

⁹ See, e.g., *Estate of Bell v. Commissioner*, 928 F.2d 901, 904 (9th Cir. 1991) (“Congress is presumed to act intentionally and purposely when it includes language in one section but omits it in another.”). See also *Connecticut Nat’l Bank v. Germain*, 112 S. Ct. 1146, 1149 (1992) (“[i]n interpreting a statute a court should always turn to one cardinal canon before all others. . . . [C]ourts must presume that a legislature says in a statute what it means and means in a statute what it says there.”).

¹⁰ 48 CFR Ch. 1.

¹¹ 48 CFR Ch. 8.

¹² Pub. L. No. 98-369.

In contrast to the contracting authorities cited by the Proposed Rule, 38 U.S.C. § 8153 provides that “[i]f the health-care resource required is a commercial service, the use of medical equipment or space, and is not to be acquired from [an institution affiliated with the VA] any procurement of the resource may be conducted without regard to any law or regulation that would otherwise require the use of competitive procedures for procuring the resource, but only if the procurement is conducted in accordance with the simplified procedures prescribed pursuant to clause (ii).”¹³

The obligation for competition is additionally underscored later in § 8153. Clause (ii) authorizes the Secretary to prescribe simplified procedures for the procurement of health-care resources.¹⁴ The clause includes the requirement that “such procedures shall permit all responsible sources, as appropriate, to submit a bid, proposal, or quotation (as appropriate) for the resources to be procured and provide for the consideration by the Department of bids, proposals, or quotations so submitted.” Section 8153 then requires that [a]ny procurement of health-care resources other than those covered by subparagraph (A) or (B) shall be conducted in accordance with all procurement laws and regulations.¹⁵

The procurement of the health care resources covered by the Proposed Rule must be conducted, therefore, in accordance with all procurement laws and regulations, *e.g.*, those found at 48 CFR Chapter 1 and Chapter 8, which do not contain any provisions allowing VA to establish a limitation on costs, but rather fully support negotiated contracts based on full and open competition. None of the statutory authorities cited in the Proposed Rule exempt VA from the requirements of 48 CFR or from any other federal procurement law.

While the Proposed Rule makes a nod to the governing authority to the FAR and VAAR, the intent of VA is to subvert these contracting regulations. The Proposed Rule states that “[i]n the absence of an amount negotiated between VA and the provider under the [FAR], this new methodology will allow VA to pay the lesser of an amount negotiated under the [VAAR], the applicable Medicare or VA Fee Schedule rate, and the billed charge” and that “[t]he [P]roposed [R]ule would give preference to ‘[t]he amount negotiated by VA and the provider under [FAR], 48 CFR Chapter 1.’”¹⁶

The real intent of the Proposed Rule, however, follows at § 7219: “proposed § 17.56(a)(1) does not fully reflect VA’s existing statutory and regulatory authority to negotiate rates through the contracting authority in 38 U.S.C. § 1703 and the regulatory procedures set forth in 48 CFR Chapter 8, or to apply rates negotiated by a repricing agent. Accordingly, in proposed paragraph (a)(2)(i) and (a)(2)(ii), we added a clarifying amendment to specify that negotiating such agreements is the preferred method for

¹³ 38 U.S.C. § 8153(a)(3)(B) (emphasis added).

¹⁴ *Id.*

¹⁵ 38 U.S.C. § 8153(C) (emphasis added).

¹⁶ 75 *Fed. Reg.* 7218 at 7219 (emphasis included).



determining payment amounts for all non-VA physician and other health care professional services only if such amount is lesser than would be payable under the applicable Medicare or VA Fee Schedule rate and billed charge.¹⁷ In other words, even to the extent that negotiated contracts survive the implementation of the new rule, the new rate mechanism would act as a limitation on reimbursement. Clearly, this outcome is contrary to VA’s statutory authority and contrary to public policy.

(3) The Proposed Rule, If Implemented, Would Violate Other Regulatory Provisions and the Veterans Health Administration’s Guidance for Non-VA Dialysis Care.

The Veterans Health Administration policy for the authorization and payment of dialysis care administered to veterans by non-VA health care providers is described in VHA Directive 2007-025, Sept. 12, 2007. This VHA directive states that “dialysis care must be provided on an ongoing, long-term basis,” and requires that “[dialysis] should generally be authorized under a contract rather than on a fee for service basis.”

38 CFR § 17.52, governing hospital care and medical services in non-VA facilities, also requires that individual authorizations be used only “[w]hen demand is only for infrequent use.” As VHA Directive 2007-025 acknowledges, dialysis care clearly does not fit under the category of “infrequent use,” and the use of individual authorizations to pay for dialysis care.

Because implementation of the Proposed Rule would effectively mean that negotiated agreements would only be used when the rate obtained thereunder was less than that payable under the applicable Medicare or VA Fee Schedule, it is clear that existing VA contracts with higher than Medicare rates would be allowed to expire at the end of their current base or option year, and that any future “negotiated” procurements would include a VA-dictated rate cap which would render most prospective offerors economically unable to bid.

B. The Proposed Rule’s Overly Simplistic Analysis of Medicare’s Payment Policy Fails To Accurately Anticipate or Capture Effects of Future Changes.

In the Proposed Rule, VA proposes to pay for ESRD services based on 2008 Medicare claims data that reflect the soon-to-be-outdated composite rate and payment rates for separately billable items. The Proposed Rule sets forth a rudimentary analysis of a payment system that failed to consider the myriad clinical, payment and operational changes associated with the pending Medicare prospective payment system (“PPS”) for dialysis services.

In discussing its methodology, VA points out that it edited 2008 claims data to eliminate outliers, and those claims that have more than one unit of service. For dialysis drug claims, VA

¹⁷ *Id.* (emphasis added).

eliminated claims that have only one unit of service. From this basic approach, the VA measured cumulative savings from dialysis providers of up to 39 percent by adopting Medicare rates, and thus concluded that the adoption of Medicare pricing was reasonable “because most health care providers are accustomed to Medicare rates.”¹⁸

There are serious problems with this conclusion and with the underlying proposal to tie dialysis payment to Medicare rates. The proposal does not take into account the complexities associated with significant pending changes to the Medicare end-stage renal disease payment system in 2011, discussed more fully below, which are scheduled to shift providers to a PPS where Medicare pays one “bundled” payment to an ESRD facility for the majority of services provided to a dialysis patient. The Proposed Rule’s conclusions are tied not to the evolving new system (which has yet to be finalized), but to current law that is scheduled to sunset on December 31, 2010, and thereby misstates both the case for savings and provider readiness to adjust to new rates.

In short, a central element of the Proposed Rule’s rationale – that providers are “accustomed” to Medicare rates – is erroneous, given the near-term application of sweeping payment system changes that expose dialysis providers to great financial, operational and clinical uncertainty. Many providers are neither “accustomed to” nor, ready for what will be new Medicare payment policy starting in 2010. In recognition of that uncertainty, the payment system changes are scheduled to be phased in over a four-year transition period, allowing dialysis providers to ease into the new payment regime.

(1) **The Proposed Rule Fails To Consider Medicare’s ESRD Prospective Payment System “Bundle”.**

A core flaw in VA’s proposal is that it does not take into consideration the significant Congressionally-mandated transformation that the Medicare ESRD payment system will undergo in 2011, and the associated complexities for Medicare, providers and patients associated with it.

Medicare currently pays dialysis facilities a predetermined payment for each dialysis treatment furnished, using a payment system first implemented in 1983. The partial prospective payment – called the composite rate – is intended to cover the bundle of services, tests, certain drugs, and supplies routinely required for dialysis treatment and is adjusted to account for differences in case mix and local input prices. At present, the composite rate excludes several injectable drugs – such as erythropoietin, vitamin D, and iron – that have been widely adopted into medical practice over the past two decades. Providers are paid separately for these services. This is the framework upon which the Proposed Rule relies to establish future VA payment amounts, even though the framework itself is only six months away from dramatic, multidimensional reorganization.

¹⁸ *Id.* at 7226.



In 2011, the Medicare ESRD payment system will be broadly transformed to comply with mandates in the Medicare Improvements for Patients and Providers Act of 2008 (“MIPPA”).¹⁹ The MIPPA statute refined and modernized Medicare’s payment policies for outpatient dialysis care and created a full prospective payment system for dialysis care. The law modernized the dialysis payment method by expanding the payment bundle, greatly enlarging the range of items and services subject to it, imposing an automatic across-the-board reduction of 2 percent from newly established rates, introducing incident patient and facility-level adjusters, and instituting a state-of-the-art quality improvement program that has yet to be issued in proposed form by the Centers for Medicare & Medicaid Services (“CMS”), – the entity responsible for implementing the new “bundled” system.

Under the more comprehensive prospective payment system, Medicare would not pay the manufacturer or supplier directly; rather, it would pay the ESRD facility, which then would negotiate a separate payment amount with the supplier or manufacturer for items and services related to the treatment of ESRD. Beginning in 2011, the MIPPA statute mandates that Medicare payment for ESRD will be based on a bundled payment system (*i.e.*, one “bundled” payment to the ESRD facility per-patient per-treatment) that includes:

- (i) items and services included in the composite rate as of 2010;
- (ii) injectable biologicals used to treat anemia – erythropoiesis stimulating agents – and any oral form of such agents;
- (iii) other injectable medications that are furnished to individuals for the treatment of ESRD and are paid for separately under Part B, and any oral equivalent of such medications; and
- (iv) laboratory tests and other items and services furnished to beneficiaries for the treatment of ESRD (excluding vaccines).²⁰

According to CMS’ proposed rule issued September 29, 2009, the costs for these items would form the basis for an unadjusted base rate per patient tied to utilization data from the lowest of three prior years (2007, 2008 or 2009).²¹ The unadjusted base rate would then be subject to a variety of new, untested and operationally complicated payment adjustments, including a standardization adjustment to eliminate overall positive effects of case mix and geographic adjustments; an adjustment to ensure that the outlier policy, which makes additive payments for certain high cost cases, is budget neutral; and an adjustment required by MIPPA that dictates a mandatory 2 percent reduction to ensure that spending under the new system equals 98 percent of that spent under current law.

¹⁹ Pub. L. No. 110-275.

²⁰ Social Security Act (“SSA”) §1881(b)(14)(B) (42 U.S.C. §1395rr(b)(14)(B)).

²¹ 74 *Fed. Reg.* 49922 (Sept. 29, 2009).

The adjusted base rate would then be subject to still other facility and patient level adjustments, including those that adjust the rate for patient case mix (*e.g.*, patient weight, body mass index, a variety of complex comorbidities, and other patient characteristics)²², high-cost patients, and low-volume facilities. Additional adjusters have been proposed or discussed for incident patients for their first 120 days of dialysis therapy, and for patient race. In addition, there will be adjustments for geographic factors, pediatric facilities, and for facilities located in rural areas. All of these adjustments are structurally supported by proposed criteria that in many instances may not be accurate or predictive and may be unduly burdensome and complex to collect and report, both for CMS and providers, depending on how they are finalized.²³ Given the multiple moving policy components that impose substantial new systems and compliance mandates on providers, a multi-year transition policy is included to allow facilities to adjust to the variety of new obligations imposed by the PPS over time. Under MIPPA, dialysis providers will have until 2014 to fully phase in to the new system.

Finally, MIPPA requires the Secretary to develop a Quality Incentive Program (“QIP”) that ties facility payment to a provider’s clinical performance based on established quality measures. The QIP will impose payment reductions to providers that do not meet or exceed a total performance score. Introduction of the QIP marks the first time that CMS has linked financial incentives to beneficiaries’ quality of care, resulting in a payment system tied closely to health outcomes. Importantly, CMS has yet to issue a proposed rule governing these novel payment innovations.

CMS clearly recognizes the complexity of the new ESRD payment system and, as a result, is still developing its final details. The Agency collaborated closely with Congress in developing the MIPPA policy in 2008 and has been at work on implementation since then. Following the release of its proposed rule, CMS sought unprecedented public input from stakeholders over a longer-than-usual, 90-day comment period (issued in explicit recognition of the complexity of issues surrounding the rule and allowing stakeholders additional time to evaluate), and held several formal Agency stakeholder meetings to entertain clinical, operational and legal concerns with its proposed rule. The timing of a final rule has not yet been set.

²² The proliferation of new adjustments for patient case mix is another operational and administrative complexity dialysis providers will confront under Medicare’s new system and an area that CMS will most likely continue to adjust as the new system is implemented. For instance, providers frequently do not have the information to complete claims, either because the diagnostic information required is not available or because the information required is too dated and not within the dialysis facility’s control, resulting in inequitable treatment for patients depending on the availability of prior information alone.

²³ For instance, proposed criteria to identify facilities eligible for the low-volume adjustment are vague and not specific enough to state how facilities would qualify for it. The KCC has urged CMS to consider a different, more distinct and stable set of low-volume criteria that ties the adjustment to low total volume of treatment across all payers, with exceptions for cases of geographic over-capacity, and a measure of Medicare and Medicaid dependence. It is unclear whether CMS will adopt the KCC’s recommendation, or proceed with its more complicated criteria set forth in its proposed rule.



VA's Proposed Rule completely disregards the legal, clinical and operational challenges involved in developing and implementing the new ESRD PPS. By basing VA payments on 2008 Medicare claims data alone, with no recognition of the significant changes pending for the Medicare ESRD payment system, VA's Proposed Rule oversimplifies a complicated and rapidly changing quality-based payment system and fails to identify how it will match and replicate these policy innovations, even as it struggles to effectively manage and make accurate payments under current law,

For instance, VA has reported its own systematic failures in connection with administering the current system. A 2009 report from the VA Office of Inspector General ("OIG"), which was cited in the Proposed Rule, assessed payment accuracy for non-departmental fee-based care, including dialysis services, and concluded that the VHA had not established an adequate organizational structure to support and control the complexities of the program.²⁴ The Report noted that VA improperly paid 37 percent of outpatient fee claims by making duplicate payments, paying incorrect rates, and making other less frequent errors, such as paying for the wrong quantity of services. As a result, the OIG estimated that in Fiscal Year 2008, VHA overpaid \$225 million and underpaid \$52 million to fee providers, or about \$1.126 billion in overpayments and \$260 million in underpayments over five years.²⁵ The OIG notes that VA staff made these payment, justification and authorization errors because VHA lacked an adequate organizational structure to support and control complex programs. Specifically, the OIG cites a failure to develop current and comprehensive fee policies and procedures, identify core competencies and establish mandatory requirements for staff, including clear oversight responsibilities and procedures.

It is difficult to see how VA, lacking the resources and controls identified by the OIG to appropriately administer current payment systems the OIG calls complex, could quickly improve performance, educate and train staff, reduce its error rate and maintain access to quality dialysis services under the new system, which by its nature requires profoundly more complex clinical, operational and technical resources than current law.

With only six months remaining before implementation of the new system, many crucial issues remain unresolved, including ones with important implications like payment for and delivery of oral medications in the dialysis facility and their potential inclusion in the reimbursement bundle, the nature and extent of final patient case mix adjusters that impose significant information collection burdens on providers delivering care, payment for clinical laboratory tests, and the operation and impact of payment adjusters that cumulatively function to force both CMS and facilities to undergo rapid systems changes in order to meet the new system's start date of January 1, 2011. It is unclear whether or how the VA is prepared to administer the complex elements of the new payment system, particularly when CMS itself has yet to resolve these issues or to publish the final rule with respect to the new system.

²⁴ See Department of Veterans Affairs, Office of Inspector General, *Audit of Veterans Health Administration Non-VA Outpatient Fee Care Program*, Report No. 08-02901-185 (Aug. 3, 2009).

²⁵ *Id.* at i.



(2) **Dialysis Facility Economics Are Too Fragile to Absorb the Addition of Thousands of New Patients at Medicare Reimbursement Levels.**

The Proposed Rule fails to consider the unique characteristics of the Medicare ESRD program that result in a challenging economic environment for dialysis facilities. Currently, Medicare payments are inadequate to support provider function. Medicare payments under the current system are made at or below a facility's cost, and most facilities treat high volumes of Medicare patients. Dialysis facilities are disproportionately dependent on Medicare, which, under the new PPS, is scheduled to reduce current rates further still, by two percent in 2011 to account for anticipated efficiency gains associated with the new PPS. Indeed, "nine in ten prevalent hemodialysis patients had some form of Medicare coverage in 2007."²⁶ The remaining proportion of patients has access to private or other insurance coverage. This private or other coverage provides crucial cross subsidization to keep many dialysis facilities open.

The Medicare Payment Advisory Commission ("MedPAC") projected the Medicare margin for dialysis facilities to be 2.5 percent in 2010, but this projection did not take into account the two percent reduction in total spending that MIPPA mandates in 2011, and presumes full collection of the 20 percent co-insurance payment. Nearly 50 percent of those on dialysis are dually eligible for Medicare and Medicaid, and most state Medicaid programs do not pay the full 20 percent co-insurance. MedPAC's analysis also fails to consider and account for many additional necessary costs, as their analysis is limited to Medicare "allowable" costs. In short, the current and future economic environment for dialysis facilities with high Medicare dependence is unstable.

VA's proposal to tie its payment rates to Medicare exacerbates these precarious economics. It enlarges the pool of patients for whom Medicare rates will apply, endangering and threatening dialysis facility function. VA's authority to adjust the dialysis facility patient mix on its own is without foundation. Imposing Medicare rates on 1,888 providers and the 10,500 veterans they serve will have significant financial consequences, especially for small providers less able to manage disturbances in payer mix created by the Proposed Rule.

C. The Proposed Rule Would Interfere with VA's Mission to Provide Health Care to Veterans and Hinder Access to Care.

The provision of health care to veterans is a core Veterans Administration mission. According to the VHA mission statement, VA "serve(s) the needs of America's veterans by providing primary care, specialized care, and related medical and social support services. To accomplish this mission, VHA needs to be a comprehensive, integrated healthcare system that provides excellence in health care value, excellence in service as defined by its

²⁶ United States Renal Data System ("USRDS"), *2009 USRDS Annual Data Report ("ADR"), Volume Two: Atlas of End-Stage Renal Disease in the United States* at 258.

customers, and excellence in education and research, and needs to be an organization characterized by exceptional accountability and by being an employer of choice.”

Dialysis facilities share that mission to provide quality care to our nation’s veterans. Dialysis facilities operate, however, as willing providers, and are not obligated to provide dialysis care to veterans. Furthermore, facilities themselves do not admit patients; they only admit dialysis patients who are referred by nephrologists.

Currently, dialysis providers are able to serve VA patients because, in most cases, the VA rates cover the costs of the services provided. The same is not true of Medicare. If the Proposed Rule is implemented, and Medicare rates become the norm, the VA reimbursement rate would be less than the providers’ cost, and most current providers would decline to either bid on a VA contract that includes the cost limitation envisioned by the Proposed Rule, or to accept patients via individual authorizations.

Dialysis is a service VA is required to provide as part of the veterans medical benefits package.²⁷ Dialysis is a limited resource within VA’s health care system and, therefore, the VA is largely dependent on the private sector to provide this service to veterans.²⁸ The importance of this relationship between the VA and private sector dialysis providers is starkly illustrated by the analysis included in the Proposed Rule: in Fiscal Year 2008, 1,888 health care providers furnished dialysis to 10,500 veterans.²⁹ These numbers demonstrate that VA cannot provide dialysis care without the support of the private sector. The Proposed Rule would impose an economically unstable payment regime on private sector dialysis providers, and jeopardize the care of thousands of veterans per year.

VA’s own experience with dialysis demonstrates that the private sector is more effective, and more cost efficient, at providing dialysis services than VA. For example, the Agency’s Washington DC VA Medical Center chronic dialysis unit closed, at least in part due to cost and resource limitations. We note that the financial analysis in the Proposed Rule contains no data on the costs to VA of running its own dialysis units. No action should be taken on the Proposed Rule until VA makes a complete disclosure of its own costs, and the proposed payment schedule under the Proposed Rule is placed in the context of those costs.

The wholesale adoption of Medicare rates by the VA disturbs the fragile economic foundation supporting dialysis providers by enlarging the pool of patients for which Medicare rates would apply. By expanding the reach of the Medicare rate structure that pays providers at or below cost, the Proposed Rule creates an unintended consequence in the likely outcome of a facility’s decision to stop admitting veterans, forcing them to seek care at potentially greater distances from their homes, thereby compromising patient adherence to treatment schedules and clinical outcomes. In a well established study of 20,994 dialysis patients prepared in the

²⁷ Veterans Health Administration Directive 2007-025, Sept. 12, 2007.

²⁸ *Id.*

²⁹ *See 75 Fed. Reg. 7218 at 7224-25.*

American Journal of Kidney Diseases in 2008, researchers concluded that the time required to travel to dialysis therapy adds considerable burden to dialysis patients, and longer travel time is associated significantly with greater mortality risk and decreased health-related quality of life for patients.³⁰

Without proper funding, providers' ability to continue delivering adequate services to veterans will be compromised by the Proposed Rule. Unprofitable facilities may close, limiting patient access to care, or increased industry consolidation will occur to keep less profitable facilities open. Patients displaced by closed facilities or involuntary discharge will report to hospital emergency rooms, increasing the volume at hospital-based facilities to a level that may be unsustainable.

CMS is nearing the end of a long process aimed at transforming the ESRD payment system, and is continuing to work to ensure that the new system improves care for vulnerable beneficiaries on dialysis. VA's Proposed Rule would represent a step back from the progress that has been made in previous years in ensuring widespread access to this lifesaving therapy.

III. CONCLUSION AND RECOMMENDATIONS

The Proposed Rule undermines VA's own statutory mandate to contract with private sector health care providers for non-departmental services, such as dialysis care. As set forth above, the KCC and KCP believe the Proposed Rule is problematic since it (1) fails to establish specific authorities allowing VA to limit reimbursement for non-emergency medical services; (2) violates obligations under federal procurement law; and (3) fails to adequately follow its own program guidance relating to the provision of non-VA dialysis care. Moreover, the Proposed Rule fails to consider the myriad changes in payment and regulatory policy and clinical practice for dialysis facilities arising out of the new PPS, and, by extending the reach of Medicare's rates to over 10,000 new patients, jeopardizes fragile facility economics that risk constriction or closure as a consequence. Very importantly, we are concerned about the significant hardship it would impose on veterans receiving dialysis at non-VA hospitals. Accordingly, we believe the Proposed Rule should be withdrawn.

The Medicare ESRD program is one of CMS' most complex, evolutionary and challenging payment and regulatory systems. If VA desires to reduce costs by promulgating rules related to fee basis services, dialysis care is the wrong place to start. The impact of the Proposed Rule (or analogous rulemaking) on simpler, fee schedule-dependent categories of services like clinical laboratories and outpatient surgeries, that are tied to fixed amounts without complex adjustments or clinical performance measurements, should be demonstrated before dialysis care is brought under this rubric.

³⁰ Moist, et al. *Travel Time to Dialysis as a Predictor of Health-Related Quality of Life, Adherence, and Mortality: The Dialysis Outcomes and Practice Patterns Study (DOPPS)*; 51 AMERICAN JOURNAL OF KIDNEY DISEASES, No. 4 (April 2008) pp. 641-650.



If VA feels the Department has the legal standing to finalize this Proposed Rule, a conclusion the KCC and KCP feel is unsupported, VA should evaluate and study the impact and effect of the Medicare PPS on providers and patients, and defer its own adoption of the Medicare payment system until the completion of MIPPA's four year transition period in 2014 and the impact of the new Medicare PPS on both patients and providers has been fully assessed. Until then, VA should continue contracting as it does under the current fee care program for dialysis services with providers

The KCC and KCP appreciate your consideration of our comments, concerns and suggestions regarding the Proposed Rule. If you have any questions or would like to discuss further any of the issues we presented here, please do not hesitate to contact Cherilyn Cepriano at (202) 744-2124 for the Kidney Care Council or Kathy Lester (202) 457-6562 for Kidney Care Partners.

Sincerely,

Christopher Ford
Kidney Care Council

Kent Thiry
Kidney Care Partners