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**BY FEDEX AND ELECTRONIC SUBMISSION**

May 4, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-3818-P  
PO Box 8012  
Baltimore, MD 21244- 8012

**Subject: CMS-3818-P, Comments Regarding Conditions for Coverage for End-Stage Renal Disease Facilities; Proposed Rule**

Dear Dr. McClellan:

On behalf of the American Association of Kidney Patients (“AAKP”), I am writing to comment on the proposed rule for end-stage renal disease (dialysis) facilities (CMS-3818-P), published in the *Federal Register* on February 4, 2005. Below, we briefly describe AAKP, and then provide AAKP’s comments.

• **About the American Association of Kidney Patients (AAKP)**

**Background.** The American Association of Kidney Patients (AAKP) ([www.aakp.org](http://www.aakp.org)) was founded in 1969, and is the nation’s only education and advocacy organization for people with kidney disease both patient-led and managed. Each year, AAKP serves over 12,000 members and, through its programs, hundreds of thousands of other Americans who have either lost kidney function (and live with dialysis or transplant) or have chronic kidney disease (CKD). The *average* life expectancy for individuals following initiation of dialysis therapy is short, about 5 years. But AAKP’s membership includes many long-term dialysis survivors, who live full and productive lives through aggressive attention to their health care, a core mission of AAKP. Indeed, most kidney patients face not only the challenge of kidney disease, but other medical conditions as well, such as diabetes and hypertension.

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**AAKP's General Principles in Evaluating Public Policies.** AAKP reviews proposed government policies with respect to several core principles: Will the proposed policy improve access, quality and outcomes, and affordability of care to America's kidney patients, and does the proposed policy respect the principle that *the physician and patient make a joint determination of the care plan best suited for that patient?*

- **AAKP's Comments on the Proposed Dialysis Facility Conditions of Coverage (CoC)**

AAKP first provides general comments on the proposed rule, followed by comments on specific provisions.

1. **General Comments on Proposed Rule.**

AAKP commends the Centers for Medicare and Medicaid Services ("CMS") for undertaking comprehensive revision of the dialysis facility conditions of coverage (CoC), which have not been fully revised since their initial publication in June 1976 – 29 years ago. AAKP notes that under the Medicare statute CMS has *broad plenary authority* to prescribe regulations that providers of dialysis services must meet in order to qualify for Medicare payment.<sup>1</sup>

**Nine points:**

***First, AAKP believes that revising the dialysis facility CoC should occur more frequently than every 29 years. At a minimum, AAKP recommends CMS publish in the Federal Register a notice requesting public comment on the need to revisit the dialysis facility CoC every three years – in addition, of course, to using voluntary consensus bodies to establish or update clinical performance measures and technical expert panels to address important issues; and the formal and informal advice CMS receives from kidney community stakeholders on an ongoing basis.***

***Second, AAKP encourages CMS to issue the final rule on the updated CoC as soon as possible.*** Although the Medicare Modernization Act apparently only requires final rules be published within 3 years of the proposed rule, CMS can and should act more quickly – perhaps within the minimum required 60 days.

***Third, AAKP recommends CMS solicit the help of patients and kidney health professionals – physicians, pharmacists, nurses, technicians, social workers, and administrators – in drafting the interpretative guidelines, which “operationalize” the rule and are used by State survey and certification in determining compliance.***

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<sup>1</sup> See Section 1881(b)(1) of the Social Security Act for general authority, and 1881(f)(7) for specific authority related to reuse of dialyzers. Sections 1881(b)(5)(B) through (D) provide CMS with broad authority to obtain data from dialysis providers. Section 1881(c) establishes ESRD network organizations to assure that dialysis patients are provided appropriate care.

***Fourth, AAKP supports CMS's move to CoC that are patient-centered, evidence-based, and outcomes-oriented, with clear expectations for dialysis facility accountability and a facility process for quality improvement. AAKP is encouraged that patient participation in care planning and implementation is strongly encouraged by the proposed rule<sup>2</sup>, with a focus on both medical care and rehabilitation. AAKP also describes below the importance of psychological services.***

In this regard, CMS describes the rulemaking as a “fundamental shift in our regulatory approach,” from one that is highly prescriptive to one focused on outcomes.<sup>3</sup>

**Among other advantages, this approach can provide dialysis facilities with the flexibility to innovate. AAKP recommends that CMS develop a process to identify dialysis facility innovations that improve care, and to publicly recognize and encourage dialysis facilities to share innovative “best practices.”**

**Of course, any shift to outcomes depends on measures and standards. An important initiative in this regard is the updating, revising, expanding, and reporting of clinical performance measures (CPM).<sup>4</sup>** Currently, CMS has identified three CPMs – dialysis adequacy, anemia management, and vascular access<sup>5</sup> – which are reported for a 5-percent sample.<sup>6</sup> CMS states its intention in the proposed rule “to propose ESRD performance standards that dialysis facilities would be *required* to meet *as well as* propose a method to recognize updates in existing consensus-based patient-specific performance measures”<sup>7</sup> (italics added).

**AAKP endorses CMS's commitment to CPM requirements and to expand the minimum performance standards for dialysis facilities.<sup>8</sup>** CMS apparently intends to identify a “voluntary consensus body” (or bodies) to develop additional measures and standards. Any new performance measures would be evaluated by CMS, and those standards that meet CMS's “needs for the effective administration of the ESRD program” would be adopted through additional rulemaking.<sup>9</sup> AAKP recommends that CMS be proactive in this process and that CMS fund the work of any voluntary consensus body. In 1994, CMS's initiative was essential to prompting development of the current CPMs (originally the ESRD Core Indicators Project).

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<sup>2</sup> See, e.g., § 494.70

<sup>3</sup> 6187.

<sup>4</sup> CMS's interest in clinical performance measures is discussed at 6188-6190, and 6231-6232.

<sup>5</sup> Link: [www.cms.hhs.gov/esrd/1d.pdf](http://www.cms.hhs.gov/esrd/1d.pdf)

<sup>6</sup> See 6189

<sup>7</sup> 6190

<sup>8</sup> 6232

<sup>9</sup> 6190

**CMS is concerned, however, that performance standards could encourage “cherry picking” and discourage facilities from accepting resource-intensive patients. CMS should examine which factors or patient characteristics require more resources, including staff time, and consider facility-based adjusters, in addition to or as an alternative to case-mix adjusters.<sup>10</sup>**

***Fifth, AAKP believes that conditions, standards, and measures are only as effective as surveillance and enforcement.*** In 2003, Senator Charles Grassley<sup>11</sup> and the General Accounting Office<sup>12</sup> advised CMS on deficiencies in State survey and certification for dialysis facilities – and AAKP asks how much progress CMS is making in addressing those concerns. **AAKP endorses prompt implementation of planned improvements in the CMS ESRD information systems over the next 2 to 3 years, as described in the proposed rule, which will allow better monitoring of the quality of care.<sup>13</sup>**

***Sixth, AAKP wishes to emphasize that there can be no quality dialysis care without access to dialysis.*** As noted below (“Definitions” and “Condition: Care at Home”), access has been an issue for dialysis patients requiring nursing home care. Although outside the scope of the proposed rule, AAKP is deeply concerned about the lack of data about access in rural and inner city areas, and encourages CMS to contract with a network organization or other appropriate entity to examine this issue and draft recommendations on geographic access standards. Such information might be very useful to Congress, which has, for example, addressed the issue of access to hospital care in rural areas by enacting the Medicare critical access hospital program.

***Seventh, CMS should also develop cost estimates and reimburse dialysis facilities for any additional services required by kidney patients identified in this rule.*** For example, in our comments below, AAKP recommends improved infection control, the use of consultant pharmacists, a shift to ultrapure dialysate, and the elimination of dialyzer reuse.

***Eighth, although outside the scope of the proposed rule, AAKP endorses the concept of “pay for performance” (P4P), under which reimbursement for health and rehabilitation services for kidney patients – including dialysis -- is linked to quality of care.*** As AAKP President Brenda Dyson noted in a recent article, “Just like every other American, [AAKP’s] members expect accountability and quality in any purchase

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<sup>10</sup> 6232

<sup>11</sup> Grassley letter to HHS Secretary Tommy Thompson, November 6, 2003, Link: <http://finance.senate.gov/press/Gpress/2003/prg110603.pdf>

<sup>12</sup> General Accounting Office, “Dialysis Facilities: Problems Remain in Ensuring Compliance with Medicare Quality Standards”; Washington, DC, October 2003. Link: [www.gao.gov/new.items/d0463.pdf](http://www.gao.gov/new.items/d0463.pdf)

<sup>13</sup> 6198-6190, 6231-6232

decision, including their health care services. Isn't that just common sense?"<sup>14</sup>

**Moreover, P4P can provide incentives for quality, and is a more sophisticated tool than the sanctions permitted under current law for dialysis facilities who are not in compliance with regulations.**<sup>15</sup>

*Lastly, AAKP again raises the call for a "National Commission on Improved Kidney Patient Outcomes."* Mortality rates in ESRD are unacceptably high, and there is substantial evidence that patients do not receive all needed medical care. Although dialysis treatment is an essential element in the care plans of the nation's ESRD patients, quality medical care requires broad multidisciplinary coordination of medical care (given that many patient's have multiple medical conditions, which often are not fully treated). There are also many other opportunities to improve care and reduce costs to Medicare, including slowing the progression to ESRD among chronic kidney disease patients (CKD), better chronic disease management, advances in new technology and biomedical solutions, more transplantation, and improved patient education.

## **2. Comments on Specific Provisions of the Proposed Rule.**

### **I. General Provisions (Part 494—Subpart A)**

#### **A. Definitions (§ 494.10)**

**Definition of "Home Dialysis" in an Institutional Setting.** At 6191, CMS requests comment on whether the definition of "home" for "home dialysis" should also include institutional settings such as nursing homes. In AAKP's view, the term "home dialysis" is properly reserved for dialysis care in a personal home – although as described below, following additional research, CMS may wish to craft a new definition for "institutional home dialysis."

Typically, home dialysis patients are highly motivated and assume direction for their care; in addition, a home patient is typically the only person receiving dialysis in the "home".

Nursing home patients are simply a different group of patients. Indeed, CMS makes this point under the preamble section entitled "Dialysis of ESRD Patients in Nursing Facilities and Skilled Nursing Facilities" (pp. 6212 et seq.):

In the current ESRD regulations, the home dialysis training requirement presents a significant barrier in providing home dialysis to NF or SNF residents as the

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<sup>14</sup> Brenda Dyson, "The quality imperative: Why the kidney community must take charge", *Nephrology News and Issues*, October 2003, 98-99.

<sup>15</sup> For current sanctions for noncompliant facilities, see Section 1881(g) of the Social Security Act. See also proposed rule, "Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End State Renal Disease (ESRD) Facilities", at 6245-6246

patient may be untrainable and may not have a ready caregiver who could be co-trained to assist the resident in performing dialysis. ... We have received correspondence requesting that the home-dialysis training requirement be waived for NF or SNF residents. It has been our longstanding policy to encourage home dialysis. We are also aware of the current limitations relative to severely debilitated patients who are ineligible for home dialysis based on the training requirement. Given the relative acuity of nursing home patients, there are safety concerns associated with allowing patients in nursing homes to be home dialysis patients. These patients may be less able to voice symptoms/problems than the typical ESRD home patient. In addition, the dialysis care of a patient who requires nursing home services may be more complex than the dialysis care of an independent home dialysis patient, and given their frailty, these patients may be more vulnerable than an independent home dialysis patient. Because of this, we have significant safety concerns about encouraging home dialysis, provided by multiple caregivers, who may not have any dialysis experience, in this setting.

Nonetheless, as we discuss more fully below, under “Condition: Care at Home (Proposed § 494.100)” there may be valid reasons for providing “home dialysis” at an “institutional home.” From a plain reading of the statute, CMS has broad authority to provide a higher payment for home dialysis – e.g., which includes equipment purchase.<sup>16</sup> Higher payment may be appropriate because nursing home patients may be more expensive, both because of the small numbers per facility and also because such patients may require more intense services to successfully dialyze. Indeed, higher payment might improve access to nursing homes for ESRD patients, which has been a persistent problem, according to the Inspector General of the U.S. Department of Health and Human Services.<sup>17</sup>

AAKP’s concern is that “home dialysis” should not be a pretext for a lesser standard of dialysis treatment for ESRD patients living in an institutional home. AAKP’s notes that crafting an informed “institutional home dialysis policy” requires better data about the number (and future number) of patients in nursing homes (and other institutions such as assisted living or rehabilitation centers) who need dialysis – and under what arrangements dialysis is provided today. For example, some nursing facilities have established cooperative ventures with a local dialysis provider, serving as “landlord” to a program established on-site.<sup>18</sup>

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<sup>16</sup> See Sec. 1881(f) of the Social Security Act.

<sup>17</sup> Office of Inspector General, U.S. Department of Health and Human Services, “Medicare Beneficiary Access to Skilled Nursing Facilities: 2000”; Washington, DC, 2000. Link: <http://oig.hhs.gov/oei/reports/oei-02-00-00330.pdf>

<sup>18</sup> See, e.g., Robert MacKreth, “Developing an On-Site Dialysis Treatment Center” (Adapted from the submission by the Glengariff Health Care Center, Glen Cove, NY), 2001. Link: [www.nursinghomesmagazine.com/Past\\_Issues.htm?ID=393](http://www.nursinghomesmagazine.com/Past_Issues.htm?ID=393)

**AAKP recommends that CMS should contract with a network organization to convene a technical expert panel (TEP) to revisit CMS's interim guidance<sup>19</sup> and survey this matter. The TEP may wish to consider drafting a new definition and provide recommendations regarding "institutional home dialysis" that address both the quality and payment issues discussed above.**

AAKP revisits these comments below under the section "Condition: Care at Home (§ 494.100), below.

**B. Compliance With Federal, State, and Local Laws and Regulations (§ 494.20)**

1. **Comment.** AAKP supports the requirement that dialysis facilities be in compliance with all Federal, State, and local laws and regulations, including, of course, participation in the quality improvement activities of the ESRD networks.<sup>20</sup>
2. **Off-Label Drug" Use.** CMS is "proposing that dialysis facilities must be in compliance with the appropriate Federal, State, and local laws and regulations regarding drug and medical device usage."<sup>21</sup> AAKP asks that this provision be clarified to ensure that physicians are not restricted from appropriately prescribing Part B covered drugs in a dialysis facility, including "off label" use of such drugs.

**II. Patient Safety (Proposed Part 494—Subpart B)**

**A. Condition: Infection Control (§ 494.30)**

1. **Proposal for Infection Standard and Reporting.** Effective infection control is essential to patient well-being, but infection is a serious problem among kidney patients, according to United States Renal Data System.<sup>22</sup> **AAKP recommends improved infection surveillance – specifically: (1) data elements regarding septicemia and infection specified in the core data set should be implemented forthwith; (2) that CMS should consider establishing an appropriate clinical performance measure or standard; and (3) public reporting of facility infection rates on Dialysis Facility Compare.**

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<sup>19</sup> "Clarification of Certification Requirements and Coordination of Care for Residents of Long-Term Care (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services" (March 19, 2004). Link: [www.cms.hhs.gov/medicaid/survey-cert/sc0424.pdf](http://www.cms.hhs.gov/medicaid/survey-cert/sc0424.pdf)

<sup>20</sup> See Sec. 1881(c) of the Act regarding the authority of ESRD networks to conduct quality improvement initiatives.

<sup>21</sup> 6191

<sup>22</sup> See United States Renal Data System, "Chapter 6—"Outcomes: hospitalization & mortality," 2004 *USRDS Annual Data Report (ADR) Atlas*. Link: [www.usrds.org](http://www.usrds.org).

2. **Hepatitis C (§ 494.30(a)(1))**. AAKP recommends the final regulations follow the CDC recommendations for testing dialysis patients for hepatitis C. Medicare should reimburse for routine testing of hepatitis C.

3. **Designation of Responsibility for Infection Control Program (§ 494.30(b)(2))**. Given scope of the medical director responsibilities provided elsewhere in the proposed rule,<sup>23</sup> AAKP believes the medical director should be responsible for the infection control program. The medical director may delegate specific duties to a registered nurse or other qualified individual, but the medical director should be the accountable individual.

**B. Condition: Water Quality (§ 494.40)**

1. **Water Quality Standard**. AAKP strongly supports adding a new condition for water quality to the conditions of coverage.

2. **AAMI Water Quality Standards**. CMS incorporates by reference certain water quality and equipment standards of the Association for the Advancement of Medical Instrumentation (AAMI) in the proposed conditions of coverage. As a general matter, AAKP believes dialysis facilities should meet the most current AAMI standards, and new or updated standards should be promptly adopted. AAKP recommends that CMS incorporate by reference any future updates or revisions of the applicable AAMI standards.

3. **Ultrapure Dialysate**. CMS invites comments on ultrapure dialysate (at 6195). AAKP notes that a substantial literature implicates non-ultrapure dialysate in chronic inflammation among hemodialysis patients; that European standards for dialysate contaminants more stringent than in the United States, which may be one factor accounting for lower mortality among European dialysis patients compared to U.S. patients; and at least one large dialysis organization offers a dialysis treatment protocol based on single-use dialyzers with ultrapure dialysate.

**AAKP strongly recommends prompt adoption of an ultrapure dialysate standard. In addition, CMS should estimate the costs of adopting ultrapure dialysate and commensurate water quality standards, and if there are substantial costs in a changeover, compensate appropriately.**

**C. Condition: Reuse of Hemodialyzers and Bloodlines (§ 494.50)**

AAKP opposes reuse of dialyzers, and as noted above at least one large dialysis organization has moved to single use of dialyzers. AAKP believes at best the proposed condition provides the minimum acceptable standards for reuse. Among other issues,

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<sup>23</sup> See § 494.150

AAKP is concerned with reports that dialyzers may be routinely used 30 or more times. AAKP strongly recommends CMS contract for a technical expert panel to examine all facets of reuse and make recommendations to improve current practice.

**D. Condition: Physical Environment (§ 494.60)**

**1. Facility Temperature. As the preamble notes, temperature complaints are common in dialysis facilities. AAKP supports both setting temperature at a consensus patient level, and encouraging facilities to make reasonable accommodations. CMS should also consider including the costs of purchase and laundry of blankets in facility reimbursement.**

**2. Automatic External Defibrillator (AED). AAKP strongly supports a requirement that all dialysis facilities have an AED, including small, rural facilities, where the proposed rule only requires access to a defibrillator. ESRD patients are at high risk for cardiac events, and an AED provides the most robust technology for quick intervention.**

CMS requests comment on whether small, rural facilities should receive a waiver on the defibrillator requirement. AAKP supports an AED requirement for such facilities. Medical care may be less available in a rural area, and in any case would establish a lower standard of care for rural facilities. As noted in “General Comments” (above), AAKP is very concerned about the financial viability of rural and inner city facilities, but believes this matter should be addressed with a new payment system for critical access dialysis facilities. Lastly, from a brief internet survey, the retail prices of AEDs are sharply lower than the prices estimated in the proposed rule, and even greater discounts may be available when bought through a group purchasing organization.

**III. Proposed Part 494—Subpart C (Patient Care)**

**A. Condition: Patients’ Rights (§ 494.70)**

**1. General Comment. AAKP strongly supports modification of the existing condition that a patient (or their representative) must be informed of his or her rights and responsibilities at the beginning of treatment at a facility. AAKP supports expansions or additions to the existing condition for “Patient Rights” – including (1) references to privacy and confidentiality; (2) the right to establish an advance directive, (3) the right to be informed about all treatment modalities; (4) the right to be informed about the internal grievance process, (5) the posting of phone numbers for the ESRD network and State survey and certification organizations, and (6) 30 days’ prior notice of involuntary discharge.**

**2. Information a Patient Can Understand (§ 494.70(a)(2)). AAKP recommends that facilities document that patients have demonstrated their understanding of information.**

3. **Right to Participate in Care (§ 494.70(a)(5))**. AAKP strongly supports element (5), which replaces text in the current rule, “due consideration is given to the [patient’s] preferences,” with the patient right to participate in all aspects of his or her care. Element (5) reads, “(5) Be informed about and participate, if desired, in all aspects of his or her care, including advance directives, and be informed of the right to refuse treatment and to refuse to participate in experimental research.”<sup>24</sup>

4. **Treatment Modalities (§ 494.70(a)(6))**. In addition to informing patients of all available modalities, AAKP recommends that facilities must inform patients where other treatment modalities are offered if the facility does not offer a modality (e.g., home dialysis).

5. **Access to Social Workers and Dietitians (§ 494.70(a)(10))**. AAKP recommends this standard be modified to ensure patients are specifically informed about availability of social worker and dietitian services.

6. **Involuntary Discharge (§ 494.70(b))**. AAKP recommends that patients should not be discharged for “non-compliance” with the medical regimen. AAKP also recommends CMS review and adopt recommendations of the report, “Decreasing Dialysis Patient-Provider Conflict: National Task Force Position Statement on Involuntary Discharge” (April 2005). This report was drafted by the “Decreasing Dialysis Patient-Provider Conflict Project” (DPC), sponsored by the Forum of ESRD Networks. AAKP also recommends CMS should examine relevant State patient abandonment laws. AAKP comments further on discharge policy below under “Condition: Governance.”

7. **Posting of Rights (§ 494.70(c))**. In addition to posting State agency and ESRD network complaint numbers, AAKP recommends posting the telephone number and other contact information of the Medicare Ombudsman.<sup>25</sup>

**B. Condition: Patient Assessment (§ 494.80)**

1. **Comment**. AAKP strongly supports the addition of the new condition for patient assessment – with a prompt initial evaluation (20 days) and follow-up evaluation at three months (which includes an assessment of how a new patient is adjusting to his or her treatment plan).

2. **Bone Disease (§ 494.80(a)(5))**. AAKP recommends rewording element, “(5) Evaluation of factors associated with renal bone disease,” to read, “(5) Evaluation of

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<sup>24</sup> 6249

<sup>25</sup> See “CMS Hires Medicare Ombudsman Dan Schreiner To Be ‘Voice’ For Medicare Beneficiaries” (3/22/05). Link: [www.cms.hhs.gov/media/press/release.asp?Counter=1393](http://www.cms.hhs.gov/media/press/release.asp?Counter=1393)

**factors associated with mineral metabolism and renal bone disease,” to reflect current terminology.**

**3. Psychosocial Evaluation (§ 494.80(a)(7)). AAKP recommends element, “(7) Evaluation of psychosocial needs,” be modified to read, “(7) Cognitive and behavioral assessment, and evaluation of psychosocial needs.”** The facility should be aware of a patient’s cognitive abilities to effectively engage a patient in his or her care planning (see § 494.70(a)(2)), and given the ongoing attention to “difficult” or “non-compliant” patients, a behavioral assessment should be part of the problem-solving process. AAKP also notes that psychological conditions such as depression are associated with higher use of health care resources and poorer health outcomes generally, and recognition and treatment of such conditions is very important.

**4. Consultant Pharmacist. AAKP recommends a consultant pharmacist should be included as part of the facility’s interdisciplinary team.** ESRD patients have special vulnerability to drugs because patients typically take multiple medications, not only to manage kidney failure, but other medical conditions, such as diabetes and hypertension. In addition, with the new Medicare drug benefit slated to begin January 1, 2006, prescription drug plan formulary considerations will be an important new factor in the successful assessment and care of ESRD patients.

**C. Condition: Patient Plan of Care (§ 494.90)**

**1. Outcomes and Timetables. AAKP strongly supports the proposed text that a plan of care “must include measurable and expected outcomes and estimated timetables to achieve these outcomes.”** AAKP recommends that CMS establish a project with a network organization to examine how dialysis facilities draft and execute measurable outcomes and timetables, with the goal of identifying “best practices.”

**2. Clarification of “Community Accepted Standards”.** The proposed regulation states, “The outcomes specified in the patient plan of care must allow the patient to achieve current evidence-based community-accepted standards.” AAKP notes the term “community-accepted standards” is not included under definitions (§ 494.10) and is unacceptably vague. Read literally, the minimum standard of acceptable dialysis care could vary by zip code. If CMS means by “community-accepted standards,” the product of a voluntary consensus body (as discussed in the preamble), that should be so stated.

**3. Referrals. AAKP recommends that a plan of care should include appropriate referrals for all needed physical or psychological care and rehabilitation services not otherwise provided at the facility, by the patient’s physician(s), or by other health care professionals.** Such referrals may also include referral to the new CMS Chronic Care Improvement Program (CCIP), a pilot program

focusing on diabetes and chronic heart failure management<sup>26</sup>, and public vocational rehabilitation and employment assistance services.

**4. Minimum Threshold Values. AAKP recommends inclusion of minimum threshold values in the patient plan of care if such values would improve patient care.** However, AAKP raises the concern if including values in regulation might make future changes to the minimum values – as clinical practice evolves – difficult,<sup>27</sup> because changes would require formal rulemaking. AAKP asks whether such values might be included with same effect in subregulatory guidance.

**5. Mineral Metabolism and Bone Disease. AAKP recommends the plan of care include an element for “Mineral metabolism and bone disease.”** Treatment of mineral metabolism disorders (hyperphosphatemia, hypercalcemia, and secondary hyperparathyroidism) and bone disease is fundamental to patient well-being and is treatable.<sup>28</sup> The proposed rule also cites the importance of “active Vitamin D” as an “important breakthrough in quality-of-life.”<sup>29</sup> AAKP notes that a technical expert panel convened by Network and is completing its report (expected to be delivered to CMS in June 2005).<sup>30</sup>

Although outside the scope of the proposed rule, AAKP recommends that Medicare provide a dental benefit to ESRD patients. Bone disease among kidney patients is universal, and reimbursed medical care should include treatment of bones supporting the teeth and damage and loss of teeth due to deterioration of supporting bones.

**6. Medication Therapy Management. AAKP recommends that the plan of care include medication therapy management.** The goals of medication therapy management are to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. Medication therapy management is a key element of the new Medicare prescription drug benefit, and dialysis facilities should consider obtaining resources available under that program.

**7. Transplant Surgeon (§ 494.90(a)(5)). AAKP opposes the elimination of the transplant surgeon as a member of the interdisciplinary team. AAKP recommends that the requirement be retained that a transplant surgeon sign every plan of care.** Transplantation is a highly desirable treatment for end-stage renal disease, and removal of the transplant surgeon from the interdisciplinary team guarantees that patients will not

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<sup>26</sup> More information on CCIP at [www.cms.hhs.gov/medicarereform/ccip](http://www.cms.hhs.gov/medicarereform/ccip)

<sup>27</sup> CMS acknowledges this issue elsewhere in the proposed rule, at 6218.

<sup>28</sup> See, e.g., Block, G.A., et al., “Mineral Metabolism, Mortality, and Morbidity in Maintenance Hemodialysis”; *J Am Soc Nephrol* 15:2208-2218, 2004. Abstract link:

[www.jasn.org/cgi/content/abstract/15/8/2208](http://www.jasn.org/cgi/content/abstract/15/8/2208)

<sup>29</sup> 6207

<sup>30</sup> See slide show, “Bone Disease Clinical Performance Measures for Patients with Kidney Failure,” at [www.cms.hhs.gov/quality/esrd/BoneDisease.pdf](http://www.cms.hhs.gov/quality/esrd/BoneDisease.pdf)

be exposed to the most current thoughts/state-of-the-art consensus about suitability for transplantation.

**8. Monthly Physician Visit (§ 494.90(b)(4)).** AAKP recommends a dialysis facility ensure that all “healthy” dialysis patients are seen by the physician who provides their ESRD care at least twice a month at the facility, as evidenced by a progress notes placed in the facility’s medical records. Unstable or unwell patients may require more physician visits per month at the center.

**9. Patient Education and Training (§ 494.90(d)).** AAKP strongly endorses the inclusion for the first time of a standard in the conditions of coverage for patient and family education/training as an element in plan of care. AAKP would modify the language of Standard 494.90 with the words in italics, “The patient care plan must include, as applicable, education and training, *including peer education, for patients ...*.” In AAKP’s view, ESRD patients can only be active partners in their care when well informed about the medical and non-medical aspects of their care, and patients who are active partners are more likely to survive and thrive. AAKP strongly agrees with the statement in the preamble to the proposed rule, “Educating and training patients and their families is key to a successful transition to a life with dialysis.”<sup>31</sup>

**10. Pre/Post Dialysis Session Assessments.** AAKP recommends systematic, standard elements to assess a patient’s condition pre- and post-dialysis be listed in the regulation, rather than solely in the interpretive guidance. Such elements may include patient report, examination of access site, heart rate/rhythm, GI status, and signs of fluid overload.

**D. Condition: Care at Home (§ 494.100)**

**“Home Dialysis” in an Institutional Setting.** AAKP discusses this issue above under “Definitions” (§ 494.10) and repeats that recommendation: CMS should contract with a network organization to convene a technical expert panel (TEP) to revisit CMS’s interim guidance,<sup>32</sup> survey this matter, and make recommendations. The TEP may wish to consider drafting a new definition and recommendations regarding “institutional home dialysis” that both address the quality and payment issues discussed above.

**E. Condition: Quality Assessment and Performance Improvement (QAPI) (§ 494.110)**

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<sup>31</sup> 6210

<sup>32</sup> “Clarification of Certification Requirements and Coordination of Care for Residents of Long-Term Care (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services.” (March 19, 2004). Link: [www.cms.hhs.gov/medicaid/survey-cert/sc0424.pdf](http://www.cms.hhs.gov/medicaid/survey-cert/sc0424.pdf)

1. **Comment.** AAKP **strongly** supports the addition of a new condition for quality assessment and improvement. There is no way we are doing the best job possible, and every day there are new ways to improve care.
2. **Patient Participation in QAPI.** AAKP recommends that the QAPI condition include a requirement that facility patients be solicited for suggestions to improve the quality and safety of care provided at the facility – in addition to the element of the program scope, “patient satisfaction and grievances” (§ 494.110(a)(2)(vii)).
3. **Program Scope (§ 494.110(a)).** AAKP recommends that program scope be expanded to include **infection control, mineral metabolism and bone disease, staff education, and transplant referral.** Regarding “staff education,” AAKP recommends adding this element to program scope in response to patient complaints that staff are unable to explain the treatment process, important aspects of clinical care, or operational policies, or are uninformed about patient rights. We have discussed above the reasons above for adding infection control and mineral metabolism.
4. **Common Survey Instrument of Patient Satisfaction.** In response to CMS’s request for comment on the value of utilizing a common instrument for assessing patient’ experience of care,<sup>33</sup> AAKP recommends this approach, at a minimum, to provide comparable information across facilities. Facilities would be free, of course, to supplement the common survey with its own measures. AAKP further recommends that such instrument be administered by an independent third party when patients are not on dialysis. AAKP notes that CMS has made a substantial investment in ESRD Consumer Assessment of Health Plan Survey (CAPHS), and that this instrument is well designed and tested. In addition, there are other well-established instruments that assess physical, mental, and clinical outcomes that might also be administered on a periodic basis.
5. **Facility Specific Standards for Enforcement.** In response to CMS’s request for comment,<sup>34</sup> AAKP endorses the use of commonly agreed upon clinical standards as requirements subject to enforcement. AAKP also endorses CMS’s proposed text for “Condition: Clinical Standards” and “Standard: Performance Expectations.”<sup>35</sup> As AAKP notes above (§ 494.90), we share CMS’s concern<sup>36</sup> that including clinical values in regulation might make future changes to the minimum values – as clinical practice evolves – difficult,<sup>37</sup> because changes would require formal rulemaking. AAKP asks whether such values might be included with same effect in subregulatory guidance.

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<sup>33</sup> 6217

<sup>34</sup> 6218

<sup>35</sup> 6219

<sup>36</sup> 6218

<sup>37</sup> CMS acknowledges this issue elsewhere in the proposed rule, at 6218.

**IV. Administration (Proposed Subpart D—Administration)**

**A. Condition: Personnel Qualifications (§ 494.140).**

**1. Medical Director Qualifications (§ 494.140(a)). AAKP recommends that CMS retain the requirement that a medical director be board certified or board eligible, pending a better explanation of why this requirement should be discontinued.**

**2. Dialysis Technician Qualifications (§ 494.140(e)). AAKP believes that a 3-month on-the-job training program is not sufficient for employment as a dialysis technician. AAKP recommends that this job training should follow (or be contemporary with) successful completion of a national technician certification program. AAKP does not believe this recommendation is controversial. As CMS notes elsewhere in the proposed rule, “dialysis technicians are now the primary caregivers in many dialysis units.”<sup>38</sup> At least 5 states, including Texas, California, Arizona, Ohio, and Oregon, already recognize a national standardized examination to qualify as a dialysis technician. Dialysis industry legislation now before Congress would require that a dialysis technician: (A) has completed a training program in the care and treatment of an individual with chronic kidney failure who is undergoing dialysis treatment; (B) has been certified by a nationally recognized certification entity for dialysis technicians; and (C) is competent to provide dialysis-related services.<sup>39</sup>**

**3. Consultant Pharmacist. AAKP recommends a consultant pharmacist should be included as part of the facility’s interdisciplinary team (identical recommendation made above at § 494.80).**

**B. Condition: Medical Director (§ 494.150)**

**AAKP endorses CMS’s proposals to strengthen the role of the facility medical director, including responsibility for the quality assessment and performance improvement program (QAPI) (§ 494.110), development and approval of patient care policies and procedures manual, and compliance with the facility’s discharge and transfer policies and procedures. As noted above, AAKP also recommends the medical director be responsible for the infection control program (§ 494.30).**

**C. Condition: Relationship with ESRD Network (§ 494.160)**

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<sup>38</sup> 6230

<sup>39</sup> See S. 635, the “Kidney Care Quality and Improvement Act of 2005”.

As AAKP comments above (§ 494.20), participation in the quality improvement activities of the ESRD networks is a legal responsibility of dialysis facilities. AAKP also believes participation is a moral responsibility.

**D. Condition: Governance (§ 494.180)**

1. **Governing Body.** AAKP recommends that facilities solicit nominations from among facility patients for an individual to be included in the governing body as an advisor.

2. **Qualified and Trained Staff (§ 494.180(b)).** Given the large percentage of dialysis patients whose care is reimbursed by Medicare, from an “active purchaser perspective” Medicare has a special responsibility to devise and enforce standards, including standards for staff. AAKP makes two recommendations:

First, AAKP would modify CMS’s proposal (§ 494.180(b)(2)) that a registered nurse “must be present in the facility at all times that patients are being treated,”<sup>40</sup> to “present and available”.

Second, AAKP recommends CMS revisit what constitutes “adequate number of qualified and trained staff”. Specifically, AAKP recommends CMS delineate the responsibilities of all staff – including nurses, dialysis technicians, social workers, and dieticians – in a manner comparable to the responsibilities of the medical director (§ 494.150).

In addition, although “acuity based staffing plan” may be desirable, clearer, more detailed specifications are needed to evaluate this proposal. Moreover, unless there is some staff-to-patient ratio, facilities may vary widely in the level of service to patients, in effect providing a different level of benefit (or “bundle”) for the same reimbursement. AAKP believes a technical expert panel could promptly address this issue.

3. **Training Program for Dialysis Technicians (§ 494.180(b)(5)).** AAKP supports the “requirement for a written approved training program ... that is specific to dialysis technicians.” However, as noted above (494.140), AAKP recommends successful completion of a national technician certification program as well.

4. **Internal Grievance Process (§ 494.180(e)).** AAKP strongly supports a requirement for an internal grievance process. AAKP recommends patient involvement in the design and administration of the internal grievance process, and routine reporting to the network organization of the number and topic of

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**complaints.** AAKP concurs with the CMS statement, “We believe a good internal grievance process is an invaluable tool in resolving patient grievances in a positive and expeditious manner for both the patient and the facility.”<sup>41</sup>

**5. Discharge and Transfer Policies and Procedures (§ 494.180(f)). AAKP supports the proposal to hold the dialysis facility accountable for adherence to the facility’s patient discharge and transfer policies and procedures. As noted above (§ 494.70), AAKP recommends CMS review and adopt recommendations of the report, “Decreasing Dialysis Patient-Provider Conflict: National Task Force Position Statement on Involuntary Discharge” (April 2005).**

**6. Furnishing Data and Information for ESRD Program Administration (§ 494.180(h)). As we note in “General Comments” at the beginning of this letter, AAKP believes that conditions, standards, and measures are only as effective as surveillance and enforcement. Full participation in reporting existing CPMs would be an important part of this effort, as well as full implementation of the VISION system. We also incorporate by reference our comments regarding minimum performance standards for dialysis facilities, and remedies for cherry picking” and factors that might discourage facilities from accepting resource-intensive patients.**

**7. Disclosure of Ownership (§ 494.180(i)). AAKP recommends that ownership information of a dialysis facility be available to any member of the public upon request.**

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In closing, AAKP appreciates the hard work and dedication of the CMS staff in revising the dialysis facility conditions of coverage. Once again, CMS is making a positive difference in the lives of kidney patients. If AAKP can otherwise be helpful on this matter, please do not hesitate to contact me or Kris Robinson, AAKP’s Executive Director, at (800) 749-2257 or [krobinson@aakp.org](mailto:krobinson@aakp.org).

Sincerely,

Brenda Dyson  
President

cc: Barry Straube, M.D.