



The Voice of All Kidney Patients

September 12, 2005

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Kent Thiry
Chairman, Kidney Care Partners
c/o DaVita, Inc.
601 Hawaii Street
El Segundo, CA 90245

Dear Kent,

I am writing to inquire about Kidney Care Partners' (KCP) position on AAKP's recent proposal to Congress to provide bonus incentive payments under Medicare to physicians (and other qualified health professionals) and dialysis facilities for establishment, management, and maintenance of AV fistulas.

Let me also take this opportunity to request KCP's views on certain other matters. First, AAKP is considering taking a public position on S. 635/H.R. 1298, the "Kidney Care Quality and Improvement Act of 2005" – and, of course, we need a thorough understanding of all 12 sections.

Second, AAKP is interested in KCP's position on an improved reimbursement system for "critical access" rural and inner city dialysis clinics. AAKP has long supported "cost plus" reimbursement for such clinics – in addition to our support for composite rate increases. Although there is apparently no systematic data on access to dialysis by rural and inner city patients, we are concerned by an ongoing spate of press reports of clinic closures in those areas.

AAKP and KCP Fistula Legislative Proposals

On August 24, 2005, AAKP wrote to the Chairs of the Congressional Committees with jurisdiction over Medicare with a proposal for bonus payments to physicians (and other qualified health professionals) and dialysis facilities for establishment, management, and maintenance of AV fistulas. Detailed information on the AAKP proposal – including the letters to the Committee Chairs – is available on our website.

We are concerned that some in the dialysis industry may be lobbying Congress *against* this proposal. In the current issue of the health trade publication, *Inside CMS* (9/8/05), a "dialysis provider representative" was quoted as follows – "We would not support decoupling the provision from the legislation [i.e., AAKP's stand-alone fistula proposal outside KCP's S. 635/H.R. 1298]. ... The [fistula] provision is included in the bill [S. 635/H.R. 1298] to achieve savings along with an automatic update."

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We have two questions regarding fistula legislative proposals. First, what is KCP's position on AAKP's fistula bonus payment proposal? Second, how does Congress view KCP's fistula proposals – specifically, is section 101 of S. 635/S. 1298 acceptable to Congress and scores savings? Stated otherwise, which proposal is better, or are the proposals perhaps complementary?

With regard to S. 635/H.R. 1398, section 101 is entitled, “Modification of Physician Surgical Reimbursement for Dialysis Access Procedures to Align Incentives for Cost and Quality,” and has two provisions:

The first provision (sec. 101(a)) would direct the Centers for Medicare and Medicaid Services (“CMS”) to evaluate whether “the full range of dialysis access procedures” should be covered by ambulatory surgical centers (“ASCs”). Given that section 1833(i)(1) of the Social Security Act already requires CMS “to specify ... surgical procedures that can be safely performed in an ASC and to review and update the list of ASC procedures at least every two years” – and, in fact, the most recent ASC coverage revisions were published in May 2005¹ – has KCP pursued this regulatory option – and with what success?

The second fistula provision (sec. 101(b)) requires CMS to “review the relative value units (“RVUs”) determined under section 1848(c)(2) of the Social Security Act that are applicable with respect to physicians’ services for vascular access procedures; and ... revise such units to accurately reflect the difficulty of such procedures.”

If we understand this provision correctly, Congress would direct CMS, in effect, to bypass the established annual American Medical Association (“AMA”) and Medicare regulatory process for revising CPT codes and rebasing CPT RVUs. (In any case, couldn't CMS accomplish this by substituting “G” codes?) Is the AMA on board with this proposal? Has KCP pursued the regulatory alternative – and with what success?

Let me note that AAKP supports revamping Medicare payments under the physician fee schedule for accesses – our question is whether Congress will even consider section 101.

Lastly, assuming Congress would adopt section 101, has CBO scored savings?

AAKP's proposal for bonus incentive payments may be simpler and more feasible. Moreover, given AAKP's strong belief that patients have already waited too long for fistulas – after all the definitive work establishing fistulas as the superior form of access was done over a decade ago – we believe action is needed sooner rather than later. Indeed, without CMS's leadership with the “Fistula First” initiative, would we even be having this discussion?

One more point. If AAKP's fistula proposal does score savings, AAKP believes a community-industry dialogue on strategy would be important. Certainly, AAKP would be open to supporting reallocation of savings to dialysis facility payment increases, but we also hope all parties would recognize the unmet health care needs of kidney patients. Of course, Congress is the actual decision maker here.

Other Provisions of S. 635/H.R. 1298, the “Kidney Care Quality and Improvement Act of 2005”

First, let me state – again and for the record – that AAKP strongly supports proper reimbursement of the nation's dialysis facilities. In particular, AAKP supports an “automatic” update to the composite rate.

However, as you know, AAKP's longstanding position is that reimbursement must be linked to quality. Isn't it just commonsense that any organization that represents patients would hold this view – and any organization that does not cannot credibly claim to represent patients?

¹ “Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures,” Interim Final Rule [CMS-1478-IFC], 5/4/05 (70 CFR 23690); www.cms.hhs.gov/suppliers/asc/1478_42805.pdf.

But AAKP's view on linking reimbursement to dialysis quality is also tactical. In 2003 and 2004, when AAKP discussed KCP membership with Gambro CEO Larry Buckelew and others, we repeatedly made the point that in dealing with Congress and CMS every health care provider – including dialysis facilities – would have to step up on the quality issue.² For example, in Medicare Modernization Act of 2003 (“MMA”), Medicare hospital updates were made contingent on quality data reports for the first time.

If AAKP's position on linking quality and reimbursement looked “radical” in 2003, today it's mainstream, even downstream. For more detail on AAKP's perspective on reimbursement lobbying, please see my article, “The quality imperative: Why the kidney community must take charge,” published in *Nephrology News and Issues*.³ This article was based in part on our debriefing of Hill and dialysis industry representatives on why the industry did not receive more reimbursement consideration in MMA.

Turning now to questions and comments on other specific provisions of S. 635/H.R. 1298:

- **Sec. 102—Demonstration Project for Outcomes-Based ESRD Reimbursement System.** Under section 102, Congress would mandate CMS to “establish demonstration projects ... [to] evaluate methods that improve the quality of care provided to Medicare beneficiaries with end-stage renal disease.” CMS shall provide “financial incentives” to improve quality, and pay “particular attention to improved patient safety, better vaccination rates, and improved care for diabetes.”

This proposed mandate is incremental to CMS's existing demonstration authorities – and active ESRD demonstration projects. CMS has broad demonstration project authority (see 42 U.S.C. § 1395b–1), in addition to other specific authorities provided by Congress in recent years. Indeed, CMS invites unsolicited demonstration project proposals.⁴

Re existing ESRD demonstration projects, CMS: (1) recently announced an award to RMS DM, LLC (DaVita subsidiary), to prevent further development of illnesses among beneficiaries with chronic kidney disease which may lead to further complications and ESRD⁵; (2) is expected to announce awardees for its ESRD disease management demonstrations, to test payment and delivery models for more efficient and coordinated care and improved quality to ESRD patients;⁶ and (3) publish shortly draft RFP for demonstration projects of a bundled case-mix adjusted payment system.⁷

Two questions. First, although new ESRD demonstration authority for CMS may have value (here and sections 301 and 302, below), is this what kidney patients really need – or should the priority be more consistent application of proven treatments and technologies? Think fistulas and mineral metabolism for starters. Indeed, the three priorities listed in section 102 – vaccinations, patient safety, and diabetes management – already appear superseded by other CMS initiatives.

In this regard, in October 2003 AAKP proposed a “National Commission on Improved Kidney Patient Outcomes,” to develop a coherent roadmap for improving kidney patient outcomes. We urge KCP's support for this project.⁸

² The Bush Administration made its first major statement re revamping Medicare, entitled “21st Century Medicare,” in July 2001. That statement includes a commitment to improving quality of care in Medicare. Link:

www.whitehouse.gov/news/releases/2001/07/medicare.html

³ Link: www.aakp.org/AAKP/Forms/BrendaNNI.pdf

⁴ Link: www.cms.hhs.gov/researchers/priorities/how_to_kit.pdf

⁵ Link: www.cms.hhs.gov/media/press/release.asp?Counter=1499

⁶ Link: www.cms.hhs.gov/researchers/demos/esrd_demo.asp

⁷ Link: www.cms.hhs.gov/faca/esrd/default.asp

⁸ www.aakp.org/AAKP/pr2003.htm#AAKP%20CALLS%20FOR%20DIALYSIS%20QUALITY%20COMMISSION%20IN%20RESPONSE%20TO%20GAO%20REPORT

Indeed, AAKP supports the Grassley-Baucus Medicare Value Purchasing Act of 2005 (S. 1356) in part because this legislation promises a more comprehensive approach to identifying quality opportunities.

Second, under the plain language of section 102, CMS could presumably use payment withhold as a “financial incentive”? Is this KCP’s intent?

- **Sec. 103—Required Training for Patient Care Dialysis Technicians.** Section 103 generally requires dialysis technicians complete a training program; be certified by a nationally recognized certification organization for dialysis technicians; and otherwise be competent to provide dialysis-related services.

AAKP is on record as supporting technician training and certification.⁹ And from an initial reading of comments submitted in response to CMS’s proposed dialysis facility conditions of coverage, there appears to be broad support in both the dialysis industry and in the kidney community for technician training and certification. Again, isn’t this a matter of commonsense – indeed, where else in medicine are individuals without any formal training allowed to provide a medical service with the responsibility and skills required of dialysis technicians?

Yet, if CMS includes a technician training and certification requirement in the final rule on the dialysis facility conditions of coverage, might this provision also be superseded?

- **Sec. 201—Establishment of Annual Update Framework for Medicare ESRD Composite Rate.** Section 201 would increase the composite rate by 2.5 percent in 2006; provide for an annual increase or update of less than full marketbasket from 2007 through 2014; and in 2014 and thereafter provide annually a full marketbasket update. In addition, this section would permit CMS to increase the composite rate to account for certain other costs in providing dialysis services.

Frankly, we found the provision that the industry would accept updates for seven years (through 2014) at less than marketbasket surprising – and perhaps unsustainable, given the Medicare Payment Advisory Commission’s finding in 2005 that in aggregate industry margins are negative.¹⁰ Have we understood this provision correctly?

We assume that the decision to accept less than marketbasket – even in a bill that is simply a marker – was a tactical decision. However, AAKP reserves the right to endorse only full marketbasket updates – of course, in conjunction with quality.

Let me also note that in AAKP’s comments to CMS on conditions of coverage, AAKP encouraged CMS to reimburse dialysis facilities for any incremental services required by kidney patients identified by the rule (see FN 9 for link). For example, these services might include improved infection control, use of consultant pharmacists, a shift to ultrapure dialysate, and elimination of dialyzer reuse.

We have a number of purely technical questions about this section that we will pose to KCP staff.

- **Sec. 202—Extension of Medicare Secondary Payer.** This provision would extend the period for which Medicare is the “secondary payer” for a Medicare beneficiary with ESRD who has certain group health insurance coverage from current law 30 months by an additional three months, to 33 months.

AAKP has had a mixed view about secondary payer extensions. On the one hand, private health insurance coverage may provide a better benefit to kidney patients; on the other, AAKP has been concerned that secondary payer extensions could accelerate loss of private coverage. In 2003, AAKP recommended to Washington representatives of the dialysis industry that the industry commission a study of the impact on private insurance

⁹ See AAKP’s comments on dialysis facility conditions of coverage: www.aakp.org/AAKP/Advocacy/conditionscommentsletter.pdf

¹⁰ See www.medpac.gov/publications/congressional_reports/Mar05_Ch02e.pdf

coverage with secondary payer expansions – after all, we thought the industry also would want to be assured that private coverage remains intact. Although that suggestion was not taken, we again encourage you to investigate this issue.

- **Sec. 203—GAO Study and Report on Impact of G-Codes.** This provision would direct the Government Accountability Office (“GAO”) to study “the impact of the temporary codes for nephrologists’ services applicable under the fee schedule for physicians’ services” (commonly known as “G-codes”). Does KCP support the principle that physicians should deliver a service in order to be paid by Medicare?
- **Sec. 301—Support of Public and Patient Education Initiatives regarding Kidney Disease.** Section 301 would mandate two other Medicare demonstration projects – (1) one to increase public awareness about prevention of kidney failure; and (2) another to enable individuals with ESRD to develop self-management skills. Again, in line with our comments on section 102, AAKP wonders if these initiatives should be actual programs, not demonstrations.
- **Sec. 302—Medicare Coverage of Kidney Disease Patient Education Services.** Section 302 has two provisions. One provision would provide 6 sessions of kidney disease education to Medicare beneficiaries expect to require transplant or dialysis; the other would establish a demonstration program on how blood flow monitoring affects the quality and cost of care for ESRD beneficiaries.

Regarding the patient education proposal, do you think this might be expanded to include peer training – and how have you rebutted criticism that health professionals and dialysis facilities are already compensated to provide such education services?

Regarding the blood flow demonstration project, we require more information, but if this is a service required by kidney patients, Medicare should pay for it – period.

- **Sec. 401—Improving The Home Dialysis Benefit.** Needless to say, AAKP is a strong advocate of home dialysis options. However, CMS already has broad authority under section 1881(e) and (f) of the Social Security Act to pay for home equipment and ancillary costs and conduct demonstrations. How would this provision expand that authority?
- **Sec. 402—Institute Of Medicine Evaluation and Report on Home Dialysis.** This assignment might be delegated to the “National Commission on Improved Kidney Patient Outcomes,” described above.
- **Sec. 403—End-Stage Renal Disease (ESRD) Advisory Committee.** We are reviewing this provision.

Access and Reimbursement for Critical Access Facilities


As noted above, AAKP is interested in KCP’s position on an improved reimbursement system for “critical access” rural and inner city dialysis clinics. AAKP has long supported “cost plus” reimbursement for such clinics – in addition to our support for composite rate increases. Although there is apparently no systematic data on access to dialysis by rural and inner city patients, we are concerned by an ongoing spate of press reports of clinic closures in those areas.

In 2003, our Washington representative approached a number of industry and community organizations to support a separate payment system for “critical access” dialysis facilities, only to be told a composite rate increase was the industry’s sole priority. We thought this was shortsighted – if only given the large number of rural States, and again urge careful thought to the unique needs of such dialysis facilities.

In closing, AAKP appreciates KCP's interest in quality care for the nation's kidney patients. AAKP believes – as I am sure you do – we are all more likely to succeed when patients and providers work together. If you have any questions, please feel free to contact me (bdyson@aakp.org); Kris Robinson, AAKP's Executive Director/CEO (krobinson@aakp.org); or AAKP's Washington representative, Dr. Alexander Vachon (avachon@hamiltonppb.com).

And on behalf of both AAKP and myself, I thank you and your dialysis industry colleagues for your outstanding efforts during the Katrina crisis. I live in Mississippi and work on a daily basis with dialysis patients – the need here has been tremendous.

Sincerely yours,

A handwritten signature in black ink that reads "Brenda Dyson". The signature is written in a cursive, flowing style.

Brenda Dyson

President

American Association of Kidney Patients