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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) 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.

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.¹

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.

¹ 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 rule², 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.³

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).⁴ Currently, CMS has identified three CPMs – dialysis adequacy, anemia management, and vascular access⁵ – which are reported for a 5-percent sample.⁶ 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”⁷ (italics added).

AAKP endorses CMS's commitment to CPM requirements and to expand the minimum performance standards for dialysis facilities.⁸ 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.⁹ 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).

² See, e.g., § 494.70

³ 6187.

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

⁵ Link: www.cms.hhs.gov/esrd/1d.pdf

⁶ See 6189

⁷ 6190

⁸ 6232

⁹ 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.¹⁰

Fifth, AAKP believes that conditions, standards, and measures are only as effective as surveillance and enforcement. In 2003, Senator Charles Grassley¹¹ and the General Accounting Office¹² 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.¹³**

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

¹⁰ 6232

¹¹ Grassley letter to HHS Secretary Tommy Thompson, November 6, 2003, Link:

<http://finance.senate.gov/press/Gpress/2003/prg110603.pdf>

¹² 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

¹³ 6198-6190, 6231-6232

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

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.¹⁵

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

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

¹⁵ 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.¹⁶ 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.¹⁷

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.¹⁸

¹⁶ See Sec. 1881(f) of the Social Security Act.

¹⁷ 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>

¹⁸ 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

AAKP recommends that CMS should contract with a network organization to convene a technical expert panel (TEP) to revisit CMS's interim guidance¹⁹ 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.²⁰
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."²¹ 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.²² **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.**

¹⁹ "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

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

²¹ 6191

²² See United States Renal Data System, "Chapter 6—"Outcomes: hospitalization & mortality,"2004 *USRDS Annual Data Report (ADR) Atlas*. Link: 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,²³ 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,

²³ 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.”²⁴
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.²⁵

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

²⁴ 6249

²⁵ 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

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 management²⁶, 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,²⁷ 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.²⁸ The proposed rule also cites the importance of “active Vitamin D” as an “important breakthrough in quality-of-life.”²⁹ AAKP notes that a technical expert panel convened by Network and is completing its report (expected to be delivered to CMS in June 2005).³⁰

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

²⁶ More information on CCIP at www.cms.hhs.gov/medicarereform/ccip

²⁷ CMS acknowledges this issue elsewhere in the proposed rule, at 6218.

²⁸ 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

²⁹ 6207

³⁰ See slide show, “Bone Disease Clinical Performance Measures for Patients with Kidney Failure,” at 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.”³¹

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,³² 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)

³¹ 6210

³² “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

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,³³ 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,³⁴ 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.”³⁵ As AAKP notes above (§ 494.90), we share CMS’s concern³⁶ that including clinical values in regulation might make future changes to the minimum values – as clinical practice evolves – difficult,³⁷ because changes would require formal rulemaking. AAKP asks whether such values might be included with same effect in subregulatory guidance.

³³ 6217

³⁴ 6218

³⁵ 6219

³⁶ 6218

³⁷ 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.”³⁸ 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.³⁹**
- 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)

³⁸ 6230

³⁹ 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,”⁴⁰ 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

⁴⁰ 6229

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."⁴¹

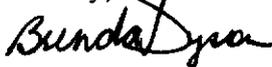
5. Discharge and Transfer Policies and Procedures (§ 494.180(f)). AAKP supports the proposal to hold the dialysis facility accountable for adherence to the facility's patient discharge and transfer policies and procedures. As noted above (§ 494.70), AAKP recommends CMS review and adopt recommendations 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.

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.

Sincerely,



Brenda Dyson
President

cc: Barry Straube, M.D.



UNIVERSITY OF KENTUCKY

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**Division of Nephrology, Bone
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May 2, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear CMS Review Committee:

Thank you for the opportunity to comment on the CMS Program; Conditions for Coverage for End Stage Renal Disease; Proposed Rules. The amount of hard work that went into these revisions is very significant, and we applaud those that put in the time to prepare this extensive document.

As a Physician Assistant (PA) and a Nurse Practitioner (NP) serving in Nephrology working along side our attending nephrologists, we do have an important concern. PAs and NPs are currently providing daily assessment and ongoing care of patients in dialysis facilities across the nation. These physician services provided by NPs and PAs are currently reimbursed through CMS. Unfortunately, neither Nurse Practitioners nor Physician Assistants are mentioned in this document. This could lead to problems with reimbursement for physician services provided by NPs or PAs as well as regulatory and liability issues.

NPs and PAs function as dependant practitioners with their supervising physician counterpart. The Nephrology PA and NP are the natural compliment to the Nephrologist in order to extend quality nephrology physician services to this increasingly needy population. Statistics from the US Bureau of Labor and Statistics coupled with data on the number of chronic kidney disease patients indicates that the number of patients starting dialysis is quickly outpacing the number of nephrologists available to adequately care for them. The RPA (Renal Physician Association), ASN (American Society of Nephrology) and CMS have accepted a Nephrology PA and NP as a natural compliment to the multidisciplinary team.

Of particular concern is CFR Proposed Sec. 494.90 (b) (4) "Plan of Care" where specifically it states:

"494.90 (b) (4) would specify that the facility must ensure every patient is seen at least monthly by a physician providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician or communicated from the physician's office and placed in the beneficiary's medical record.

This statement seems to exclude the Physician Assistant and Nurse Practitioner from seeing the patient for the purpose of the monthly progress note.

We recommend that the language in 494.90 (b) (4) should be amended to read:

"Sec. 494.90(b) (4) would specify that the facility must ensure every patient is seen at least monthly by a physician, physician assistant or nurse practitioner providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician/physician assistant/nurse practitioner or communicated from the physician's office and placed in the beneficiary's medical record."

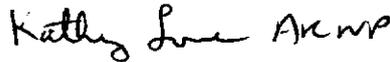
Please strongly consider our suggestion so that the spirit of this document to improve quality patient care does not end up limiting that same access to quality care by eliminating the NPs and PAs from the health care team.

Feel free to contact us with any questions.

Sincerely,



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Centers for Medicare & Medicaid Services
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 PO Box 8012
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May 2nd 2005

To Whom It May Concern

I am writing in response to the newly proposed changes in conditions of coverage for dialysis facilities. The following one is of particular concern: Section 4944. The "GRAND FATHER CLAUSE". Having worked in the dialysis field since 1988 I have come across several BSW's, BA's MFI - MSW's & PhD in the work force. These professionals have a wealth of information, skills, and experience that no degree can replace. These were the professionals that were in the "trenches" since the last 1976 and have weathered the storms of the dialysis world. Also they have always been monitored and supervised by LCSW. What criteria is being used to now decide this this change this law. It is my firm opinion that these few should remain "GRANDFATHERED IN" and allowed to provide the high quality of service they have been doing since 1976. To eliminate the clause would be detrimental to the dialysis patients and a disregard for their contribution and years of service. PLEASE CONTINUE TO HAVE THESE GRANDFATHERED INDIVIDUALS SERVE THE DIALYSIS PATIENTS.

Sincerely
 Rusi Alamshe



Rec'd
5/5/05 d.n.w.

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May 2, 2005

Mark B. McClellan, M.D, Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8012
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Reference File Code: CMS-3818-P

Dear Dr. McClellan:

The American College of Clinical Pharmacy (ACCP) appreciates the opportunity to provide comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease (ESRD) facilities as published in the *Federal Register* notice of February 4, 2005. In particular, we are providing comments concerning Proposed § 494.140 ("Personnel Qualifications") with regard to the role of a pharmacist within the dialysis facility, as well as the facility's appropriate responsibility for pharmaceutical services and the efficient use of medications as a part of the revised conditions of coverage.

ACCP is a national professional and scientific society representing almost 10,000 clinical pharmacist practitioners, researchers, and educators. Our members have been among the profession's leaders for almost three decades in developing and providing professional services, consultation, cutting-edge clinical research, and educational programs that improve the quality of medication use in the health care settings in which they practice.

Within ACCP's membership are approximately 200 members whose practice activities focus on nephrology, chronic kidney disease, and related medical conditions. These specialized practitioners are key thought leaders in the field who provide medication therapy management and pharmaceutical care services to dialysis patients as well as patients at earlier stages of chronic kidney disease. Many are actively involved within the clinical nephrology community, and have served on task forces such as the National Kidney Foundation's K/DOQI guidelines development groups. They have taken a leadership role in educating the pharmacy and medical communities about the growing prevalence of chronic kidney disease and the important role that pharmacists play in optimizing the quality of care of patients with mild, moderate, and severe kidney disease (references provided as Appendix A).

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We are pleased to note the proposed rule's recognition of the contributions of pharmacists in improving the quality and cost-effectiveness of medication use in various patient populations. Patients served by ESRD facilities are a particularly relevant target population in which to assure the safe and appropriate use of medications due to:

- the severity of their medical condition(s);
- the prevalence of co-morbidities that frequently require complex drug therapy regimens; and
- the substantial clinical impact that dialysis procedures have on the pharmacodynamics and pharmacokinetics of the medications taken by ESRD patients.

Consequently, ACCP urges that the revised conditions of coverage provide for the inclusion of qualified pharmacists, in either an employed or consultative capacity, as integral members of the multidisciplinary teams within Medicare-approved dialysis facilities.

Among the reasons that ACCP believes pharmacists should be included as an integral member of the dialysis facility's multidisciplinary team are the following:

- Dialysis patients are prescribed medication regimens that are highly complex. Dialysis patients require an average of 10-12 prescribed medications and thus must take as many as 70 tablets or capsules daily. This represents more than twice the number of medications consumed by the typical non-ESRD Medicare patient. Several studies have documented non-adherence to prescribed medications in dialysis patients and the improvements in outcomes that have been associated with pharmacists' interventions to enhance medication adherence.
- Dialysis patients must have their dosage individualization based on the mode of dialysis they are receiving and the hemodialyzer being used, since both can significantly impact the dosage of and response to medications. Pharmacists have published a substantial body of original research in this area and have written many of the review articles that are utilized to guide drug dosing in such patients.
- Dialysis patients have multiple co-morbid conditions that increase the need for multi-drug regimens that increase the risk of clinically significant drug interactions. Dialysis patients also typically require frequent inpatient hospital admissions and have fluctuating biochemistry profiles that further complicate drug therapy regimens, placing them at increased risk for adverse medication outcomes. Pharmacists are uniquely qualified to provide the clinical review and consultation services that can promote safer and more effective medication use.
- Positive clinical and financial outcomes have been reported when pharmacists are involved in the management of conditions (including anemia, metabolic bone disease, and diabetes mellitus) that frequently occur in ESRD patients. The provision by pharmacists of effective medication therapy management, both for individual patients and those served by hospital-affiliated dialysis facilities has resulted in as much as \$4 of health care cost savings for every \$1 spent on pharmaceutical care.

- The role of pharmacists in providing medication therapy management services to at-risk Medicare beneficiaries is recognized within the scope of the new Part D drug benefit which begins in January 2006. This policy and benefit should logically be a part of the services provided to Medicare beneficiaries receiving services from ESRD facilities.

ACCP makes the following specific recommendations regarding the role of pharmacists as members of the dialysis facility multidisciplinary team:

- 1) A comprehensive medication review for each dialysis patient should be conducted by a pharmacist prior to or at the initiation of dialysis and at clinically appropriate intervals thereafter. Documentation of the review should include generation of an updated list of medications including drug name, dose, frequency, and special instructions. All medication-related problems should be documented and a plan of action to prevent or correct the problems should be recommended to the medical director of the facility. The pharmacist should provide counseling and education to patients to assure understanding of the proper use of their medications and to promote adherence with the medication regimen.
- 2) A regular review of laboratory studies should be conducted by a pharmacist to evaluate the appropriateness and effectiveness of prescribed medication regimens. A collaboratively-developed plan to modify the medication therapy as necessary should be developed and implemented based on the facility's policies and procedures. Examples of laboratory procedures that relate to medication therapy management protocols are provided in Appendix B.
- 3) The development of protocols and guidelines for the clinical use of medications should be managed by the pharmacist in collaboration with the medical director and other multidisciplinary team members in order to promote patient safety and high-quality, cost-effective drug use. In addition, a continuous quality improvement program should be implemented and administered by the pharmacist for such protocols and guidelines to evaluate the outcomes of the protocols should be in place.
- 4) The development and implementation of policies and procedures for the control, preparation, administration, storage, and management of medications, including sterile products, should be managed by the pharmacist in consultation with the medical director and other team members.
- 5) The pharmacist should coordinate the medication management for dialysis patients that is delivered within the facility with other community-based providers of disease and medication management programs.

In addition to these specific recommendations concerning the role of the pharmacist, ACCP encourages CMS to evaluate and revise as necessary the payment policies affecting ESRD facilities to assure that payment levels are appropriate to support the activities of pharmacists described in these recommendations. Given the substantial body

of evidence demonstrating the effectiveness of pharmacists' interventions in promoting safer and more cost-effective medication use, such payment policy adjustments would likely produce net savings to Medicare as a result of reductions in rates of hospitalization and consumption of other health care services that are known to occur in patients whose medication regimens are ineffectively managed.

In summary, ACCP believes that an active clinical role for pharmacists as part of the multidisciplinary team within ESRD facilities will contribute substantially to the stated objectives of CMS for revising the conditions of coverage – namely that they:

- be founded on evidence;
- be patient-centered;
- promote outcomes desired for Medicare and Medicaid beneficiaries;
- establish a framework for the collection and reporting of consensus-driven performance standards;
- set clear expectations for dialysis facility accountability; and
- stimulate improvements in processes, outcomes of care, and beneficiary satisfaction.

ACCP and its members involved in caring for patients covered under the ESRD benefit would be pleased to work with the Centers for Medicare and Medicaid Services to further develop and refine the conditions of coverage in order to facilitate the active involvement of pharmacists as members of the ESRD facility's multidisciplinary team. Please feel free to follow up with us at any time.

Sincerely,



Michael S. Maddux, Pharm.D., FCCP
Executive Director



C. Edwin Webb, Pharm.D., M.P.H.
Director, Government and Professional Affairs

Appendix A - Selected References in Nephrology Pharmacy Practice

Identification of drug-related problems in CKD/ESRD patients:

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Appendix B – Selected Laboratory Parameters for Medication Management

Laboratory Parameter	Indication for Monitoring	Pharmacist Role
Hemoglobin and Hematocrit Iron Indices	Anemia of Chronic Kidney Disease	<ul style="list-style-type: none"> • Foster achievement of K/DOQI guidelines by adjusting doses of EPO appropriately** • Evaluate for EPO resistance • Appropriately initiate and monitor IV iron therapy. Pharmacists are most able to interpret the current therapeutic controversies surrounding IV iron (e.g. dosing in hyperferritinemia and differentiation of the safety/toxicity profiles of the available agents. regarding
Calcium, phosphorus, parathyroid hormone (PTH), alkaline phosphatase, albumin	Renal Osteodystrophy	<ul style="list-style-type: none"> • Foster achievement of K/DOQI guidelines for calcium, phosphorus and PTH • Evaluate patients for best phosphate binder choice by evaluating data on risks, benefits, safety tolerability and cost • Optimize PTH suppression with vitamin D analogs and calcimimetic agents which require expertise in dosing and monitoring
Electrolytes (sodium, potassium, bicarbonate)	Hyperkalemia Metabolic acidosis	<ul style="list-style-type: none"> • Evaluate for drug-induced causes of hyperkalemia (e.g., ACE inhibitors, angiotensin receptor blockers)
Blood urea nitrogen, serum creatinine, albumin, transferrin	Dialysis Adequacy Malnutrition	<ul style="list-style-type: none"> • Evaluate for causes of suboptimal adequacy (e.g., heparin dose, access thrombosis) and adjust or initiate drug therapy where indicated. • Determine optimal pharmacologic interventions for malnutrition when indicated
Complete blood count	Thrombocytopenia Neutropenia Microcytosis Macrocytosis	<ul style="list-style-type: none"> • Evaluate for drug-induced causes (e.g., heparin-induced thrombocytopenia, vancomycin-induced neutropenia) • Evaluate for folate/B₁₂ deficiency
Drug Concentrations (digoxin, phenytoin, gentamicin/vancomycin)	Therapeutic drug monitoring	<ul style="list-style-type: none"> • Pharmacists are extensively trained in pharmacokinetics of drugs that require dose modifications in CKD to optimize efficacy and minimize adverse events.

MAY 05 2005

RENAL LEADERSHIP COUNCIL
Providers of Quality Care for the Nation's Dialysis Patients

May 5, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: CMS-3818-P: Conditions for Coverage for End Stage Renal Disease Facilities

Dear Administrator McClellan:

These comments are being submitted by the Renal Leadership Council ("RLC") in response to the Conditions for Coverage ("Conditions") for end stage renal dialysis facilities. 70 Fed. Reg. 6184 (February 4, 2005).

The RLC is a coalition representing the four largest entities providing dialysis care and services to Medicare beneficiaries: DaVita, Fresenius Medical Care North America, Gambro Healthcare US, and Renal Care Group, Inc. Collectively, these suppliers operate over 2,700 dialysis facilities in 42 states that provide dialysis care to approximately 200,000 patients. Each of these companies will be submitting more detailed comments on this proposed rule. These comments, therefore, are intended to highlight and address some of the broader policy issues and concerns raised by these Conditions.

Dialysis Facilities or Comprehensive Care Providers?

The RLC is concerned that the Conditions stand to impose new obligations and responsibilities upon dialysis facilities that go beyond their role in the continuum of care, which at its core is to ensure that patients receive safe and effective *dialysis treatments*. Over the past several years, there has been thoughtful dialogue between the renal care community and policymakers about the extent to which that role should be expanded to include the provision of medical care and services beyond the dialysis procedure itself. Concurrent with these broad policy considerations has been the increased prevalence of disease management/chronic care delivery models.

The proposed Conditions, particularly some of those within §494.80 and §494.90, contain clear elements that would place dialysis facilities on a path toward becoming something akin to long term care providers and disease managers. We agree that Conditions for Coverage for dialysis facilities should be designed to ensure that patients receive appropriate care related to dialysis, and a number of the proposed Conditions are

consistent with this principle. However, a primary concern we have with some of the Conditions is that they appear to be disconnected from the reality of the reimbursement associated with providing dialysis treatment (i.e., the composite rate).

Dialysis reimbursement policies are undergoing fundamental changes that make it difficult to adequately meet the challenges facing our members, especially in light of the fact that the dialysis patient population is becoming increasingly medically complex. If dialysis facilities are required to assume additional responsibilities for the health care needs of medically complex patients, such as some of those included within the proposed Conditions, it is imperative that Medicare's dialysis reimbursement policies be appropriately and sufficiently adjusted to meet those responsibilities.

As CMS is well aware, our members continue to believe that dialysis payment policy refinements effectuated by the MMA have resulted in a net decrease to non-hospital based facilities, notwithstanding the fact that Congress intended to increase the composite rate. It bears reiterating that dialysis facilities operate with very low payment to cost ratios under current program guidelines, projected by the Medicare Payment Advisory Commission in its March 2005 Report to the Congress to be just below 0% this year. In addition, the lack of a market basket adjustment or annual update factor for the dialysis composite rate will intensify all the more our members' reliance upon the legislative process for payment updates; indeed, many of these Conditions, if implemented, would necessitate such updates.

Can Dialysis Providers Be Reasonably Expected To Satisfy the Conditions?

The additional cost implications presented by some of the proposed Conditions must be viewed not only financially, but also pragmatically. Can dialysis facilities reasonably be expected to meet some of these Conditions in the first place? For example:

- (1) It is by no means certain under current dialysis facility operating conditions that our members can "provide the necessary care and services" related to patients achieving appropriate levels of productive activity, including the educational needs of pediatric patients.
- (2) There is currently no covered benefit for the "care and services" the Agency is requiring facilities to provide to patients in order to achieve and maintain an effective nutritional status.
- (3) Requirements for anemia management are not consistent with current payment policies that preclude the initiation of erythropoietin therapy for an individual new to dialysis until their hemoglobin drops to 10g/dL if they have not been treated with erythropoietin prior to initiating dialysis.
- (4) There is no reimbursement for "monitoring of arteriovenous grafts and fistulae for stenosis" as is required in the Conditions.
- (5) Transplant referral tracking is a new responsibility that dialysis facilities are expected to carry out without additional resources and which seems to duplicate what the Agency intends to be the transplant center's responsibility, as reflected in the proposed Conditions of Participation for transplant centers published earlier this year. We suggest that once a transplant center notifies a dialysis facility that a patient is a candidate for transplantation, it is a reasonable requirement that the facility note the patient's transplant status in the plan

of care along with other reasonable requirements the transplant center stipulates, such as periodic blood sampling or testing. The interdisciplinary team need not “track” or “monitor” the status of these transplant candidates on a monthly basis or make contact with the transplant center on a quarterly basis. It should be incumbent on the transplant center to notify the facility of the status of each patient. We are also concerned that inappropriate information could be communicated to the transplant center during these routine quarterly contacts. For example, the facility staff could mention the patient has the flu and the transplant center could remove the patient from the waiting list when, in fact, that should not be done. We believe it is in the patient’s best interest that they remain active on the transplant list unless and until the patient’s nephrologist feels the patient’s condition has deteriorated to the point that he or she should have a discussion with the transplant team about the patient’s transplant status.

Notwithstanding the fact that many of these services or requirements are not included within the current composite rate paid for dialysis, are not covered benefits, are duplicative of requirements or responsibilities of other Medicare providers, some of these Conditions seem to go well beyond the role of dialysis suppliers.

Life Safety Code Issues

Under the Conditions, numerous dialysis facilities will be required to have sprinkler systems. Many facilities are leased from private lessors who will be unwilling to install such systems, thereby forcing the facility to either undergo the expense on its own, or relocate to a building with sprinklers. The former option will cost thousands of dollars; the latter will be disruptive to facility operations and may compromise, if only temporarily, timely access to care for patients, though for some patients a facility’s relocation could be overly problematic. Requirements for defibrillators, alarms, and monitors all represent potential new costs for some facilities; these are very much underestimated in the Impact Analysis. Does CMS plan to treat these costs as new costs for payment rate-setting purposes?

Inclusion of Standards in the Conditions

It has been nearly three decades since the original Conditions were issued. In this intervening period, the field of renal medicine has made significant advancements and improvements in many areas, including the development of new pharmacologic agents to address the sequelae of renal failure that are untreatable by dialysis alone, safer and more efficient technology, and the articulation of clinical outcomes and related performance standards for a number of clinical outcomes. Many of these advancements have been incorporated into the National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative (K-DOQI), which have been adopted by the field and the Agency as acceptable practices and standards. The K-DOQI guidelines are a valuable and critical component to the renal care field. Dialysis facilities have accepted the goals and targets defined by K/DOQI and, in many cases, as the CPM data show, have exceeded it.

Nevertheless, we are concerned about how the inclusion of these "minimum" standards will be applied when facilities are surveyed for recertification. For example, while one of the K/DOQI recommendation for dialysis dose is $Kt/V \geq 1.2$, and the data for the industry indicates that 94% of patients meet this criteria, it is important for the Conditions to acknowledge that not all (100%) patients can achieve this standard for any number of reasons, some of which relate to the patient and not to the facility.

Thus, we propose that the inclusion of K/DOQI standards as desirable outcomes for all patients be more specifically defined in terms of the facility as goals and expectations for "more than 80% of its patients" when making a determination of a facility's continued participation in the Medicare program.

Laboratory services

Currently, the Conditions for Coverage stipulate that the dialysis facility must make laboratory services available, and if the facility does not provide laboratory services, they must make arrangements to obtain these services with a laboratory certified under CLIA. We recommend the following language be added to the Condition for Laboratory Services because of billing problems that have been identified when tests for dialysis patients are performed by a laboratory other than the dialysis facility's primary lab. Such laboratories are unaware of other tests that have been performed during the month and cannot therefore apply the complex billing rules for dialysis patients to determine which tests are reimbursable by Medicare. Local laboratories have been sensitized to this problem such that in some areas access to STAT testing has become a problem.

- (1) If a dialysis clinic does not provide laboratory services, it must make laboratory services available by entering into an agreement with a CLIA certified clinical laboratory to serve as the dialysis facility's primary laboratory.**
- (2) To ensure that composite rate lab tests for each ESRD beneficiary are accounted for in a single, centralized database for proper application of ESRD laboratory billing rules, composite rate lab tests performed by any other laboratory must be billed through the primary laboratory.**
- (3) If a dialysis facility uses the services of a secondary laboratory, the secondary laboratory must be CLIA certified and must enter into an agreement with the dialysis facility or the facility's primary laboratory to bill the dialysis facility or the primary laboratory for lab tests that are subject to ESRD lab billing rules.**
- (4) The dialysis facility's primary laboratory is the single laboratory permitted to bill Medicare for laboratory tests listed as composite rate laboratory tests.**
- (5) The primary laboratory must agree to electronically furnish the dialysis clinic with laboratory test data upon request for submission to ESRD Networks.**

Conclusion

We appreciate the fact that CMS has devoted considerable efforts over the years toward quality improvement efforts in the renal care field. The Agency has earned the collective cooperation and consensus of dialysis providers in pursuit of these kinds of efforts, such as K-DOQI. The renal community is proud of the fact that it has defined quality, developed performance standards, been measured against the standards and had the outcomes of individual facilities reported publicly, without any federal requirements to do so.

Not only have dialysis facilities agreed to voluntarily measure themselves against these standards, providing outcome data routinely to CMS in a number of forms, but also it has done so without any remuneration for the submission of such data. In fact, dialysis facilities actually *pay* for the submission and evaluation of their data through the \$0.50 per dialysis treatment contribution to fund the renal network organizations. We, therefore, found it interesting to note in the April 25, 2005 proposed rule for the inpatient hospital prospective payment system, that CMS is creating incentives for hospitals that submit quality data by giving them a full market basket update, and effectively penalizing hospitals not submitting data.

It is perplexing to us why CMS would not seek to reward dialysis facilities for defining and submitting quality data on a voluntary basis *at their own expense* (\$.50 per treatment), in the absence of incentives or requirements to do so. Hopefully, in light of the Agency's approach to the submission of hospital quality data, CMS will consider similar policies for dialysis facilities.

In summary, we are pleased to see this proposed rule, but we believe the final rule should contain regulations that are consistent with Medicare payment policy; it should contain requirements that are focused on the primary responsibility of dialysis facilities, which is to deliver safe, effective dialysis treatments; and, it should focus solely on matters that are under the facility's direct control.

Sincerely,

A handwritten signature in black ink that reads "Mats Wahlstrom". The signature is written in a cursive, slightly slanted style with a long horizontal line extending to the right.

Mats Wahlstrom, Chair
Renal Leadership Council

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May 5, 2005

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on Conditions of Coverage for ESRD Facilities

Dear Administrator McClellan:

As a Nephrology Nurse for close to 30 years, I have literally grown up in dialysis using the current "Conditions of Coverage" as one of the facilities main references-sometimes referred to as the facility's "bible". I have been a staff nurse, CQI coordinator, educator, manager, and administrator. Currently, I travel across the nation educating hemodialysis staff on providing patients with a safe and efficient treatment thru the use of the Crit-line monitor for Fluid Management.

I commend the Agency's decision to update the "Conditions of Coverage". As you do so, please consider the following comments. These are based on my years of experience as well as observations noted in facilities throughout the industry and our nation.

Background

I wholeheartedly agree with the shift toward a patient outcome-based system that focuses on quality. The majority of my comments will be to assist in helping attain that goal.

While noting that Dialysis is "the process of cleaning the blood" please also state it's role in fluid removal. Adequacy of dialysis is both toxin and fluid removal.

Definitions

494.10: Please include a definition for "New Patient". Are you referring to "new" to dialysis, or new to the facility-as in a transfer in from another facility? Clarification is necessary for compliance to the patient assessment requirements.

Clarifications of the definition of "direct supervision" cited in 494.140 (e) (3) needs to be made. I interpret direct supervision to mean that the supervisor is not only on premise, but actually in the room that the treatment is being performed. If this is not clarified- the

supervisor may be in a room –floors and minutes away from the actual patient and treatment.

Please clarify the definition of “patient reactions”. Surveillance of this is discussed in later sections. Are you referring only to surveillance of possible water purification reactions, or adverse reactions (intradialytic morbidities) that occur related to other factors occurring during the dialysis process? Currently intradialytic morbidities (Nausea/vomiting, hypotension, cramping etc.) are not routinely tracked. I believe they should be as they are preventable and can cause long-term patient damage. In the majority of facilities these have been considered as an expected part of the treatment- and they should not be. Some facilities actually use hypotension as a sign of getting the patient to their “Dry” weight. The K/DOQI guidelines 15-16 in the Adequacy section, note that hypotension should not be used as an indicator of Dry weight. They actually go on to say that they are especially concerned with the clinical practice of causing hypotension to establish dry weight. Intradialytic morbidities should be tracked as the first step in identifying the problem, determining the cause, and ultimately preventing it.

Please add the definition for “Nursing Facility”. Is this referring only to long-term facilities, or does it also include hospital settings?

Please also add the definition and clarification for “medical injuries”. Is this referring to intradialytic morbidities?

Infection Control

494.30 I am disappointed with the Proposed Rule in regards to Hepatitis C Screening. It seems to be based on Medicare reimbursement issues rather than the establishment of prudent and good policy for beneficiaries. I recommend screening at least on admission to a facility and semi-annually.

In order to assure oversight of infection control practices, the actual designation of a registered nurse as the infection control or safety officer is a prudent recommendation. Actually designating someone as accountable is the first step to making it happen.

Water Quality

I am in agreement with CMS that AAMI should be used as the appropriate authority on water quality. I encourage the change in reduction in the allowable dialysate colony counts from 2000 cfu/ml to 200cfu/ml moving toward a more pure dialysate as current evidence has demonstrated that this improves patient outcomes

Physical Environment

494.60

The proposed conditions do not define what "sufficient space" is for providing needed care. I do believe a minimum recommendation is needed. I believe not defining this will lead to "cramming- in" patient stations to increase census for financial gains. The current existing recommendation has prevented this. The proposed conditions state that "this detail is better left to the judgment of the facility staff". I can assure you the "facility staff" is not currently and will not in the future be asked their opinion on this subject.

494.60 (c) (2) (i): I do not think that the conditions of coverage should propose that the temperature be maintained that is comfortable for the majority of patients. I believe dialysis facilities do make reasonable accommodations for their patients, sometimes at the expense of the staff. The cause of the patient feeling cold is not as simple as outlined in the proposal. The dialysis patient is "cold" related to numerous physiological factors, i.e. anemia, uremia has affected their metabolic rate, they are immunosuppressed, they are mainly inactive during the process. The basic dialysis procedure is not programmed to decrease the patient's temperature, but it is to maintain a constant temperature. As fluid is removed from the patient their temperature is rising- Not falling as the proposal suggests, and if the dialysate temperature is greater than the patient's temperature- both factors leads to vasodilatation, and ensuing intradialytic symptoms. Thermal control -maintaining the dialysate temperature no higher than 36 C is a well documented principle of dialysis. This is done in order to keep the patient's temperature the same as the pre-temperature. If not done adequately, the patient's post temperature will be higher than his pre-temperature, and the patient will have an increased risk of all related dialysis symptoms. References include K/DOQI guidelines 15-16 in the adequacy section. If patients are cold, it is important to warm them from outside the body thru appropriate dress and blankets to keep their own body heat in. Encouraging exercise during dialysis may also be recommended to increase their comfort. Increasing the room temperature would often require temperatures that cause the dialysis staff (who are wearing their appropriate personal protective gowns) to become overheated and most likely would still NOT keep the patient's warm. Basic education with the patient on the causes of feeling cold and appropriate means to prevent it are actually what is needed and should be proposed. This is the number one complaint of patients- and the causes need to be addresses appropriately. The answer is not to increase the room or dialysate temperatures. The recommended proposal will not only Not solve the issue, but it has the potential of creating more conflict in the dialysis environment.

494.60(d) (3): I am in agreement that AEDs should be required in all dialysis facilities that are not located in a facility that has its own emergency team. AEDs have been around long enough, and have been made simple enough that they should now be a standard safety requirement.

The existing 405.2140(b) (3) specifies that the facility have a nursing / monitoring station from which adequate surveillance of patients receiving services can be made. I recommend not eliminating this - it is not only a physical environment issue- but a safety issue. It is imperative that the patients be in full view of the staff at all times- and there are many non-

interactive moments in dialysis. This is consistent with what is stated on page 71, under proposed 494.70(a) (3) and (4) concerning privacy: “we are not necessarily advocating physical barriers in dialysisbecause patients should be in view of staff at all times during the treatment to ensure safety”.

Patient Assessment

494.80

I am in agreement that a systematic patient assessment is essential to improving quality of patient care and outcomes. However, in proposed 494.80(a) I would like to add the evaluation of intradialytic symptoms- frequency, causes, treatment, and mostly preventative plan. As stated earlier under “patient reactions”, these symptoms are not being tracked on a routine basis, often are considered a “normal” part of dialysis, and usually are only band-aided (administration of saline or a hypertonic medication- often unnecessarily) versus identifying the cause and preventative plan of care. Evidence is now showing that these are not just transient events- but are causing long –term effects on the patient (i.e. cardiovascular as well as cerebral effects). Assessment can be easily done thru a simple facility occurrence or variance reporting system.

I recommend that a definition on “new” patient needs to be clarified as stated in Definitions above.

I recommend that the initial assessment be done by a number of dialysis days (9) versus 20 calendar days- whichever comes first.

494.80(c) Along with ensuring that patients receive a sufficient dialysis treatment by monitoring the dose in terms of Kt/V, monitoring fluid status is equally important. The Hemo study concluded that Kt/V above standard does not substantially reduce mortality or morbidity on our patients. Dialysis treatments should not be considered as only “rinsing” treatments. Appropriate fluid removal is also part of adequate treatments and should be reviewed on a monthly basis as well. In the adequacy section of the K/DOQI guidelines, guideline 15-16 , the work group suggests that efforts be undertaken to develop accurate methods of measuring intravascular volume and relate these changes to BP measurements/ and prevention of intradialytic complications. I recommend that not only intradialytic symptoms be monitored and recorded every treatment as stated above, and re-assessed for improvements on a monthly basis , but pre-post BPs, and the Number and type of antihypertensives be monitored on a monthly basis as well.

In accordance with the K/DOKI recommendation that methods of measuring intravascular volume need to be developed, the use of current Blood volume monitoring technologies that are in existence need to be encouraged.

Along with a comprehensive annual reassessment, I recommend a monthly summary be done for all patients to ensure stability is maintained. A very simple tool can be devised that would not cause unnecessary burdens to the facility staff, yet quickly assess that quality outcomes are being achieved.

The definition of unstable needs to include the assessment of intradialytic symptoms.

Inadequate dialysis needs to also include an assessment of volume status-minimally Pre and Post BP, as well as the number and type antihypertensive meds, Dry weight changes, and intradialytic symptoms, admissions for CHF. Fluid overload as well as hypovolemia has been associated with negative outcomes in mortality, hospitalization, and quality of life. The effects of both on the Cardiovascular system have been well documented.

Since the definition of unstable is somewhat subjective, and can not be made without assessment- I do not believe that a simple monthly summary is unreasonable.

Minimally, it would identify those who are not clinically stable and lead to changes in the Plan of Care proactively. Unfortunately, in the current proposal, an unstable patient might be missed- and the assessment be delayed

Plan of Care

494.90 As stated above, I feel a simple tool can be developed for monthly summary.

As well as including the performance measures for intradialytic symptoms, Volume status (Pre/post BPs, number and type of antihypertensives, dry wt changes, admissions for CHF), I also recommend that bone disease management performance measures should be incorporated more specifically into the patient plan of care.

Since fluid status has been associated with increased morbidity, mortality, and hospitalizations, I recommend that each facility designate a registered nurse as a Fluid Manager.

The definition of adequacy must include not only Kt/V but also volume status as stated. Under Patient Assessment.

494.90(b) (2): The Plan of care timeline for implementation should be measured by the number of treatments rather than number of days i.e.: 21 days or 9 treatments whichever comes first

494.90(a) (4) I agree that routine monitoring of the vascular access needs to occur monthly. Reimbursement of facilities for access blood flow measurements thru the current methods of Delta H, TQA, or transonic flow measurements needs to also occur in order for this service to be routinely performed.

I recommend that each facility have a registered nurse as the vascular access coordinator on the interdisciplinary team.

494.90(b) (4) I am surprised by the rule that associates a higher payment to a physician who provides more visits within each month to an ESRD patient.

I would like to suggest that a payment incentive be considered for more frequent patient assessments from the facility team as well. Perhaps that would override any additional burden for more than annual patient assessments and promote proactive assessment of the "stable" patient.

I agree that physicians should periodically see their patients while they are undergoing dialysis and would like to see a required recommendation.

Condition: Care at Home

494.100

Dialysis of ESRD Patients in Nursing and Skilled Nursing Facilities

I am not sure I understand the definition of Nursing facility- is this referring to patients being dialyzed in a hospital setting???

494.180(b) (2): I agree that a registered nurse needs to be on premise whenever in-center patients are being treated. In addition, clarification needs to include that this is an experienced dialysis nurse. Experienced needs to be defined as more than just receiving an in-service. If the procedure is delegated to the LPN or PCT, then direct and immediate supervision should also be required for hemodialysis to ensure patient health and safety.

I do believe a statement concerning patient to caregiver ratios should be addressed.

e. Monitoring: I agree that the proposal require that a certified ESRD facility be responsible for monitoring the care of the ESRD patient in the NF or SNF.

I also agree that it is imperative that the trained caregivers not only be present in the room at all times during hemodialysis, but the if the procedure is being delegated by the RN to a PCT or LPN, that the experienced dialysis RN provide direct and immediate supervision of this treatment. I have observed too often that unlicensed personnel are delivering a hemodialysis treatment in a patient room, with no experienced RN on premise. I have also observed them administrating blood products, Epogen, and other medications. They believe they are covered under the facility RN covering the floor – who is not experienced in dialysis. The facility RNs many times are not even aware of the status of the caregiver, and assume that they are performing to their limitations only. They are overwhelmed and unable to quickly and competently handle patient complications if called upon to help by the dialysis caregiver..

This needs to be specifically clarified for all facilities discussed to ensure that the health and safety of NF and SNF hemodialysis patients is protected.

QAPI

A definition for medical injuries needs to be clarified. Does this include the intradialytic morbidities that I have discussed in previous sections? I suggest that a tracking system for each of these events be developed in order to identify incidents, causes, and preventative measures. Currently these are not routinely tracked unless a severe adverse outcome occurred. Numerous caregivers have come to believe that these are acceptable and transient, partly because they are not monitored. Adding these to the facility variance or occurrence report may be all that is needed.

I agree with the OIG findings stated on page 135 that medical injuries are not systematically monitored in dialysis facilities – the facility variance report could be the first step in correcting this issue.

A patient satisfaction survey is reasonable and should include their satisfaction with the prevention of intradialytic symptoms and effects of the treatment on quality of life.

I agree that the facility needs to collect and analyze clinical data about the components of their care processes. Along with the clinical performance measures cited in the 2002 OIG report, Fluid -Volume status of their patients, and the occurrence of intradialytic morbidities, as described in previous sections, needs to be added. In accordance with the K/DOKI recommendation that methods of measuring intravascular volume need to be developed, the use of current Blood volume monitoring technologies that are in existence that would meet this requirement, need to be encouraged.

494.110(a) Program scope

As stated previously as well as adding Fluid- volume status as part of adequacy, and defining Medical injuries to include intradialytic morbidities, I would also include infection control and bone disease management in this area. The addition of these performance measures would add to the achievement of improved patient outcomes, patient safety and patient satisfaction.

Personnel Qualifications

494.140(b) (3) (i): Since the Registered nurse holds the license for independent practice, and delegates to the PCT and LPN, the conditions can not permit the LPN/ LVN to be in charge. LPNs in most states are limited to observing, documenting and reporting to the RN and are not giving the necessary training for assessing patient conditions. In addition, in the the United States, there is no state in which an LPN can supervise an RN.

As discussed in VI.A.2 –a registered nurse has the necessary professional training and expertise to coordinate care in the unit... In agreement with this statement- only the RN can be in charge.

494.140(e) Dialysis Technicians

I would encourage the wording of care provided under the supervision of the registered nurse to change to the “ongoing, immediate and direct” supervision.

I strongly believe that to ensure patient safety, it would be prudent to recommend that patient care technicians should be certified through a nationally recognized certification program in order to ensure that the minimum level of education and competency is completed.

I agree with the 3 month experience (but redefine as "clinical" experience) after the facility training program. It takes this amount of time minimally to go from orientee to novice to experienced with this complicated treatment and delicate patient population.

I would also consider defining more time for hands-on direct care prior to working with the acute care hemodialysis patients.

I agree that it should be under the direct supervision of the registered nurse since that is who is ultimately accountable to ensure that they are delegating activities that the PCT has the knowledge, skill level and competency to complete.

494.80(a) (3) I do recommend that there should be a requirement within the proposed conditions for coverage that each dialysis facility ensure a routine assessment of patient medications by a pharmacist. We have poly-pharmacy in dialysis. Many of the adverse effects that occur during treatments are related to the numerous meds, and their combinations. Numerous providers are prescribing the medications. A pharmacist as part of the team could assist in identifying potentially harmful combinations, and help relate the patient's symptomology to their medications. With so many new medications on the market, and the amounts prescribed to our patients, a pharmacist could be an invaluable addition to the team. Currently the facility staff have barely enough time to make sure they document what the patient is taking. We need someone to help the staff decide what the patient needs- and most importantly what can be discontinued.

Governance

494.180(b)(1) A requirement for an acuity-based staffing plan to assure adequate staffing and appropriate staff-to-patient ratios would be highly desirable- and not that difficult to create. It is much needed. I see Pct ratios between 3-6 and RN ratios anywhere from 6 to 24. A minimal standard ratio should also be recommended.

494.180(b) (2) Please add a dialysis experienced registered nurse must be present in the facility at all times that patients are being treated.

494.18(b) (4) I applaud your decision to retain the existing requirement that all employees have an opportunity for continuing education. This is very lacking and much needed, even with the current requirement.

Thank you for the opportunity to comment on the Proposed Conditions of Coverage,

Diana Hlebovy, BSN, RN, CHN, CNN



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NATIONAL RENAL ADMINISTRATORS ASSOCIATION

May 3, 2005

The Honorable Mark McClellan
Administrator
Attention: CMS-3818-P
Centers for Medicaid and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3818-P Comments on Notice of Proposed Rulemaking on Conditions for Coverage for End Stage Renal Disease Facilities

Dear Dr. McClellan:

The National Renal Administrators Association (NRAA) welcomes the opportunity to comment on this very important NPRM regarding the proposed revisions to the End Stage Renal Disease Conditions for Coverage.

The NRAA is a voluntary organization representing professional managers of dialysis facilities and centers throughout the United States. We represent free-standing and hospital-based facilities, which are for-profit and non-profit providers located in urban, rural, and suburban areas and serving dialysis patients in all settings.

The NRAA supports the fundamental shift in the proposed conditions for coverage from a focus on procedural standards to a focus on the patient's experience in the care delivery setting and on patient outcomes. However, we believe it is essential to appropriately fund the requirements, recommendations and quality improvement criteria.

Delineation of Responsibility (Proposed §414.330 (a))

The proposed regulations state "home hemodialysis services provided in a NF or SNF should be provided under the direction of a certified dialysis facility that is responsible for the dialysis care provided to the ESRD patients, for assuring that the NF or SNF is capable of providing pre and post dialysis care and for assuring that there is coordination of care between the two entities...."

The dialysis facility cannot be made responsible for the care provided by other licensed health care providers over which they have no control or ownership. A dialysis facility cannot assure appropriate personnel will be on duty at a nursing home (or a hospital for that matter) when the hiring, firing and scheduling of staff is not under the domain of the dialysis facility. In addition, the dialysis facility does not participate in the choice of a nursing home for a patient. The decision is made by the patient, patient's family and their insurance provider. If it is critical that nursing home staff be capable of providing pre and post dialysis care, then Nursing Facility

(NF) and Skilled Nursing Facility (SNF) management should be required to accept only patients for whom they can adequately provide care. These criteria should then include pre and post care for hemodialysis patients dialyzing in a dialysis center but living in a NF or SNF.

Equipment, Supplies, and Support Services (Proposed §414.330(a)(2)(ii)(C))

The proposed regulations would require that the patient's supplier report to the facility every 30 days all services and items furnished to the beneficiary so that the information can be documented in the patient's medical record. It is unclear how and what to document to meet the requirement. The NRAA agrees with collecting data at least every 2 months but it is prescriptive to require that the documentation of delivery of supplies be kept in the medical record. These records should be allowed to be kept separate from the medical record.

The NRAA requests a clarification as to how and what needs to be "documented" (e.g., "proof of delivery of supplies, including items delivered.")

Training (Proposed §414.330 (d))

The proposed regulations suggest the certified dialysis facility should be responsible for providing training to NF or SNF staff and to all caregivers.

It should be the responsibility of the nursing home to provide training for their staff in order to adequately care for the patients they accept. They have control over the admissions of patients to their facility, full knowledge of the diagnosis, and are the most familiar with the qualifications of their staff.

Dialysis facilities cannot control which nursing homes accept dialysis patients nor can dialysis facilities control the insurance company's selection of nursing homes for their subscribers. The expense of providing education for every nursing home caring for dialysis patients is unreasonable.

Monitoring (Proposed §414.330 (e))

The proposed regulations state that the ESRD facility should (1) periodically assess the ability of the staff (NF or SNF staff and caregiver) responsible for the care of the ESRD patient to be sure they are competent in their tasks. This should apply only in cases where the dialysis provider has trained the individual providing home dialysis services.

Comparable care for nursing home patients should be equal to care provided in other settings for home patients (such as the patient's home) versus comparisons to in-center care.

Provisions of Proposed Part 494 Subpart A (General Provisions)

Basis and Scope (Proposed §494.1) Subpart A

Definitions (Proposed §494.10) "Self-Dialysis" – change "little" to "*limited*" to include units that are "self care units" such as nocturnal where staff are there to support patients and assist as necessary.

The NRAA supports including a NF or SNF in the definition of a patient's "home" setting. These settings are indeed the patient's residence while they are receiving care in these institutions. We recommend revising the definition of *home dialysis* as follows:

"Home dialysis means outpatient dialysis performed at home or in the patient's residence by an ESRD patient (or caregiver, provided the individual performing such dialysis has completed the course of training required in § 494.100(a) of this part."

Compliance with Federal, State, and Local Laws and Regulations (Proposed §494.20)

The NRAA generally supports the requirement for Medicare-certified ESRD facilities to maintain compliance with appropriate Federal, State and local laws with one exception. It should be noted that several states prohibit Medicare-certified facilities from providing erythropoietin (EPO) to home dialysis patients due to an interpretation of state pharmacy laws that the facility staff is "dispensing" the medication. This can create obstacles to achieving and maintaining adequate control of anemia. In addition, CMS regulations prevent pharmacies from billing Medicare if they dispense Epogen. Therefore, pharmacies cannot bill and, if providers cannot dispense, then the distribution of Epogen to home patients becomes impractical. The alternative would be for home patients to come into a center to receive medication and that could mean one to three trips per week. This would be a distinct disincentive for patients to select a home therapy.

The NRAA recommends that CMS address and correct this issue before the final regulations are released. We also recommend that a mechanism for a waiver or an exception for Medicare-certified ESRD facilities be created to allow for provision of prescribed EPO by the Registered Nurse (RN) responsible for home training and support, similar to other home supplies such as saline, heparin or peritoneal dialysis solutions.

Provisions of Proposed Part 494 Subpart B (Patient Safety)

Infection Control (Proposed §494.30)

The NRAA recognizes the importance of appropriate infection control measures for the safety of both patients and staff. We agree that this issue deserves identification as a separate condition for coverage. We support adoption of the Centers for Disease Control and Prevention (CDC) recommendations for infection control practices for hemodialysis units, and the HICPAC guidelines referenced in the proposed rule; most facilities have already incorporated these into practice. We have concerns about adoption of the AIA Guidelines for Design and Construction of Hospital and Health Care Facilities. We believe this would add an unnecessary cost burden to facilities. ESRD providers that are currently certified and do not have isolation stations should be allowed a "grandfather" clause and not be required to build an isolation station. In addition, particularly for rural providers, we believe an exception to this requirement should be allowed that would give small facilities the option of not building an isolation station, but identifying an alternate provider with an isolation room located within a reasonable distance (e.g. within 30 miles)

Another area of concern is the requirement in §494.30(b)(2) for an RN to be designated as the Infection Control or Safety Officer. We do not believe that the duties of an Infection Control or Safety Officer require the knowledge or skills of an RN. Implementation of this proposed requirement would most likely require adding additional RN hours for the facility. Due to the current nationwide nursing shortage, many facilities are already challenged to provide RN coverage to meet daily patient care needs. In those cases, an additional RN would likely be required to meet the Infection Control/Safety Officer responsibilities. This would add significant cost to the facility operation, both for recruiting and training, as well as the RN's salary expense. At present, it is the responsibility of the Medical Director to assure that there are appropriate policies, procedures and practices in place to address infection control and a safe environment. Often the facility's Safety Officer is an experienced Biomedical technician due to the many physical plant issues related to safety. It is incorrect to assume that an available RN currently exists in every dialysis facility to assume this role, particularly considering the shortage of nurses and the fact that the wage index is based upon 1980s data. The cost of one additional RN on staff equates to:

RN with benefits @\$25.00 per hour + 30% benefits would be

$\$25.00 \times 2080 \text{ hours per year} = \$52,000$

$\$52,000 \times 30\% \text{ benefits} = \$15,600$

Total for one RN per year = \$67,600

$\$67,600 \times 4400 \text{ facilities} = \$297,440,000.$

The NRAA suggests leaving the ultimate responsibility with the Medical Director to appoint a qualified individual as the Infection Control/Safety Officer. In many cases there may be a licensed practical nurse or an experienced patient care technician who could fulfill these duties with appropriate oversight in a more cost effective manner.

The NRAA believes facilities should practice fire and evacuation procedures annually, with verbal reviews quarterly. We request further clarification of the LSC waiver provisions. Would this be a paper review or require a site visit? We also recommend that CMS establish reimbursement for hepatitis C screening to allow for early detection.

Water Quality (Proposed §494.40)

The NRAA does not support a requirement for ultrapure dialysate. It is not clear at this time that the additional costs associated with ultrapure dialysate would result in significant benefits to patients.

The reference to sampling locations for bacterial or endotoxin testing suggests taking samples from the first and last outlets in the loop. The NRAA recommends changing the wording to sampling from multiple outlets along the loop as the definition of a loop does not allow for a beginning and an end.

Water (Proposed §494.40(a)(2))

The NRAA believes that on page 6195, column 1, RD 52 is misquoted / mischaracterized when it is suggested that monthly samples be drawn from “++ Outlet of the water storage tanks, if used” and “++ concentrate or from bicarbonate mixing tank.”

When incorporating references to RD 52 which is a detailed guideline for “how to” achieve many different end goals, it should be kept in mind that those goals may be reached in ways other than those suggested in the guidelines. It should be sufficient to require tests for chlorine break through and ask dialysis staff to show how they ensure there is no chlorine break through when their first line of defense fails. Items such as Empty Bed Contact Time (EBCT) and frequency of carbon replacement should not be prescriptive as an EBCT of 10 may be overkill in one scenario but not enough in another. We suggest staying outcome oriented and that the wording be revised “*to provide adequate EBCT to be effective.*”

RD 52 allows for samples from the storage tank outlet for troubleshooting purposes, BUT does not recommend monthly samples from that site. Bicarb mixer cultures should come from the water inlet to the mixer, NOT from the tank or concentrate in the tank.

RD 52 recommends minimizing but not prohibiting the addition of fresh to already mixed batches of bicarbonate. The NRAA recommends the language allow bicarb to be used within the specified time suggested by the manufacturer.

RD 52 of 2004 offers additional solutions to RD 62 of 2001 and should be considered more up to date on certain subjects. For example, RD 624.3.13 states the UV lamp device shall be equipped with an on line monitor of radiant energy output that activates a visual alarm indicating the lamp needs replacement. However RD 52 recommends another way to maintain the output of the lamp and that is to replace the lamp at predetermined intervals, e.g. every 8,000 hours or approximately annually. Since AAMI standards are continuously updated, facilities should be allowed flexibility in the process to provide the desired outcome.

Water (Proposed §494.40 (c)(2))

Regarding the proposal to require chlorine/ chloramines testing of water samples prior to each patient shift or every 4 hours whichever is shorter, the NRAA is uncertain as to how a shift is determined by CMS. Different providers may have different interpretations of a “shift.” Every 4 hours is easier to track but what would determine whether a provider is out of compliance if it is not exactly at the 4 hours (e.g., if the check was at midday and the following check is at 4:04pm). What are the interpretive guidelines for the surveyor?

The NRAA recommends that the proposal include language defining a shift, or have a 15 minute window on the 4 hour rule.

Water (Proposed §494.40 (e))

The proposal to require active surveillance of hemodialysis reactions during and following dialysis is unclear. What is the interpretation of “following” dialysis?

The NRAA recommends a further clarification to "following" dialysis such as, "*after post assessment with subsequent discharge by the nurse or caregiver.*"

Re-Use of Hemodialyzers and Bloodlines (Proposed §494.50)

Section 1881 (f)(7) states that..."facilities that fail to follow reuse protocol will be subject to denial of participation in the Medicare program et al...."

The NRAA believes that denial of program participation is too drastic a measure. This should be invoked only if multiple patients are affected simultaneously and under only one condition or standard. Interpretive guidelines should clearly identify what denotes just cause to deny participation and/or payment and how the affected treatments for denial of payment would be determined. For example, if reuse is considered out of compliance, and the facility chooses to go to non-reuse dialyzers until compliance is reinstated, the facility should not be denied program participation.

Physical Environment (Proposed §494.60)

Emergency preparedness of staff (Proposed §494.60 (d))

While many providers may certify patient care staff in CPR annually (or every two years), there are also many who conduct annual CPR training without the expense of actual certification. The NRAA feels that the requirement for CPR certification is too onerous and costly as it may require the facilities to keep a trained CPR instructor on staff. In addition there is a certification fee through the American Heart Association of approximately \$25.00 per person. Assuming there would be approximately 15 persons per facility to certify each year, the annual cost would be over \$1 million:

$$15 \text{ staff} \times 4400 \text{ facilities} \times \$25.00 = \$1,650,000$$

We believe the requirement should state "*CPR training must be provided annually.*"

Emergency equipment and plans (Proposed §494.60 (e))

The NRAA believes that patients in small, rural facilities may receive the most benefit from use of an AED. The NRAA supports the requirement that all Medicare-certified dialysis facilities have an AED available for life support for dialysis patients.

Provisions of Proposed Part 494 Subpart C (Patient Care)

Patients' Rights (Proposed §494.70)

The NRAA agrees that the facility must be responsible for informing patients of their rights and responsibilities "when they begin their treatment" at that facility. However, the NRAA is concerned about the time frame.

Currently, social workers tend to have this as one of their key responsibilities and it will be burdensome for the social workers to meet this requirement the very first day of the patient's treatment.

The NRAA believes dialysis facility staff can review the overall patient rights with patients during their first treatment and then the designated staff, (i.e. social worker) should review in detail within the first month of treatment. The NRAA also recognizes the patients' right to determine how they wish to develop advance directives. Facilities should be required only to present information on advance directives, not require completion.

Patient Rights, informed of treatment modalities (Proposed §494.70(a)(6))

The NRAA agrees that patients must be informed of all treatment modalities and alternatives. Patients must be able to choose their treatment option and make an informed decision.

Providing patients with information about what treatments are offered meets only half the need without informing them *where* treatments are offered. Facilities should provide patients with information regarding all modality options, even if they do not offer home dialysis at that facility. Patients should be provided with resources that could include Home Dialysis Central (www.homedialysis.org) for locations where different types of home dialysis are offered or the US Transplant (www.ustransplant.org) for information about transplant facility-specific data.

Patient Rights, patient informed of patient care policies (Proposed §494.70 (a)(8))

The NRAA concurs that patients need to be fully informed regarding the facility's reuse of dialyzers. The NRAA has concerns as to the degree in which and by whom the facility's reuse policies and procedures are shared with the patient and whether the patient is given the option of consenting or not consenting for the dialyzer and/or supplies to be reprocessed.

Not all facilities that reprocess dialyzers/supplies offer consistent patient education about the policies and procedures related to this process, nor do they necessarily assure that the patient fully understands the reuse process. Examples: a. patients need to understand how their facility protects their safety when reusing dialyzers, b. patients need to understand the risks and benefits of reuse, and c. patients need to be given the option to refuse the reuse of their dialyzers and/or bloodlines.

The NRAA recommends that the reuse consent contain all the necessary elements of risks, benefits and alternatives and that the patient has the right to refuse. If it is the facility's policy to reuse, then exceptions have to be made for patients who refuse.

Patient Rights, patients fully informed by a physician of their medical condition (Proposed §494.70 (a)(9))

The NRAA firmly believes that patients need to be fully informed of their medical condition. The patient's own physician, and preferably nephrologist, has the most comprehensive knowledge about the patient's medical status and, because of the trusting relationship, is the best one to share this information with the patient and/or his/her agent.

The NRAA believes the language is ambiguous. Is this to be a physician, as written, or the patient's physician and does this physician need to be a nephrologist?

The NRAA recommends that "*a physician*" be deleted in the statement "be informed by a physician regarding his or her own medical condition unless contraindicated" and that the language be changed to "*their physician or nephrologist or physician extender (NP or PA).*"

Patient Rights, discharge and transfer of patients (Proposed §494.70 (b)(1) and (2))

The NRAA agrees that the patient be informed of the facility's policies for transfer, discharge, and discontinuation of services. Every facility should have the right to discharge a disruptive patient when they are a threat to themselves, patients and staff. However, we believe if circumstances warrant, a psychiatric referral and evaluation should be considered before discharge. If the behavior requires a response from local law enforcement it may warrant immediate discharge.

Facilities should not be able to discharge a patient who merely disagrees with staff. Facility staff must recognize the difference between a patient demonstrating anger versus a patient threatening violence. Staff needs to be trained on how to tell the difference and how to diffuse difficult situations. A 30 day written notice to terminate care is reasonable.

The NRAA recommends that when patients commit or threaten violence, this should be reported to the authorities and the patient should be screened as to whether he/she is dangerous to self or others. Patients should be informed up front that specific steps are followed. Circumstances in which facilities notify local law enforcement and/or refer patients for psychiatric evaluation and treatment for reducing risk of harm to self or others need to be explicitly and clearly outlined. Patients should know that a facility has the right to call local authorities if they behave in a violent manner or threaten violence and patients who are dangerous to themselves or others should be referred for evaluation. Patients causing disruption in the unit, scaring other patients who feel threatened even by verbal abuse or foul language, may warrant a 30 day notice.

Patient Assessment (Proposed §494.80)

The NRAA fully supports elimination of the facility medical director and home dialysis program physician (if not provided at the facility at which the patient has initiated treatments) as part of the interdisciplinary team while allowing "a nephrologist or physician treating the patient for ESRD." This is a welcome change in the proposed regulations and should ease the facility's burden in the patient assessment and care planning process.

The NRAA agrees that a systematic patient assessment is essential to improving quality of care and patient outcomes. Further, the NRAA concurs that, ideally, the facility's interdisciplinary team should include the patient and/or designee. However, this is not always feasible, and, in fact, the patient and family often decline to participate through no fault of the facility or the efforts of its interdisciplinary team.

The NPRM states "the interdisciplinary team consisting of, at a minimum, the patient (if the patient chooses) or the patient's designee..." This implies that one or the other must participate in the comprehensive assessment. Further, in paragraph one of 494.90, it states that "the interdisciplinary team must..." Again, implying that the patient or designee must participate in the development of the patient care plan. Yet in the summary of contents, it states "the members

of the interdisciplinary team would include the patient (if he or she chooses)...” and in another section of the NPRM, acknowledges that the patient and family may decline to participate and states that the patient must only sign the plan of care. These variations in wording are confusing.

The NRAA recommends the following: Change the first sentence of paragraph one in 494.80 to read *“the patient or his/her designee (if he or she chooses)...”*

The NRAA also recommends that a nurse practitioner or physician assistant working under the supervision of a nephrologist be able to complete the physician portion of the assessment.

Frequency of Assessment of New Patients (Proposed §494.80 (b))

The NRAA agrees that new patients must be assessed in a timely fashion. However, the proposed standard (b) states “frequency of assessment of new patients.” What is the definition of a new patient? Is it defined as a patient new to dialysis or a patient new to the facility, such as a transfer into the facility?

The NRAA suggests that the definition of new patient be clarified to mean a patient new to dialysis who does not have a documented comprehensive assessment on record

Frequency of Assessment of New Patients (Proposed §494.80 (b)(1))

The proposed standard states, “an initial comprehensive assessment must be conducted within 20 calendar days after the first dialysis treatment.” This timeline does not address treatment days, missed treatments or options for patients re-hospitalized. In addition “first dialysis treatment” needs to be clarified to avoid confusion with the first dialysis in a hospital.

The NRAA believes a timeframe for the initial comprehensive assessment is appropriate. In this regard, the NRAA suggests the following: *“An initial comprehensive assessment must be conducted within 30 days of admission to the dialysis facility or the by 10th outpatient treatment, whichever occurs later”* in order to allow for adequate time and interaction with the patient to complete the assessment. There should be an exception for patients transferring into a facility in which the interdisciplinary team is the same.

Frequency of Assessment of New Patients (Proposed §494.80 (b)(2))

The NRAA agrees that reassessment of patients is appropriate during the early stages of their adjustment to dialytic therapy.

It is unclear whether the 3-month requirement is for reassessment of the patient after the start of dialysis therapy or if it applies to all patients admitted to a facility, including transfers?

The NRAA believes a timeframe of within 3 months is reasonable and consistent with meeting patient needs. However, “new patient” should be clarified as a patient initiating dialysis for the first time, or those who require initiation of a CMS 2728; this would include patients with transplant rejections who have been off dialysis for a long time.

Assessment of Treatment Prescription – Patient Reassessment (Proposed §494.80 (d)(2))

The NRAA concurs that assessment of the treatment prescription is in keeping with a quality improvement focus.

There should be clarification as to what is required for the reassessment when a patient is considered unstable. One of the criteria for an unstable patient is “poor nutritional status, with unmanaged anemia and inadequate dialysis.” Unmanaged anemia and inadequate dialysis without the presence of poor nutritional status do not fit the definition of “unstable.” As written, a facility would not define a patient who has a Kt/V that is not within established limits as unstable. The NRAA believes this is appropriate as the adequacy of dialysis would be dealt with as part of the routine care of the patient.

The NRAA recommends a clarification that clearly states that all three parameters, “poor nutritional status, with unmanaged anemia and inadequate dialysis” must be present to justify a label of “unstable” and require monthly reassessment. It should also be made clear that a comprehensive reassessment is not necessary, but reassessments should be focused only on those parameters that address the patient’s unstable condition(s).

Patient Plan of Care (Proposed §494.90)

The NRAA applauds the proposed regulation’s focus on patient care based on evidenced-based standards and in keeping with quality improvement principles. The six categories required are appropriate. Additionally, linking the patient assessment and care planning process is appropriate as is the inclusion of outcomes and timeframes in the care plan.

The NRAA agrees with the elimination of the separate requirement for long-term plans as well as the change to annual care plans on stable patients. The NRAA also concurs that a transplant surgeon need not be involved considered as part of the interdisciplinary team for care and planning purposes, but would be included as needed when a possible transplant candidate is identified.

The NRAA is concerned, however, that the critical role that patients play in outcomes is not addressed in the regulations and urges that it clearly be stated that documentation/justification of the failure to comply with the treatment regimen be allowed as reason for the failure to meet criteria within the plan of care.

Development of Patient Plan of Care, Vascular Access (Proposed §494.90 (a)(4))

While the NRAA agrees that vascular access is a key component of care, there is lack of clarity as to what is expected.

The NPRM currently reads “the patient’s vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for stenosis.” We are concerned that there may be inconsistency among State Survey agencies regarding what constitutes appropriate monitoring, which could potentially create a financial burden for facilities if a Surveyor requires a particular monitoring approach.

The NRAA recommends that the regulation clarify this issue by providing examples of what is acceptable for monitoring purposes. We recommend inclusion of a requirement in §494.90(d) for documentation of patient education on the benefits and risks of various types of vascular access in keeping with the Fistula First initiative. Sufficient funding must be provided for any requirements associated with these activities.

Development of Patient Plan of Care, Transplantation (Proposed §494.90 (a)(5))

In the preamble, it states that there must be documentation in the care plan if the patient declines transplantation. Requirements in the comprehensive patient assessment (494.80 (a)(10)) specifically address patient rejection of a transplant option.

The NRAA suggests the addition of the following language as [5] [iv] (6250) in the final regulations for clarity and consistency, *“In cases when the patient meets the transplantation criteria, but declines referral, there must be documentation in the patient plan of care that the patient made an informed decision to decline renal transplantation.”*

Development of Patient Plan of Care, Rehabilitation (Proposed §494.90 (a)(6))

Rehabilitation is recognized as an important aspect of quality patient care. The role of the dialysis facility in the actual provision of rehabilitative-specific care beyond education, support and encouragement is limited.

The NPRM states that “the interdisciplinary team must provide the necessary care and services for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by the patient, including the educational needs of the pediatric patient...”

While this would be ideal, limitations are acknowledged in the preamble, stating that the facility will not be held accountable for rehabilitation outcomes that are beyond the facility’s control.

The NRAA suggests the wording be changed in the final regulations to the following, *“the interdisciplinary team must assist the patient in achieving the level of productive activity he/she desires by providing support services such as encouragement, educational materials, social worker support and referrals to community services.”*

Implementation of Patient Plan of Care (Proposed §494.90 (b)(2))

The NRAA agrees that implementation of the patient plan of care in a timely fashion is necessary to ensure quality care.

The NPRM states that the plan of care must begin within 10 days after completion of the patient assessment as specified in 494.80.

The NRAA proposes 15 days to allow adequate time for referrals required to address such aspects as vascular access and rehabilitation.

Implementation of Patient Plan of Care (Proposed §494.90 (b)(4))

The NRAA agrees that a physician providing ESRD care should see patients at least monthly.

The NPRM states "... And, periodically, while the hemodialysis patient is receiving facility dialysis." "Periodically" is vague and requires definition if used in the final regulations. Requiring the physician to see the patient on dialysis is outside the scope of authority of the facility and the facility should not be penalized if the physician sees the patient in the office and not while on dialysis.

The NRAA urges the elimination of the requirement for periodically seeing the patient in the facility. Facilities are not allowed to report costs for space required for doctor's visits, and seeing patients while "on the machine" does not provide for the privacy sometimes required for the physician assessments.

Transplantation Referral Tracking (Proposed §494.90 (c))

Transplant referral tracking is important. Communication between transplant centers and outpatient dialysis facilities, however, has historically been difficult to initiate and maintain, particularly if the communication is merely a formality. It appears that the intent of the requirement is to communicate any substantive changes in the patient's condition that would impact transplant eligibility. The patient is the contractor by choice with the transplant center and therefore the majority of communication should be between these two parties.

The NRAA recommends the following clarification as to the nature and extent of the required quarterly communication, "*The team must maintain a list of all patients on the active transplant waiting list, as provided by the transplant center. The dialysis facility must communicate any changes in the patient's eligibility for transplantation to the transplant center as they occur, or at least quarterly.*"

Patient Education and Training (Proposed §494.90 (d))

The NRAA recommends that this section also include a requirement for documentation of patient education on the benefits and risks of various types of vascular access in keeping with the Fistula First initiative.

Care at Home (Proposed §494.100)

The NRAA agrees that care provided to home dialysis patients should be equivalent to care provided to patients in a facility and appreciates the clarification of required training elements. The NRAA has concerns regarding the coordination of care responsibilities between the dialysis facility and NF or SNF settings as discussed in the preamble. Dialysis facilities are not in a legal position to be held accountable for the quality of care provided in a NF or SNF. To do so would require ownership or a management contract for that sole purpose and create a significant financial burden for the dialysis provider.

There must be coordination of care and communication between both members of the care delivery team (i.e. dialysis facility and NF/SNF) and, in this regard, the current requirement for a written document describing the relationship between the two parties should suffice. Home hemodialysis with non-medical "helpers" has been in existence for over 30 years. Once a home dialysis helper has been trained by a dialysis provider certified to provide home dialysis training

and support services, it is irrelevant whether the home dialysis is provided in a patient home or a NF/SNF. Requiring that a registered nurse be present during dialysis is expensive and unnecessary in this situation.

Furthermore, as allowed under State law, licensed practical or vocational nurses who meet the experience requirements should be approved to provide home dialysis training under the supervision of a registered nurse.

Mandated visits to the home of patients on home hemodialysis and home peritoneal dialysis should be treated differently. Home visits to patients receiving home peritoneal dialysis should be required only when medically indicated. In the absence of a need for water treatment there is not the medical necessity for home visits for peritoneal dialysis patients as there is for home hemodialysis patients. The regulation proposes to retain the existing requirements regarding periodic surveillance of the patient's home adaptation. Routine visits to the home of patients on Continuous Ambulatory Peritoneal Dialysis (CAPD) are unnecessary as there is no equipment needed and exchanges can be done in any clean area. Visits should be as needed, e.g. frequent infections.

Routine visits for Continuous Cycling Peritoneal Dialysis (CCPD) home patients should also be done as needed since there is no water treatment required and machine disinfection and repairs to equipment are typically provided by the manufacturers' personnel. Visits should be required on the same basis as CAPD patients, only as needed for frequent infections. The NRAA recommends the language be changed to read: *"...conduct periodic monitoring of the patient's home adaptation, including visits to the home for home hemodialysis patients and visits to the home for peritoneal dialysis patients if medically necessary..."*

This section also states that the "facility is required to install and maintain medically necessary home dialysis supplies and equipment prescribed by the attending physician". Consideration should be given allowing the facility to arrange for installation and maintenance of the supplies and equipment as that has become the current practice. Most of the time cyclers and hemodialysis equipment are installed by the manufacturer's representative.

The proposed regulations state that certain conditions must be satisfied to consider the NF or SNF a patient's home (for short stays, such as rehabilitation, or brief recovery time, the nursing home would not be considered the patient's home...)

A patient on a home therapy hemodialysis CAPD or CCPD prior to hospitalization should not be prevented from continuing their home therapy for a short stay in a nursing home or be denied nursing home services because they are on home hemodialysis CAPD or CCPD. If a nursing home is not considered a patient's home for short stays of rehabilitation, then certainly hospitalizations will be prolonged as patients will have the choice of staying in the hospital to get dialysis and rehabilitation or going to a nursing home without dialysis but able to get rehabilitation.

Quality Assessment and Performance Improvement (Proposed §494.110)

The regulations propose the requirement that a facility develop, implement, maintain and evaluate an effective, data-driven, quality assessment and performance improvement program that reflects the complexity of the dialysis facility's patient population and its processes of care. This approach calls for facilities to systematically collect and analyze clinical data about the components of their care processes and opportunities for improvement. NRAA agrees with the concept of continuous quality improvement.

In addition, "The OIG recommended that facilities...identifying and analyzing the cause of medical injuries and medical errors." Currently dialysis facilities complete "incident reports" for adverse occurrences but the criteria most likely vary from facility to facility. The proposed regulations name several areas that should be included in the QAPI program. These include reuse, patient satisfaction, and patient grievances. Facilities are required to set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes.

The proposed regulations suggest using the NKF-KDQOI guidelines as clinical standards. The NKF-KDOQI guidelines were developed specifically as guidelines and were not intended for use as a CQI measure as many of the guidelines are based on opinion versus evidence. Holding the dialysis community to standards that are based purely on opinion is inappropriate. In addition, the guidelines often indicate practices that are not reimbursable by CMS and, therefore, would place a significant financial burden on dialysis facilities. Only reimbursable, evidenced based guidelines should be considered as QAPI criteria for dialysis facilities

§494.110 (a) number (7) proposes that "facilities monitor patient satisfaction and grievances as part of the QAPI process...."

Many patient issues are addressed on a continuous basis as they arise during day-to-day operations. There is documentation, as necessary, in the social service or nursing or physician notes and these are usually addressed individually in patient care conferences. Patient satisfaction should be monitored but informal disputes, which some might include as "grievances" should not have to be a part of this statement.

The NRAA proposes that only formal written grievances should be "monitored as part of the QI program."

§494.110(b) states "that dialysis facility must take actions that result in performance improvements...that are sustained over time."

There is a subset of patients that will generally not meet criteria for anemia and more often albumin due to underlying conditions.

These conditions should be defined and these patients should be excluded from the denominator used to calculate the percentage of patients meeting criteria. This denominator should be facility specific.

The NRAA believes that patients in the first 3 months of dialysis, patients with active infections or malignancies and patients with ongoing systemic inflammation should be excluded from the facility's denominator used for calculation of percentage of patients achieving target criteria.

Special Purpose Dialysis Facility (Proposed §494.120)

Dialysis facilities under this heading are usually temporary and in most cases are utilized for camps for children that may last one to four weeks in duration. As noted in the proposed rule, very few of the camps (one in March 2001) have been certified. This is due to the current requirements for certification, recognizing the amount of time that the children can attend camp due to requirements of transporting (usually via bus) pediatric hemodialysis patients to a unit some distance away and dialyzing them and then transporting them back. It is not only distance that is an obstacle but also the availability of appropriate treatment times to avoid dialyzing late into the evening for small children. Under the modifications proposed in the regulation, to allow for operation under a Medicare-certified ESRD provider, more vacation camps may become available, leading to more access and to a better camp experience for pediatric patients. Some facilities are currently working around certification by limiting campers to peritoneal dialysis patients, using the camp as a "home setting." Hemodialysis patient treatments may in some cases not be billed to Medicare, thus avoiding the requirement for certification.

The proposed regulations once again indicate a preference to make a certified dialysis facility responsible for treatments provided outside of its domain, e.g. in the camps. The NRAA recommends dialysis facilities not be responsible for any care given to a patient who dialyzes in a camp of their choice. A dialysis facility cannot be made responsible for the choices made by patients except to advise them of the risks involved in their choice.

Laboratory Services (Proposed §494.130)

No comment

Provisions of Proposed Part 494 Subpart D (Administration)

Personnel Qualifications (Proposed §494.140)

Medical Director (Proposed §494.140(a))

No comment

Nursing Services (Proposed §494.140(b))

It is unrealistic to require that the Nurse Manager be employed full-time. Many small rural facilities only operate on a limited basis and have part-time nurse managers, or two facilities may fall under the direction of one Nurse Manager. The NRAA recommends elimination of this requirement.

Dietitian (Proposed §494.140(c))

No comment

Social Worker (Proposed §494.10(d))

While the NRAA agrees that it would be ideal to have an MSW in every dialysis facility, those in isolated rural areas have had difficulty recruiting and retaining MSWs. Additionally, some locations (California, for example) are experiencing a shortage of professional social workers that can make them difficult to recruit even in urban areas.

The NPRM retains the requirement for an MSW, which will perpetuate the problem some facilities have experienced in complying with the Conditions for Coverage personnel requirements.

The NRAA recommends the creation of an exception, to be granted by the state survey agency, for facilities that can document that they have tried but have been unable to hire an MSW. In such situations, the regulation should allow for a BSW-trained social worker to serve as the facility's social worker, with supervision by an MSW employed or contracted by the dialysis provider organization. The proposed rule states "we recognize the importance of the professional social worker..." The NRAA believes that a BSW *is* a professional social worker and that it should be permissible to use them when an MSW is unavailable. The NRAA does not agree that using a social worker technician is a viable solution as that would require MSW's to cover more patients to maintain the same costs.

Furthermore, the proposed regulations suggest the use of social service technicians to provide the supportive services such as information on Medicare and Medicaid benefits, transportation, housing and other concrete services.

If this suggestion is implemented, social workers may be subjected to higher patient ratios to make up the difference in the cost of providing social service technicians. This tradeoff may not be in the best interests of the patient or the social worker.

Many facilities have found patients respond better to therapeutic services when they occur in another setting that requires some personal effort by the patient to obtain. For example, captive patients (connected to dialysis equipment for treatment) may resent the intrusion of the social worker trying to counsel them while they are on dialysis and would benefit more by having to take an active role in securing counseling services by a psychologist or psychiatrist outside of the dialysis unit.

Estimated cost of a social services technician:
\$15.00 per hour X 2080 = \$31,200
\$31,200 X 30% benefits = \$9360
Total \$40,560 X 4400 facilities = \$178,464,000

Patient Care Dialysis Technicians (Proposed §494.140(e)(3))

The requirement that patient care technicians receive three months experience "under the direct supervision of a registered nurse" following the facility's training program needs clarification. Typically an RN is responsible for the oversight and training of all new patient care staff, but may have assistance from a preceptor who shares the same role as the new trainee. It is

unrealistic to require that an RN be the only experienced personnel directly involved in the training of patient care technicians for a three-month period. We recommend revising the language to remove the word "direct" and state "*This experience must be under the supervision of a registered nurse*".

If this requirement takes effect, at least one or more RN's could be needed to provide this orientation to technicians. The cost of one additional RN as previously calculated would be \$67,600. Assuming most facilities will require at least one additional RN, the total cost for each of the 4400 facilities would reach \$297,440,000. This would have a major fiscal impact on every facility.

Responsibilities of the Medical Director (Proposed §494.150)

The NRAA appreciates the clarification of the role of the Medical Director, particularly as it relates to assuring quality of care provided by attending physicians and non-physician staff via participation in the QAPI process and familiarity with facility policies and protocols.

Relationship with the ESRD Network (Proposed §494.160)

No comment

Medical Records (Proposed §494.170)

The NRAA agrees with the less prescriptive approach employed in the NPRM. The NRAA believes a specified time frame for the completion of medical records would be too prescriptive, but we would support a maximum of no more than 30 days after any significant event occurs.

Governance (Proposed §494.180)

Adequate Number of Qualified and Trained Staff (Proposed §494.180(b))

The NRAA opposes mandated staff to patient ratios as self care patients and full care patients are often commingled in the same treatment area to accommodate patient schedule requests for days and times to dialyze. The NRAA does not recommend a mandated acuity-based staffing plan due to the need to be flexible with daily schedule changes. Such changes may include patients being treated on each shift based on hospitalizations, new patient admissions, or discharges (transfer, transplant or death). If acuity-based staffing is required, a formalized daily assessment would be needed to address unanticipated changes in patient's condition, accommodating unscheduled patients who need treatment, and sick calls by staff. These issues are already taken into account during the daily operation of a clinic. Additional time taken to continuously document the evaluation of staffing ratios based on acuity would detract from RN attention to patient care.

Training Program Criteria (Proposed §494.180(b)(5)(i))

The NRAA agrees with the patient care tech program criteria for a minimal skill set.

Medical Staff Appointments (Proposed §494.180 (c)(1))

The NRAA agrees that the governing body approve medical staff appointments. However since Physician Assistants and Nurse Practitioners are the employees of physicians already approved

by the governing body, the choice of their employees should be left up to the employer. If there are issues with Physician Assistants and Nurse Practitioners, they should be addressed between the CEO of the dialysis center and the employing physician.

Governance (Proposed §494.180 (c)(2))

The NRAA agrees that it is in the best interests of patients to ensure that staff members are informed and educated about the facilities policies and procedures.

The regulation needs to address the education of staff members on a facility's policies and procedures rather than simply being informed.

The NRAA recommends that the text should be changed to reflect that patient care staff members are expected to review the facility's policies and procedures manuals to ensure their awareness of how the facility approaches patient care. These manuals should be available to all staff and updated continuously.

Discharge and Transfer Policies and Procedures (Proposed §494.180 (f))

The proposed regulations state two physician signatures would be required for an involuntary discharge: the patient's primary physician and the medical director if they are not one and the same. Only one signature should be required of one physician because delaying a discharge waiting for a second signature could put the facility and other patients in jeopardy.

Additionally, it is stated the dialysis facility should document an attempt to place the patient in another facility. If there is discord between a facility and a patient, the patient may prefer the discharging facility not contact other facilities. Also, the discharging dialysis facility may not want to contact other facilities for fear they might be accused of misrepresenting the issues to the new unit. The patient would then accuse the discharging facility of preventing them from receiving care. In some cases it is better for the discharging facility to let the patient make his/her own contacts, tell his/her own story and sell himself/herself to the new facility.

Life Safety Code (Proposed §494.60)

The proposed regulations are considering the requirement of an automatic notification of a fire to emergency forces and the use of smoke barriers in buildings over 5000 sq.ft. Each municipality has strict building codes and enforcement policies in place including, in some cities, an annual fire safety inspection by the local fire department.

The NRAA suggests that compliance with local Life Safety Codes should be sufficient protection for staff and patients. Each locality may have implemented criteria specific to the local threats of fire, flood, wind, earthquakes, etc.

Based on estimates provided by a local fire department, the cost of smoke barriers is significant as air ducts for heating and air conditioning would have to be replaced with partitions that would have to be installed in the facility.

Our research has estimated that the cost of automatic notification would exceed \$3000 per facility for installation with monthly monitoring costs of \$80.00 per month, plus the cost of 2 telephone lines (\$106.00 per month) dedicated to the fire alarm system. It is estimated 4 out of 5 facilities in the U.S. would need to install such a system based on a local survey. The estimated cost would be

\$3000 per facility X 3520 facilities = \$10,560,000
 Monthly monitoring costs = \$180.00 X 12 months X 4400 facilities = \$9,504,000 annual recurring costs.

Overall comment:

The NRAA strongly recommends that CMS surveyors be instructed to list a deficiency only once in the Statement of Deficiencies report for corrective action. We have seen one type of deficiency listed several times in a surveyor's report adding pages to make the survey look like there were several deficiencies when actually there was only one. For example, a deficiency for not testing chloramines in a timely manner could fall under several domains of the survey. Instead of listing the deficiency under the most appropriate section, surveyors have listed the **same deficiency under 10 – 12 sections of the survey.**

Implementation of the new Conditions for Coverage: Interpretive Guidelines

While the Conditions for Coverage are an important framework for the survey and certification of dialysis programs. It is the interpretation by the state surveyors that will ultimately affect dialysis providers. In this regard, the NRAA recommends that a panel of dialysis providers – Nephrologists, nurses, technicians and administrators, be convened to assist in the development of the interpretive guidelines used by the state surveyors. Since the state surveyors are not, in most cases, dialysis trained, the interpretive guidelines provide them with guidance to review the care of dialysis patients and the environment within a dialysis facility. This panel can provide valuable knowledge so that the surveyors will be able to better understand the specifics in providing care to dialysis patients.

Based on our cost projections, as described below, a regulatory impact assessment is required. We respectfully request that CMS comply with Executive Order 12866 in preparing the impact statement since it is clear that the \$100 million threshold has been exceeded by the proposed regulation.

Requirement	Projected Cost
Estimated cost of a social services technician	\$15.00 per hour X 2080 = \$31,200 \$31,200 X 30% benefits = \$9360 Total \$40,560 X 4400 facilities = \$178,464,000
RN with benefits @\$25.00 per hour + 30% benefits	\$25.00 X 2080 hours per year = \$52,000 \$52,000 X 30% benefits = \$15,600 Total for one RN per year = \$67,600 \$67,600 X 4400 facilities = \$297,440,000
Life Safety Code	\$3000 per facility X 3520 facilities = \$10,560,000

Cost of automatic notification	Monthly monitoring costs = \$180.00 X 12 months X 4400 facilities = \$9,504,000 in annual recurring costs
Emergency Preparedness of Staff	15 staff X 4400 facilities X \$25.00 = \$1,650,000

The NRAA appreciates the opportunity to comment on the proposed regulations. We would be pleased to meet with you to discuss our comments before the final regulations are promulgated. I can be reached at (407) 843-6110.



Maureen Michael
President
National Renal Administrators Association

Clarification to Comment on Proposed Section 494.30

We wish to emphasize and clarify that the NRAA does not support the requirement of an isolation room and recommends that a facility should provide an isolation station or area.



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May 2, 2005

Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

RE: Conditions for Coverage

To Whom It May Concern:

Thank you for the opportunity to respond to the conditions for coverage. Please pay special attention to the following conditions:

- 494.80 Condition: Patient assessment
- 494.90 Condition: Patient plan of care
- 494.140 Condition Personnel qualifications (d) Standard: Social Worker

Respectfully,



Angie Smith, LCSW

enclosure

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May 4, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-3818-P

-5
MAY 5 14

Dear Dr. McClellan:

I applaud CMS for issuing these proposed conditions, having participated some years ago in commenting on an earlier effort. Emphasizing patient centered outcomes, patient participation in their care planning and quality of patient care are all welcome changes from the existing Conditions of Coverage.

I am a long term ESRD patient, having begun home hemodialysis in 1971, cadaveric transplant in 1987, peritoneal and in-center hemodialysis in 1991, and living related transplant from my daughter in 1993, which I continue to enjoy. As a result of my kidney failure, I made a career change from development economist to health economist and policy analyst. I have been an active patient advocate serving on numerous NIH, CMS, OPTN task forces, past member of the Life Options Rehabilitation Advisory Council, Past President of the American Association of Kidney Patients, and past Board and committee work with UNOS and the National Kidney Foundation, currently on Board and Chair of the Public Policy Committee of the American Kidney Fund, and Board member of the University Renal Research Education Association [URREA].

I have participated in the development of comments on these Proposed Conditions of Coverage for other organizations, but wanted to include my own comments on only a few of the proposed conditions.

Patients Rights and Responsibilities--Section 494.70

- (a) ESRD patients must be fully aware of and engaged in their treatment options and participate fully in decisions regarding their care.
- (b) I suggest CMS add a condition that no patient be involuntarily discharged without documentation a program was available and implemented to resolve inappropriate behavior except in an emergency situation. Facilities should be required to involve the appropriate Networks in such situations.
- (b) I support the statement in the preamble that a patient should not be involuntarily discharged from a dialysis facility for non-adherence to the medical regimen and suggest it be specifically added to the regulations.

Patient Assessment—Section 494.8

- (a) I suggest patient assessment should regularly determine physical component scores and mental component scores from ESRD validated instruments, including baseline and annual follow-up measurement of patients' functional status and well-being. The short for of the K/DOQI Quality of Life Survey and the Medical Outcomes SF-36 have both been

Dialysis Center of Lincoln, Inc.
"Hope For The Future and Strength for Today"



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April 27, 2005

*Rec'd
5/5/05
[Signature]*

The Honorable Mark McClellan
Administrator
Attention: CMS-3818- P
Centers for Medicaid and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3818-P Comments on Notice of Proposed Rulemaking on Conditions for Coverage for End Stage Renal Disease Facilities

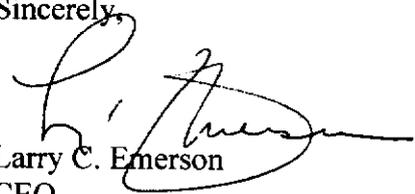
Dear Dr. McClellan:

I represent a not-for profit free standing dialysis provider in Nebraska. We currently have 4 outpatient centers located in both the urban and rural areas of Nebraska. We provide dialysis services in outpatient centers, through home programs and in acute hospital settings in Lincoln Nebraska.

We support the fundamental shift in the proposed conditions for coverage from a focus on procedural standards to the patient's experience in the care delivery setting and on patient outcomes. However, we believe it is essential to recognize the impact on small providers as they work towards the efficient and effective implementation of the Conditions of Coverage. With the limitations we face regarding our ability to provide financial, human and technological resources, our comments reflect more on the practical issues we face rather than disagreement with the concepts.

I appreciate the opportunity to comment on the proposed regulations.

Sincerely,


Larry C. Emerson
CEO

Comments on proposed Conditions of Coverage
Part 494
Dialysis Center of Lincoln
Page 2

Proposed Part 494

Provisions of Proposed Part 494 Subpart A (General Provisions)

Definitions (Proposed §494.10)

Revise definition of Self-Dialysis: Change little to **limited** to cover services that are self care where staff is there to support and assist patients who have been trained to perform self dialysis.

Revise definition Home Dialysis to include NF or SNF in the definition of a patient's home setting.

Provisions of Proposed Part 494 Subpart B (Patient Safety)

Infection Control (Proposed §494.30)

An area of concern is the requirement in §494.30(b)(2) for a registered nurse (RN) to be designated as the Infection Control or Safety Officer. We do not believe that the duties of an Infection Control or Safety Officer require the knowledge or skills of an RN. It is impracticable to assume that an available RN currently exists in the dialysis facility to assume this role. This requirement would add significant operational costs. With the accountability for of the infection control function assigned to the Quality Improvement Program adequate professional clinical management and over sight can occur.

Water Quality (Proposed §494.40)

Water (Proposed §494.40 (c)(2))

Regarding the proposal to require chlorine/ chloramines testing of water samples prior to each patient shift or every 4 hours whichever is shorter, different providers may have different interpretations of a shift. Using every 4 hours as a criteria may be easier to track but what determines if a provider is out of compliance if it is not exactly at the 4 hours interval. Which ever method is chosen should remain consistent over time.

Water (Proposed §494.40 (e))

The proposal to require active surveillance of hemodialysis reactions during and following dialysis is unclear. What is the interpretation of "following" dialysis?

Re-Use of Hemodialyzers and Bloodlines (Proposed §494.50)

The initial paragraph regarding failure of the supplier is not necessary as it is covered at Part 488 Subpart H , 488.604 and includes reference to one or more of the conditions of coverage set forth in part 494.

Provisions of Proposed Part 494 Subpart C (Patient Care)

Patients' Rights (Proposed §494.70)

It is appropriate to provide information regarding patient rights to patients prior to at the time they begin treatment. A complete review in detail can not be accomplished at this time and the facility should be allowed to cover this information during the first month of treatment in conjunction with the initial training, assessment and education efforts.

Patient Rights, discharge and transfer of patients (Proposed §494.70 b(2))

The conditions should allow for immediate discharge in appropriate circumstances.

Patient Assessment (Proposed §494.80)

Change the first sentence of paragraph one in 494.80 to read **...the patient or his/her designee (if he or she chooses)...**

We would like to recommend that a nurse practitioner or physician assistant working under the supervision of a nephrologist be able to complete the physician portion of the assessment.

Frequency of Assessment of New Patients (Proposed §494.80 (b)(1))

The proposed standard states, "an initial comprehensive assessment must be conducted within 20 calendar days after the first dialysis treatment." This timeline does not address treatment days, missed treatments or for patients re-hospitalized. In addition **first dialysis treatment** needs to be clarified to avoid confusion with the first dialysis in a hospital. **New patient** should be clarified as a patient initiating dialysis for the first time, or those who require initiation of a CMS 2728.

Thirty (30) days is a more appropriate time frame for completion of the assessment, rather than 20 days, especially as it relates to the timely involvement of the physician. The suggestion by NRAA to provide an alternative based on treatments should also be considered.

There should be an exception for patients transferring to a facility in which the interdisciplinary team is the same. A transfer between our 4 units happens frequently.

Comments on proposed Conditions of Coverage

Part 494

Dialysis Center of Lincoln

Page 4

Frequency of Assessment of New Patients (Proposed §494.80 (b)(2))

We agree that the reassessment of patients is appropriate during the early stages of their adjustment to dialysis and feel that a period of 3-6 months following the start of dialysis is appropriate, we support the 90 timeline included in the conditions.

Assessment of Treatment Prescription – Patient Reassessment (Proposed §494.80 (d)(2))

There should be a clarification as to what is required for the reassessment when a patient is considered unstable. NRAA recommends a clarification that clearly states all three parameters, “poor nutritional status, with unmanaged anemia and inadequate dialysis” must be present to justify a label of “unstable” and require monthly reassessment. It should also be made clear that a comprehensive reassessment is not necessary, but reassessments should be focused only on those parameters that address the patient’s unstable condition(s).

Development of Patient Plan of Care, Vascular Access (Proposed §494.90 (a)(4))

There is lack of clarity as to what is expected in this section. What is meant by; **the interdisciplinary team must provide the necessary care and services to achieve and sustain vascular access.** As an outpatient dialysis center we are not in a position to provide all the services and care needed to achieve vascular access. We are in a position to evaluate, monitor, recommend, educate and refer.

Development of Patient Plan of Care, Rehabilitation (Proposed §494.90 (a)(6))

There is lack of clarity as to what is expected in this section. What is meant by; **the interdisciplinary team must provide the necessary care and services for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by the patient, including the educational needs of the pediatric patient...** While this would be ideal, the facility can not be held accountable for rehabilitation outcomes that are beyond their control. We are in a position to evaluate, monitor, recommend, educate and refer.

Implementation of Patient Plan of Care (Proposed §494.90 (b)(2))

Suggest increasing from 10 to 15 days to allow adequate time for referrals required to address such aspects as vascular access and rehabilitation. Coordination of schedules, transportation and the availability of resources can be difficult especially in rural areas where travel can be significant for both providers and patients.

Comments on proposed Conditions of Coverage

Part 494

Dialysis Center of Lincoln

Page 5

Implementation of Patient Plan of Care (Proposed §494.90 (b)(4))

A physician providing ESRD care should see patients at least monthly, however, this encounter should be allowed at other than the dialysis facility. The requirement should not dictate that a physician see a patient while on dialysis even periodically.

Transplantation Referral Tracking (Proposed §494.90 (c))

The patient is the contractor by choice with the transplant center and therefore the majority of communication should be between these two parties. The facility should maintain information regarding the status of a patient and cooperate with the patient and transplant center to assist the efficiency and effectiveness of the effort.

Patient Education and Training (Proposed §494.90 (d))

The inclusion of vascular access in this section is in keeping with the Fistula First initiative.

Care at Home (Proposed §494.100)

A licensed practical or vocational nurse who meets the experience requirements should be approved to provide home dialysis training under the **supervision** of a registered nurse.

Mandating periodic visits to the home of patients on home hemodialysis and home peritoneal dialysis should be treated differently. Home visits to patients receiving home peritoneal dialysis should be required only when medically indicated. Home hemo dialysis requires periodic monitoring of the water system and equipment which should be the basis of the periodic visits. The need for visits, if medically indicated, should apply as well.

Provisions of Proposed Part 494 Subpart D (Administration)

Nursing Services (Proposed §494.140(b))

It is unrealistic to require that the Nurse Manager be employed full-time. Many small rural facilities only operate on a limited basis and have part-time nurse managers.

Social Worker (Proposed §494.10(d))

Those facilities in isolated rural areas have had difficulty recruiting and retaining MSWs. A BSW is a professional social worker and it should be permissible to use them when an MSW is unavailable or when used in conjunction with a consulting MSW. An exception may be practical and appropriate.

Comments on proposed Conditions of Coverage
Part 494
Dialysis Center of Lincoln
Page 6

Patient Care Dialysis Technicians (Proposed §494.140(e)(3))

The requirement that patient care technicians receive three months experience; under the direct supervision of a registered nurse needs clarification. It is unrealistic to require an RN be the only experienced personnel directly involved in the training of patient care technicians for a three-month period. A change in wording from direct to supervision is appropriate and practical.

Responsibilities of the Medical Director (Proposed §494.150)

The wording may need to be clarified, the Medical Director is acting in an administrative leadership capacity thus is responsibilities outlined are to be performed in that context.

Governance (Proposed §494.180)

Adequate Number of Qualified and Trained Staff (Proposed §494.180(b))

In small units that may be located within another facility does RN present in the facility include the larger facility or just space identified for dialysis?

Medical Staff Appointments (Proposed §494.180 (c)(1))

There are two distinct components of a medical staff; membership and credentials. Physician should be the only licensed independent healthcare professionals appointed as **members** of the Medical Staff, unless state law allows others. With regards to **credentials**; physicians, physician assistants and nurse practitioners should apply for and be granted privileges or receive credentials from the facility based on their individual education, training, experience, skills and state licensure. These non physicians would not necessarily be members of the medical staff but would be supervised by a member of the medical staff

Discharge and Transfer Policies and Procedures (Proposed §494.180 (f))

The proposed regulations state two physician signatures would be required for an involuntary discharge: the patient's primary physician and the medical director if they are not one and the same. Only one signature should be required as well as the reason.

END OF COMMENTS, THANK YOU



University of Pennsylvania Health System

Jeffrey S. Berns, M.D., F.A.C.P.
Associate Chief

Renal-Electrolyte and Hypertension Division

April 28, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8012
Baltimore, MD 21244-8012

File Code: CMS-3818-P

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in vulnerable dialysis patient population.

I am an Associate Professor of Medicine in the Renal-Electrolyte and Hypertension Division at the University of Pennsylvania School of Medicine in Philadelphia. I have been a clinical nephrologist for over 15 years. My particular areas of clinical and academic interest are proper use of medications and management of anemia in patients with chronic kidney disease, including in those who are on dialysis.

I feel strongly, and have for many years, that pharmacists should be included as a required member of the dialysis facility patient care team for a number of reasons. As I am sure you know, the average number of different medications that dialysis take each day is about 10; the potential for adverse drug effects and drug interactions is tremendous. Despite the best efforts of even the most diligent and informed physician, it is my belief that that having a pharmacist also involved in overseeing medication management of this chronically ill and often elderly population would reduce medication complications. The medication management of patients on dialysis is further complicated by the frequent involvement of multiple physicians, all prescribing medications for various co-morbid conditions. A consulting pharmacist would fulfill a valuable role in helping to coordinate pharmacologic therapy among these various providers.

In many dialysis units, dieticians and nurses are involved in the day-to-day management of anemia and bone disorders, through the execution of physician-directed algorithms. The pharmacologic management of these common problems is growing increasingly

complex (and expensive), with an increasing number of clinical practice guidelines having been developed to help deal with these problems. I think that this area also provides ample opportunity for pharmacists to optimize care, not only to enhance clinical outcomes, but I would expect that a significant financial savings would also result.

Another area in which consulting pharmacists could play a vital role is as an interface between the hospital and the out-patient dialysis facility. Medications are often changed during a hospitalization, and frequently patients become confused about which are the proper medications for them to be taking upon hospital discharge. Reducing duplicate prescriptions would again enhance safety and cost-effectiveness of care.

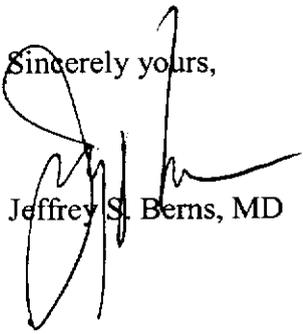
Finally, another potentially important role for consulting pharmacists would be in assisting nephrologists in optimizing antimicrobial therapy for bacterial infections, such as those related to hemodialysis or peritoneal dialysis access, as well as such common conditions as community acquired pneumonia and diabetic foot ulcers. I think that pharmacists could provide invaluable assistance in assuring that antibiotic agents are properly dosed, that they are used for an appropriate duration, that therapy initiated in the hospital is appropriately continued in the dialysis clinic, and that appropriate agents are chosen for therapy, which would help to minimize the risk of antimicrobial resistance, a growing problem among dialysis patients.

Therefore, I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist with experience or training in nephrology pharmacy.
2. The routine patient care assessment of dialysis patients should include a medication review, conducted at least once monthly and shortly after any hospital discharge by a pharmacist.
3. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.
4. Pharmacists should participate in patient care rounds with nephrologists, and should also be available to coordinate medication management with in-patient and long-term care facility pharmacists.

In conclusion, as we embark on a new era with Part D Medicare benefits, and as we face a growing and increasingly complex dialysis population in this country, I am convinced that involvement of consulting pharmacists in the care of dialysis patients will improve outcomes and enhance the safety and cost-effectiveness of that care.

Sincerely yours,



Jeffrey S. Berns, MD



UNIVERSITY OF KENTUCKY

Division of Nephrology, Bone and Mineral Metabolism/ Internal Medicine

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May 2, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear CMS Review Committee:

Thank you for the opportunity to comment on the CMS Program; Conditions for Coverage for End Stage Renal Disease; Proposed Rules. The amount of hard work that went into these revisions is very significant, and we applaud those that put in the time to prepare this extensive document.

As a Physician Assistant (PA) and a Nurse Practitioner (NP) serving in Nephrology working along side our attending nephrologists, we do have an important concern. PAs and NPs are currently providing daily assessment and ongoing care of patients in dialysis facilities across the nation. These physician services provided by NPs and PAs are currently reimbursed through CMS. Unfortunately, neither Nurse Practitioners nor Physician Assistants are mentioned in this document. This could lead to problems with reimbursement for physician services provided by NPs or PAs as well as regulatory and liability issues.

NPs and PAs function as dependant practitioners with their supervising physician counterpart. The Nephrology PA and NP are the natural compliment to the Nephrologist in order to extend quality nephrology physician services to this increasingly needy population. Statistics from the US Bureau of Labor and Statistics coupled with data on the number of chronic kidney disease patients indicates that the number of patients starting dialysis is quickly outpacing the number of nephrologists available to adequately care for them. The RPA (Renal Physician Association), ASN (American Society of Nephrology) and CMS have accepted a Nephrology PA and NP as a natural compliment to the multidisciplinary team.

Of particular concern is CFR Proposed Sec. 494.90 (b) (4) "Plan of Care" where specifically it states:

"494.90 (b) (4) would specify that the facility must ensure every patient is seen at least monthly by a physician providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician or communicated from the physician's office and placed in the beneficiary's medical record.

This statement seems to exclude the Physician Assistant and Nurse Practitioner from seeing the patient for the purpose of the monthly progress note.

We recommend that the language in 494.90 (b) (4) should be amended to read:

"Sec. 494.90(b) (4) would specify that the facility must ensure every patient is seen at least monthly by a physician, physician assistant or nurse practitioner providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician/physician assistant/nurse practitioner or communicated from the physician's office and placed in the beneficiary's medical record."

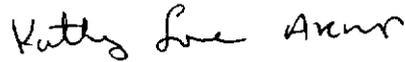
Please strongly consider our suggestion so that the spirit of this document to improve quality patient care does not end up limiting that same access to quality care by eliminating the NPs and PAs from the health care team.

Feel free to contact us with any questions.

Sincerely,



Bernard T. Botiller, PA-C
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County of San Diego

HEALTH AND HUMAN SERVICES AGENCY
JEAN M. SHEPARD, DIRECTOR

PAMELA B. SMITH, DIRECTOR
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GWENMARIE HILLEARY, ADMINISTRATOR
EDGEMOOR HOSPITAL

May 5, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: CMS-3818-P; Medicare Program; Conditions for Coverage of End Stage Renal Disease Facilities; Proposed Rule

To Whom It May Concern:

Edgemoor Hospital of Santee, California appreciates the opportunity to comment on the proposed rule regarding conditions for coverage of end stage renal disease (ESRD) facilities.

Dialysis of ESRD Patients in Skilled Nursing Facilities

Background

We are concerned about the provisions regarding dialysis in skilled nursing facilities (SNFs). We are seeing an increasing number of patients who have complex medical needs and require dialysis, but are otherwise stable. These patients could be cared for by nursing facilities.

We appreciate the Centers for Medicare and Medicaid Services' (CMS) recognition of this problem as set forth in the proposed rule. Allowing SNF residents to access home dialysis, however, does not solve the problem. We urge CMS to revise its position and make it financially feasible for nursing facility patients to receive dialysis at the bedside from a dialysis facility or the SNF.

Provision of Home Dialysis to SNF Patients Is Inappropriate

Nursing home patients who typically require dialysis are extremely fragile. The stability of their health status is precarious and can change at a second's notice. The home dialysis benefit, on the other hand, is designed for dialysis patients who are healthier and heartier than the average dialysis patient. Thus, home dialysis is not medically appropriate for the vast majority of SNF patients who require dialysis.

In addition, for these patients their stay in the SNF is a short break in the midst of on-going dialysis treatment. Rarely, if ever, are these patients on home dialysis prior to or after the SNF stay. Requiring these patients to switch from chronic dialysis to home dialysis and back again

within a one-month timeframe is unrealistic. The current system cannot support demands for such quick benefit coverage decisions. Thus, patients' continuity of care is jeopardized by the proposed rule.

For these reasons, use of home dialysis in nursing homes is inappropriate for the vast majority of nursing home residents.

Bedside Dialysis Services Provided by Dialysis Facility or Nursing Facility Covered by Medicare Statute

Currently, the vast majority of nursing home patients requiring dialysis receive such services at an off-site dialysis clinic. This situation has significant drawbacks. First, it necessitates use of an ambulance – and Medicare resources – to transport the patient to and from the clinic. Second, being transported to/from the clinic and sitting up in a dialysis chair are extremely taxing on residents whose health is already seriously compromised. Third, it requires the patient to be out of the nursing facility for a significant amount of time, missing medication administration, treatment regimens, meals and planned activities. Fourth, it is not uncommon for the resident to require accompaniment of a SNF nurse, which pulls resources away from other SNF residents.

We believe that Medicare should cover dialysis provided at the bedside in the nursing facility when provided by a dialysis facility or the nursing facility. Doing so would create a win-win situation. Nursing facility residents requiring dialysis would receive better care. Medicare would save ambulance costs. And many hospitalized dialysis patients would move sooner from the hospital to a lower level of care, thus providing for more effective and efficient use of our nation's limited healthcare resources.

Not only do we believe these options are the right thing to do, we believe that they are consistent with existing Medicare law. As set forth in more detail in the comment letter from the California Hospital Association (CHA), the applicable statutory provisions provide leeway for interpretation. **Thus, we urge Medicare to interpret existing law so as to make it financially feasible for SNF residents to receive dialysis services at the SNF, whether under a Part A stay or Non-Part A stay and whether performed by a dialysis provider or by the SNF.**

Conclusion

The number of patients who require dialysis, but could otherwise be cared for in a nursing facility are increasing. Home dialysis is inappropriate for the vast majority of nursing home residents because of their medical fragility. We urge CMS to interpret existing law in such a manner as to make it financially feasible for SNF residents to receive dialysis services from dialysis providers and SNFs at the bedside.

If you have any questions or comments, please contact Gwenmarie Hilleary at 619-956-2800.

Sincerely,


Gwenmarie Hilleary, FACHE
Administrator

**South Coast
Medical Center**



May 2, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: CMS-3818-P; Medicare Program; Conditions for Coverage of End Stage Renal Disease Facilities; Proposed Rule

To Whom It May Concern:

South Coast Medical Center appreciates the opportunity to comment on the proposed rule regarding conditions for coverage of end stage renal disease (ESRD) facilities.

Dialysis of ESRD Patients in Skilled Nursing Facilities

Background

We are concerned about the provisions regarding dialysis in skilled nursing facilities (SNFs). We are seeing an increasing number of patients who have complex medical needs and require dialysis, but are otherwise stable. These patients could be cared for by nursing facilities.

We appreciate the Centers for Medicare and Medicaid Services' (CMS) recognition of this problem as set forth in the proposed rule. Allowing SNF residents to access home dialysis, however, does not solve the problem. We urge CMS to revise its position and make it financially feasible for nursing facility patients to receive dialysis at the bedside from a dialysis facility or the SNF.

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Nursing home patients who typically require dialysis are extremely fragile. The stability of their health status is precarious and can change at a second's notice. The home dialysis benefit, on the other hand, is designed for dialysis patients who are healthier and heartier than the average dialysis patient. Thus, home dialysis is not medically appropriate for the vast majority of SNF patients who require dialysis.

In addition, for these patients their stay in the SNF is a short break in the midst of on-going dialysis treatment. Rarely, if ever, are these patients on home dialysis prior to or after the SNF stay. Requiring these patients to switch from chronic dialysis to home

dialysis and back again within a one-month timeframe is unrealistic. The current system cannot support demands for such quick benefit coverage decisions. Thus, patients' continuity of care is jeopardized by the proposed rule.

For these reasons, use of home dialysis in nursing homes is inappropriate for the vast majority of nursing home residents.

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We believe that Medicare should cover dialysis provided at the bedside in the nursing facility when provided by a dialysis facility or the nursing facility. Doing so would create a win-win situation. Nursing facility residents requiring dialysis would receive better care. Medicare would save ambulance costs. And many hospitalized dialysis patients would move sooner from the hospital to a lower level of care, thus providing for more effective and efficient use of our nation's limited healthcare resources.

Not only do we believe these options are the right thing to do, we believe that they are consistent with existing Medicare law. As set forth in more detail in the comment letter from the California Hospital Association (CHA), the applicable statutory provisions provide leeway for interpretation. **Thus, we urge Medicare to interpret existing law so as to make it financially feasible for SNF residents to receive dialysis services at the SNF, whether under a Part A stay or Non-Part A stay and whether performed by a dialysis provider or by the SNF.**

Conclusion

The number of patients who require dialysis, but could otherwise be cared for in a nursing facility are increasing. Home dialysis is inappropriate for the vast majority of nursing home residents because of their medical fragility. We urge CMS to interpret existing law in such a manner as to make it financially feasible for SNF residents to receive dialysis services from dialysis providers and SNFs at the bedside.

If you have any questions or comments, please contact Caron Goller at 949-499-7519 or Gollercl@ah.org.



Service to those affected by chronic kidney disease

May 3, 2005

Lori Hartwell
Executive Director/President

Debra Punch, MBA, RN
Chairman of the Board

Rhonda Brooks
Treasurer

Malia Langen
Secretary

Mark McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: CMS-3818-8012: Conditions for Coverage for End-Stage Renal Disease Facilities

Dear Administrator McClellan:

Board Members:
Rhonda Brooks
Sara Colman, RD
Jeffrey Davis
Greg Falconer
Lori Hartwell
Malia Langen
Debra Punch, RN
Susan Vogel, RN
Sandra Wilson, RN

Honorary Board:
Dario Frommer, Assembly
Majority Leader

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Lana Kacherova, RN
Ursula Kramer
Jeffrey Makoff, Esq.
Edward Masry, Esq.
Peter McCauley, MD
Mercy Perez, MSW
Kathy Ryan, RN
Craig Thompson
Terry Weseloh

The Renal Support Network (RSN) is a patient-run non-profit organization that provides services to those affected by chronic kidney disease. This organization was established in 1993 by Lori Hartwell, who has been living with kidney disease for more than thirty years, to help fellow kidney patients meet their non-medical needs. RSN values people with kidney disease and helps them to become self-sufficient through education, advocacy and employment resources. The RSN's goals are to help renal patients develop their coping skills, special talents and employability. And most importantly, empower patients to *help* educate fellow patients so they can learn to take control of their disease management.

RSN supports the CMS efforts to update the Conditions of Coverage for ESRD providers with a more patient outcome focus. While not specifically able to comment on many of the intricate details of the proposed changes RSN respectfully submits comments on the areas we feel most impacts dialysis patients. Future updates to the Conditions of Coverage should be done on an ongoing and timely basis with input from the community.

Appropriate clinical management and patient involvement in their care is critical to the continued improvement patient outcomes and to the most cost effective care. CMS should evaluate these goals in light of overall lower cost on both the Part A and Part B provision of services. As part of this CMS should evaluate the cost

An illness is too demanding when you don't have hope!

Renal Support Network

CMS may wish to consider developing and disseminating uniform patient education pieces to ensure that all patients receive consistent information about topics such as CKD and treatment options.

- Patients must receive a full and understandable explanation of their rights and responsibilities. Patients need to understand their critical role in determining their own outcomes, both clinically and psychologically.
- Facilities should be encouraged to develop and share discharge criteria with patients to ensure that they are fully informed and aware of what the facility expects of them.
- Any discharge of a patient from a dialysis program should be done only after exhaustive discussions with the patient. All parties should make every effort to work through their differences, if possible, to allow a patient to remain in the program of their choice. Exceptional situations that could lead to immediate discharge—such as physically threatening staff members—should also be clearly defined.
- The K/DOQI™ Guidelines are evolving and being continually updated as knowledge of how to improve outcomes for patients on dialysis expands. The final CMS regulations should be written to ensure timely updates of the Conditions of Coverage to incorporate the evolving definition of high quality care outlined by K/DOQI™ and other well-respected experts.
- Patients should be encouraged to consider home dialysis first over in-center dialysis whenever possible, since the outcomes are the better for this modality.
- In-center self care and self cannulation to preserve dialysis access should be encouraged.
- Patient rehabilitation should be encouraged, and become a focal point for helping ensure patient self-management and independence.
- An annual patient assessment (SF- 36 instrument) and follow-up should be conducted to measure each patient's functional status and well-being.

Facility Comments:

- The facility should provide a safe and comfortable environment for their patients. While RSN is not specifically able to comment on the Life Safety Codes, the dialysis facility should meet appropriate requirements to ensure patient safety.
- Facilities should provide emergency equipment, including AEDs, for use in emergencies.
- The provision of high quality water for hemodialysis treatments is important to ensure good outcomes for patients on dialysis. As such, dialysis facilities should adhere to the AAMI guidelines for water treatment. The final CMS regulations should be written to ensure timely updates of the Conditions of Coverage to incorporate the evolving definition of high quality water, as outlined by the AAMI.
- The Medical Director has historically played a key role in ensuring high-quality and consistent outcomes for patients on dialysis. It is key that a nephrologist continue to fill the Medical Director role.

Renal Support Network

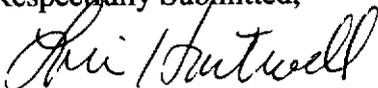
- The important role of dialysis patient care technicians requires that these individuals have appropriate training in the facility and, in the long-term, be officially certified in the care of patients.
- The Medical Director, in lieu of an infection control nurse, should be the primary individual who ensures infection control in the dialysis unit.

Appropriate clinical management and patient involvement in their own care is critical to ensure continued improvement in patient outcomes. Importantly, we believe that improved patient outcomes will also ensure more cost effective care. CMS should evaluate how the quality of care will be affected by the overall lower reimbursement for both Part A and Part B services. Importantly, CMS should evaluate how these changes may affect the financial solvency of dialysis providers, and adjust reimbursement appropriately to ensure that dialysis facility closures does not become an unintended consequence of the new policy.

Thank you for the opportunity to comment on the Conditions of Coverage. We believe that, in the future, the Conditions of Coverage should be reviewed at regular intervals, and CMS should solicit ongoing input from the nephrology community to ensure that patient care and outcomes criteria are keeping pace with current medical science. Of course, it is vital that patients be an integral part of this process.

RSN would be happy to meet with you and discuss these issues in more detail. Please contact us if you have any questions.

Respectfully Submitted,



Lori Hartwell
President/Founder

APR 25 2005

April 13, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140 as this section addresses the possible role of a pharmacist within the dialysis facility. I appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in vulnerable dialysis patient population.

As an Ambulatory Care Pharmacist presently I have the opportunity to monitor patient's Warfarin levels, pain management, diabetes and hypertension bringing patients to goal. Presently, I have several dialysis patient who generally utilize a greater amount of medications and run a higher risk of drug interactions and complications. Drug monitoring and therapy review would provide a valuable and potentially important service in reducing drug costs and medical error prevention.

I believe that consultant pharmacists should be included as part of the dialysis facility staff for the following reasons:

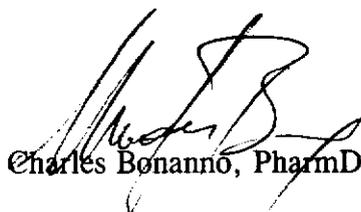
- the complex nature of drug therapy in dialysis patients,
- the pharmacokinetic complexity of drugs during dialysis
- the vulnerability of these patients for adverse medication-related outcomes,
- the need for storage, preparation, and administration of medications within the dialysis unit,
- the need for cost effective drug therapy,
- the changing nature of drug therapy that will arise due to the MMA, and
- the training of pharmacists that prepares them to serve as consultants to dialysis facilities.

APR 25 2005

Specifically, I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist with experience or training in nephrology pharmacy.
2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.
3. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis centers to assure cost-effective drug use.
5. Dialysis facilities should develop and maintain appropriate policies for the safe storage, preparation and administration of medications within the facility. These policies should be developed and maintained in consultation with a pharmacist.]

Thank you for the opportunity to discuss this matter with caring health care professionals.



Charles Bonanno, PharmD., MBA, CGP



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May 2, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: IDTF Supervision 42 CFR § 410.33

Dear Dr. McClellan:

The purpose of this letter is to request reconsideration of the requirement in 42 CFR § 410.33(b)(2) related to supervision of individual diagnostic tests at an Independent Diagnostic Testing Facility ("IDTF") to permit non-specialists to provide direct or personal supervision of diagnostic tests.
Summary of the Law.

General Supervision Requirement

Diagnostic x-ray and other tests are covered under § 1861(s)(3) of the Act and are payable under the Medicare physician fee schedule. 42 CFR § 410.32 sets forth the conditions for coverage of x-rays and other diagnostic tests. This provision requires, in part, that diagnostic x-ray and other diagnostic tests be furnished: (a) under the appropriate level of supervision by a person who meets the definition of "physician" under § 1861(r) of the Act.¹ This section does not contain any additional proficiency requirements and, therefore, any licensed physician is qualified to supervise.

Based on the description of three (3) levels of supervision in the regulations, CMS has assigned a code to each diagnostic test on the physician fee schedule to indicate whether the test requires general, direct, or personal supervision. This letter uses, for illustrative purposes, a magnetic resonance imaging exam with contrast, which requires direct supervision. Direct supervision in the office setting means that the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. For illustrative purposes, this letter refers to the direct supervision required for coverage of an MRI with contrast.²

¹ 42 C.F.R. § 410.32(b)(1); definition of "physician" at SSA 1861(r).

² See, e.g. CPT 72147, MR chest/spine with dye; 42 C.F.R. § 410.32(b)(3)(ii).

IDTF Supervision Requirements

42 CFR § 410.33(a)(1) specifies the types of suppliers who may be paid by carriers for diagnostic procedures, including physicians, group practices of physicians, approved suppliers of portable x-ray services, nurse practitioners, clinical nurse specialists under certain circumstances, and IDTFs.

Section 410.33(b)(1) generally requires an IDTF to have one or more supervisions who are responsible for the direct and ongoing oversight of the quality of the testing performed, the proper operation and calibration of the equipment used to perform tests, and the qualification of nonphysician personnel who use the equipment. This section refers to the description of general supervision in § 410.32(b)(3)(i) which does not require on-site presence but instead requires overall direction and control. Section 410.33(b)(2) IDTF supervising physicians must "evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF." The regulation defines "proficiency" by reference to specialty or subspecialty certification and permits carriers to establish other proficiency criteria.

Section 410.33(b)(2) imposes an additional duty on the physician who takes overall responsibility for the IDTF. The second part of this section requires that the IDTF's supervising physician *personally* furnish supervision for procedures that require direct or personal supervision under § 410.32. The result of this statement is that only physicians who meet proficiency standards - i.e., specialists or sub-specialists, may supervise the contrast injection in CPT 72147.

Analysis and Rationale for Change

Under the current regulations, any physician who meets basic requirements under the Act and state law may provide direct or personal supervision in a physician's office. However, in an IDTF setting, only specialists or sub-specialists are qualified to do so. As a practical matter, radiologists are the specialists most likely to be comfortable attesting proficiency to administer and interpret diagnostic imaging tests such as MRIs. In the current environment in which there is a nationwide shortage of radiologists, requiring these specialists to be physically present on site at an IDTF and personally supervise, in the example of CPT 72147, contrast dye injections, is inefficient, unnecessary, and may not ensure the highest quality patient care.

The policy behind the requirement that IDTFs must be under the general supervision of one or more physicians who meet the proficiency standards is presumably to ensure accountability for the quality of the tests rendered in IDTFs. It is necessary to directly involve specialty-trained physicians because IDTFs are not otherwise uniformly regulated by state or federal agencies.

Presumably, the reason supervision levels have been assigned to certain tests is that there is a possibility the patient may need immediate care during the test. For example, with respect to CPT 72147, physician intervention may be necessary when a patient has an allergic reaction to the dye injection. However, there seems to be no clear policy reason supporting the requirement that the specialty-trained physician, such as a radiologist, also personally oversee the patient and provide necessary patient care in the event of an emergency. In this circumstance, a physician who routinely provides direct clinical interventions would be better suited to provide this care than a radiologist. Radiologists generally have little or no routine direct interaction with patients. It would seem more logical, and more in the patient's best interest, to allow (or even require) non-specialists who routinely provide direct clinical care to administer emergency aid to patients.

Mark McClellan, M.D., Ph.D.

May 2, 2005

Page 3

Conclusion

For these reasons, we request that CMS reconsider the requirement that a specialist or sub-specialist personally provide direct or personal supervision of diagnostic tests in an IDTF setting and revise 42 CFR §410.33(b)(2) accordingly. We request that the language in that section be changed to provide that any person meeting the definition of "physician" in Section 1861(r) of the Social Security Act (the "Act") be permitted to provide direct or personal supervision of individual diagnostic tests in an IDTF. We also request a meeting as soon as possible with the appropriate CMS personnel to discuss the rationale and need for this change.

Very truly yours,
BARNES & THORNBURG LLP



Ellen L. Luepke

cc:

The Honorable Richard Lugar (IN)

The Honorable Evan Bayh (IN)

The Honorable Julia Carson (IN)

The Honorable Herb B. Kuhn, HHS/CMS/Center for Medicare Management (Director)

The Honorable Donald N. Johnson, HHS/CMS/Office of Legislative Affairs

CHDS01 ELL 269548v1

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Joshua J. Ofman, MD., MSHS
Vice President, Reimbursement
& Payment Policy

AMGEN

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May 5, 2005

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: Medicare Program; Conditions for Coverage for End Stage Renal Disease
Facilities; Proposed Rule (CMS-3818-P)**

Dear Administrator McClellan:

Amgen, the world's leading biotechnology company, appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule regarding the Conditions of Coverage for End Stage Renal Disease Facilities, published in the Federal Register on February 4, 2005 (the Proposed Rule).¹ As a science-based, patient-driven company, we are vitally interested in improving access to innovative new drugs and biologicals for Medicare dialysis patients and ensuring that beneficiaries continue to have access to existing drugs and biologicals. In this letter, we provide our comments regarding the proposed changes to the current Conditions for Coverage for facilities providing outpatient maintenance dialysis and related services to Medicare beneficiaries with end stage renal disease (ESRD).

Amgen applauds the agency's efforts to move the focus of the Conditions for Coverage from a process-orientated approach to a more patient-centered outcome approach. This shift is appropriate in the current operating environment, which has evolved into one with much more real-time reporting of patient conditions and faster adjustments in patient care plans than was envisioned in the design of the original Conditions of Coverage for dialysis facilities. The shift to a patient-centered set of proposed Conditions appropriately allows facilities to focus on the quality of care they provide rather than on meeting specific process requirements that may have little or nothing to do with patient care. After reviewing the Proposed Rule, we believe that CMS recognizes that the Conditions for Coverage should combine reasonable flexibility for

¹ 70 Fed. Reg. 6184 (Feb. 4, 2005).

dialysis centers with achievable clinical targets to ensure that dialysis patients receive high-quality care.

To that end, Amgen urges CMS to adopt several specific recommendations that should enhance both the dialysis center focus on patient outcomes as well maintain flexibility for the dialysis centers. These recommendations would also support CMS' efforts to ensure proper patient protections and Medicare payment safeguards.

With respect to anemia management under the Quality Assessment and Performance Improvement (QAPI) Program,² CMS should mandate that the National Kidney Foundation Kidney Disease Outcomes Quality Initiative ("NKF-K/DOQI™") Guidelines be used to identify the appropriate reference values for the minimum clinical standards under this program.

CMS should finalize its proposed requirement that the patient assessment include treatment plans for anemia.

CMS should mandate that the NKF-K/DOQI™ Bone and Mineral Management Guidelines be used to identify the appropriate tests and reference values into the Patient Assessment, the Patient Plan of Care, and the QAPI Program. Amgen also understands that CMS intends to incorporate these Guidelines into Clinical Performance Measures ("CPMs") later in 2005 and recommends that CMS consider incorporating the CPMs into the Conditions of Coverage Final Rule.

While Amgen recommends that CMS mandate the use of NKF-K/DOQI™ Guidelines in the above two areas, CMS should not incorporate specific clinical values into the Final Rule. Rather, the agency should adopt a more flexible mechanism to update NKF-K/DOQI™ guideline clinical targets through the use of sub-regulatory guidance to select the specific clinical values used in the Patient Assessment, Patient Plan of Care, and the QAPI Program. This approach, which should be transparent and include a comment process, would allow for faster updating of clinically appropriate targets for both anemia management and bone management than having to undertake notice and comment rulemaking to reflect changes to the pertinent Guidelines.

Mandating the Use of NKF-K/DOQI™ Guidelines for Anemia Management Standards for Patient Assessments and QAPI – [“Patients’ Rights” and “QAPI”]

Reflecting the overall change in focus for the ESRD facility conditions of participation to emphasize the patient and the results of care provided to the patient, CMS proposes a new requirement for a patient assessment that the agency believes is a prerequisite for the provision of quality care.³ This comprehensive assessment would be performed by an interdisciplinary team (composed of the patient, a physician, a registered nurse, a

² 70 Fed. Reg. at 6243

³ 70 Fed. Reg. at 6250 (proposed 42 C.F.R. § 494.90).

social worker, and a registered dietician). Part of this assessment includes an evaluation of the factors associated with anemia, such as hematocrit, hemoglobin and iron stores. The assessment must also include potential treatment plans for anemia, including the administration of erythropoietin ("EPO").⁴ While current regulations require a written Patient Care Plan for all patients, based on an assessment of the patient's needs, there is no mandated patient assessment. The introduction of such an assessment is an appropriate step to improve consistency in patient care planning across the Medicare dialysis patient population and CMS should finalize this proposal.

We strongly recommend the adoption of the NKF-K/DOQI™ Guideline 4 to determine the appropriate target hematocrit/hemoglobin values when developing a patient assessment tool in dialysis centers. As the leading independent American science and patient organization focused on chronic kidney disease and dialysis, the NKF is well-positioned to objectively develop and update the treatment standards for this fragile patient population. To that end, Amgen also recommends that Medicare require the dialysis centers to use these Guidelines (and associated clinical targets) in the development of the Patient Assessment, the Patient Care Plan anemia management targets as well as the QAPI assessment values be based on the NKF-K/DOQI™ Anemia Management Guidelines.

As mentioned above, Amgen suggests that CMS use sub-regulatory guidance (transmittals, manual issuances, et cetera) instead of notice and comment rulemaking to update specific clinical target values (like the current NKF-K/DOQI™ anemia targets used in the Proposed Rule). This would allow Medicare to stay current with the NKF guidelines and avoid the time and effort needed for notice and comment rulemaking.

Incorporate a framework for Bone Metabolism and Disease Management in the Proposed Rule – ["Patients' Rights"]

The Proposed Rule identifies the need for bone metabolism and disease evaluation in the Patient Assessment section of the rule.⁵ Amgen agrees that an evaluation of this condition is an essential part of a comprehensive patient care plan developed by a dialysis center. We believe, however, that as with anemia management, Medicare should also require a framework for bone metabolism and disease management that is more comprehensive. That framework would also be based on developing parallel Patient Care Plan and QAPI Conditions of Coverage components that would also be structured around the NKF-K/DOQI™ Guidelines. The recent excellent work in the development of the draft Bone Metabolism Clinical Performance Measures is a logical foundation to build upon for the appropriate NKF-K/DOQI™ standards to incorporate in a Final Rule.

⁴ 70 Fed. Reg. at 6250 (proposed 42 C.F.R. § 494.90(a)(3)).

⁵ 70 Fed. Reg. at 6249 (proposed 42 C.F.R. § 494.80(a)(5)).

Amgen recommends that any bone metabolism and disease management standards adopted in a Final Rule also rely on sub-regulatory guidance documents from Medicare for specific clinical targets in this therapeutic area so that future adjustments in the NKF-K/DOQI™ Guidelines can be efficiently updated without having to undertake notice and comment rulemaking.

Conclusion

Amgen and CMS share the goals of improving the health of the ESRD patients, ensuring access to therapies and continuing to improve the quality of care they receive. For these reasons, careful consideration must be given to any policy changes that may disrupt care or provide potential access problems to these patients at high risk for adverse health outcomes. To that end, the adoption of the NKF-K/DOQI™ Guidelines as the general structure for anemia management and bone metabolism and disease management in the Conditions of Coverage Final Rule would provide a public framework that is capable of timely updates. We believe that a flexible updating mechanism that uses sub-regulatory guidance best serves the interest of the patients and dialysis centers by allowing for timely and efficient revision of the clinical targets identified in a Conditions of Coverage Final Rule.

Amgen appreciates the opportunity to comment on the important issues raised in the Proposed Rule, and we look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies and that the shortfalls in the quality of care for this population as outlined in the 2001 GAO report referenced in the Proposed Rule continue to be aggressively addressed. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please feel free to contact Andy Swire or myself at (202) 585-9500 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Joshua Ofman, M.D. and MSHS
Vice President, Reimbursement and
Payment Policy Global Government Affairs



APR 26 2005

LOMA LINDA UNIVERSITY ADVENTIST HEALTH SCIENCES CENTER

Office of the President

11175 Campus Street
Loma Linda, California 92354
(909) 558-7570
Fax (909) 558-7929

April 22, 2005

Mark B. McClellan, M.D., Administrator
Center for Medicare Management
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: California Heart and Surgical Hospital

Dear Administrator McClellan:

I am writing to you regarding a matter of urgent concern. You are undoubtedly aware of the proposed development of a specialty hospital in Loma Linda, California by a group of physicians and other investors. The hospital would be known as "California Heart & Surgical Hospital" and would specialize in cardiovascular and orthopedic surgical services. The development of this hospital threatens the health and welfare of California residents and jeopardizes Loma Linda University Medical Center's ability to continue its dedicated mission of service to those in need. In addition, these developments raise concerns of national scope under the federal self-referral prohibitions (the "Stark Law") and the accompanying specialty hospital moratorium.

It appears that the promoters of this project are seeking to circumvent the Stark Law moratorium on specialty hospitals, and have submitted an advisory opinion request to CMS in furtherance of this purpose. Although we are not privy to the specific arguments that the promoters may have made in their request for an advisory opinion, we are generally aware that the promoters have asserted the position that the proposed hospital does not meet the definition of "specialty hospital" because it will have a single emergency department bed and perhaps offer some treatment for ear, nose and throat ailments. Alternatively, they appear to be arguing that the proposed hospital is "grandfathered" under the specialty hospital moratorium by virtue of having been "under development" as of November 18, 2003.

The facts that are known to the Loma Linda community refute both of these contentions. As such, we respectfully request your consideration of the following arguments, and the supporting facts:

1. **The Proposed Hospital is a "Specialty Hospital" Subject to the Moratorium.** As you are aware, under the moratorium, the "whole hospital" exception is not available to specialty hospitals. The Stark Law generally provides that a "specialty hospital" is a hospital that is primarily or exclusively engaged in the care and treatment of one of the following categories: (a) patients with a cardiac condition; (b) patients with an orthopedic condition; (c) patients receiving a surgical procedure; and (d) any other specialized

Serving the Following Core Organizations:

CLI-1200002 LOMA LINDA UNIVERSITY • LOMA LINDA UNIVERSITY MEDICAL CENTER • LOMA LINDA UNIVERSITY HEALTH CARE
FACULTY MEDICAL GROUP • FACULTY PHYSICIANS AND SURGEONS • AND OTHER AFFILIATED ENTITIES
A Seventh-day Adventist Institution

category of services that the Secretary of DHHS designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital.¹

The promoters of this project appear to be asserting the position that the proposed hospital does not meet the definition of "specialty hospital" because it will have a single emergency department bed and perhaps offer some treatment for ear, nose and throat ailments. By providing a very narrow subset of non-surgical or non-cardiac services, the physician investors are attempting to circumvent the moratorium, and engage in the very referrals that Congress has seen fit to halt, pending further analysis and consideration. In a letter from Herb Kuhn to the California Healthcare Association dated December 21, 2004, in reference to whether a limited service hospital that operates a part-time emergency department that may not be fully staffed or equipped to treat the full spectrum of emergency patients, Herb noted that "we believe the operation of such an emergency department would tend to indicate that the hospital is a specialty hospital to which the moratorium would apply."

In our view, the primary purpose of the proposed hospital is to provide cardiovascular and orthopedic services. In fact, the proposed hospital will hold itself out to the public as a specialty hospital. Its very name -- "California Heart & Surgical Hospital" -- makes clear its primary purpose -- *i.e.*, the provision of cardiac and surgical services. Note, that as further evidence of the project promoters' true intent, the original corporate name was "Loma Linda Specialty Hospital," which was changed shortly after Congress passed the moratorium -- in March, 2004. Furthermore, in a press released issued on April 5, 2004, the spokesperson for the hospital states that "the hospital will offer multi-specialty surgical services and post-surgical recovery care in a comfortable, home-like environment." By the spokesperson's own words, we can see that the primary focus of the hospital will be on specialized surgical services.

Thus, it is our contention that a hospital that looks like a specialty hospital (*i.e.*, by its name) and acts like a specialty hospital (*i.e.*, primarily providing specialty services and derives the majority of its revenues from those services) -- is in fact a specialty hospital. As such, we would urge CMS to recognize this, and conclude that the proposed hospital is in fact a "specialty hospital" within the Stark Law definition.

2. **The Proposed Hospital is not "Grandfathered."** As you know, a "grandfathered" specialty hospital is one that CMS determines was in operation or "under development" as of November 18, 2003 and for which: (a) the number of physician investors has not increased since that date; (b) the specialized services furnished by the hospital has not changed since that date; and (c) any increase in the number of beds has occurred only on the main campus of the hospital and does not exceed the greater of 5 beds or 50 percent of the beds in the hospital as of that date.² In this regard, we have heard anecdotal reports that physicians have been approached well after November 18, 2003 to invest in this project. Moreover, we have a copy of the executive summary of the private placement memorandum dated April 14, 2004, in which the project organizers were offering membership units in the project. As for the scope of services to be offered, we have been informed by inside sources that the scope of the specialized services to be offered continues to grow. Based on newspaper reports, we know that the initial projected cost of the project was expected to be \$40 million, but now exceeds \$60 million. Further, newspaper reports indicate that it was initially contemplated that the hospital would have 24 beds, but is now approaching 35 beds. We have seen this project continue to evolve and grow over the last 18 months in a manner that leads us to only one conclusion -- that as of November 18, 2003, the project was still only in preliminary stages of planning.

¹ 42 U.S.C. §1395nn(h)(7)(A) (emphasis added). Excluded from this definition are psychiatric hospitals (defined under 42 U.S.C. §1395x(f) - "primarily engaged in providing . . . psychiatric services"), rehabilitation hospitals (as defined by the Secretary), children's hospitals ("inpatients predominantly under 18 years"), long-term care hospitals ("average inpatient length of stay . . . greater than 25 days"), and certain cancer hospitals.

² 42 U.S.C. §1395nn(h)(7)(B).

In determining whether a specialty hospital was "under development" as of November 18, 2003, we understand that CMS considers whether the following had occurred as of that date: (w) architectural plans were completed; (x) funding was received; (y) zoning requirements were met; and (z) necessary approvals from appropriate State agencies were received.³

With respect to the completion of architectural plans, even if the investors had *begun* to draw up plans before November 18, 2003, the plans cannot be considered "complete" until the State of California Office of Statewide Health Planning and Development (OSHPD) reviews and approves them. We understand that the hospital's *preliminary* architectural plans were not even submitted to OSHPD until Spring, 2004, and that no formal approval of the project has yet been provided. In fact, "Hospital Vision" (which appears to be the specialty hospital's newsletter) in Volume 1, Issue 1 dated June 1, 2004, includes an article entitled "Hospital Design Nearing Completion." The article notes, "several meetings have been held during which walls have been repositioned, whole departments moved, and at one point, the hospital itself relocated. Out of this dynamic process has emerged a very exciting design that will be completed for an OSHPD submittal at the end of June." In Volume 1, Issue 2 of the newsletter dated July 2004, an article notes that "hospital leaders looked to include OSHPD in the very initial phases of the design process. Not just team members but the entire hospital development team met with OSHPD representatives in April 2004 for consultation regarding the project and early insight and feedback regarding OSHPD expectations." This demonstrates that discussions held in April, 2004 by the project organizers were, by their own words, considered to be "early." Most certainly, architectural and design plans were still being revised well after November 18, 2003 -- in fact it appears they were incomplete as much as 8 months after that date if not longer.

With respect to the receipt of funding, we understand that there had been only partial funding as of November 18, 2003, and that developers were still seeking investment after that date. We have received anecdotal reports of individuals who were in fact solicited to invest in the project after that date. As noted above, an executive summary dated April 14, 2004, reflects that investment was still being sought well after November 18, 2003. We also understand that the project had more recently lost the support of a few of its institutional investors, which would suggest that substantial funding was likely not received by November 18, 2003. With this much funding not having been received by November 18, 2003, there likewise could not have been substantial expenditures made by that date. For example, the "Hospital Vision" newsletter cited above notes that the land purchase was not completed until late 2003, but there is no discussion of any other major expenditures.

With respect to whether zoning requirements were met, we understand that the City of Loma Linda has not approved any required land use permits to date, and that these applications were not even submitted until September 1, 2004.

Finally, with respect to receipt of necessary approvals from State agencies, the hospital's license has not yet been received. As you can see from the attached photographs taken April 22, 2005, construction of the hospital has not begun even to the smallest degree, and it does not appear that any monies have been spent in that regard.

In conclusion, it appears that the investors have little or no basis for arguing that the proposed hospital was under development as of November 18, 2003. Almost 18 months later, all of the critical aspects of the hospital's development are still incomplete. Thus, we urge CMS to conclude that the proposed specialty hospital is not "grandfathered" under the moratorium.

³Pub.L. 108-173, Sec. 507(b), Dec. 8, 2003, 117 Stat. 2296.

Administrator McClellan
April 25, 2005
Page 4

A number of local and national organizations have already voiced their opposition to this project. The Loma Linda Chamber of Commerce recently voted against providing its support, along with the San Bernardino County Board of Supervisors which have adopted a position of non-support. Others who have joined in voicing their opposition to this project, to name a few, are:

California Alliance for Consumer Protection

California Congress for Seniors

American Association of Business Persons with Disabilities

California Senior Action Network

Democratic Process Center

Consumer Action

Administrator McClellan, this year, Loma Linda University Medical Center will celebrate 100 years of improving the health of the local, national and international communities that we serve. This amazing accomplishment has occurred regardless of difficult circumstances because of a deep commitment to healthcare mission and ministry, the sacrifice and dedication of competent clinicians and staff, the support of our community, and the blessing of God. The development of California Heart & Surgical Hospital, however, will undoubtedly jeopardize our ability to continue this dedicated mission of service, research and education. Therefore, we respectfully request that CMS not allow California Heart & Surgical Hospital to circumvent the Stark Law moratorium.

Thank you for your consideration of this matter. I am immediately available to you should you wish to discuss this matter of critical importance to the future of Loma Linda University Medical Center.

Sincerely,



Lyn Behrens, M.B., B.S.
President

cc: Mr. Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244 -1850

C. Duane Dauner
California Hospital Association
1215 K. Street, Suite 800
Sacramento, CA 95814



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, MD 21244-1850

DEC 21 2004

Ms. Danielle A. Lloyd
Vice President, Federal Regulatory Affairs
California Healthcare Association
1215 K Street, Suite 800
Sacramento, California 95814

Dear Ms. Lloyd:

It was a pleasure to meet with you and other California Healthcare Association (CHA) representatives on September 10, 2004. I appreciated hearing CHA's views on the physician self-referral specialty hospital moratorium established by section 507 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

I am responding to your request for clarification on whether the specialty hospital moratorium would apply to a limited service hospital that operates a part-time emergency department of fewer than five beds that may not be fully staffed or equipped to treat the full spectrum of emergency patients. Specifically, you asked whether the operation of such an emergency department in a hospital that solely treats patients with cardiac or orthopedic conditions would cause the facility to be considered a general acute-care hospital, rather than a specialty hospital, thus rendering the moratorium inapplicable to the facility.

For purposes of the moratorium, a specialty hospital is defined as a hospital that is primarily or exclusively engaged in the care and treatment of cardiac, orthopedic, or surgical patients. We believe that the hours, staffing, equipment, and services offered by an emergency department could be relevant to a determination regarding whether a hospital is "primarily or exclusively engaged in" specialty services. The operation of an emergency department such as you described would not, by itself, cause the hospital to be considered a general hospital that would not be subject to the moratorium. We believe operation of such an emergency department would tend to indicate that the hospital is a specialty hospital to which the moratorium would apply.

I hope this clarification addresses your concerns.

Sincerely,

Herb B. Kuhn
Director
Center for Medicare Management

Press Release

FOR IMMEDIATE RELEASE

April 5, 2004

Contact: William Arsenault
California Heart & Surgical Hospital
909.224.1777

NEW HOSPITAL UNDER DEVELOPMENT TO ADVANCE HEALTHCARE IN CALIFORNIA: CALIFORNIA HEART & SURGICAL HOSPITAL

Loma Linda, CA, April 5, 2004 -- Six and one-third acres of land at Barton Road and New Jersey Street in Loma Linda, CA have been purchased for the construction of a new hospital and medical office facility, California Heart & Surgical Hospital announced Monday. Hospital plans have been submitted to the city for its review.

"The hospital will offer multi-specialty surgical services and post-surgical recovery care in a comfortable, home-like environment—a unique level of personal care and comfort that will distinguish this facility in Southern California. Our goal is not only to save lives but to offer personal care that no other hospital can provide," said William Arsenault, spokesperson for the hospital.

The new, two-level hospital will be approximately 66,000 square feet and have exterior mission-style architecture with a complementing motif of interior arches and two interior gardens. Patients in each of the hospital's 24 rooms also will enjoy a patio "healing garden." Amenities also will include a café with "room-service" quality food. Patients will benefit from the finest available medical equipment and information systems technology, Arsenault added.

A local investment group, including many prominent Loma Linda physicians and the development group Medical Development Associates, LLC, will operate the surgery and recovery hospital. The California Heart & Surgical Hospital will be licensed by the California Department of Health and will exceed the stringent requirements required of medical facilities.

"We will help lead the new era in U.S. health care, offering personalized, compassionate, high quality and affordable care. Our physicians, nurses and staff will have all the tools to excel," Arsenault said. "And we will enhance the Loma Linda area's reputation for leadership in providing medical services."

According to Arsenault, the hospital will be an economic generator for the Loma Linda community, attracting new patients and their families, and retaining others who might have sought medical care elsewhere. In addition to its obvious economic benefits, the California Heart & Surgical Hospital will be a for-profit, tax-paying addition to the community tax base, he added.

"The hospital will focus on providing patients and their families with more-efficient health services to minimize the effects on their quality of life," said Arsenault.

The California Heart & Surgical Hospital is not affiliated with any other health care facility. Construction of the facility will begin within the next few months.



California Heart & Surgical Hospital
L o m a L i n d a

All inquiries are to be directed to:

William C. Arsenault

TEL: 909-224-1777

FAX: 909-924-0256

Arseault@earthlink.net

The information contained in this Executive Summary is furnished solely for consideration of a potential investment in Loma Linda Properties, L.L.C. It is not to be used for any other purpose. No warranty or representation as to the accuracy and/or completeness of the information contained herein is made. See Private Placement Memorandum for details and risks.

April 14, 2004

EXECUTIVE SUMMARY

BACKGROUND

Development is underway for California Heart & Surgical Hospital, a new state-of-the-art heart and surgical hospital to be built in Loma Linda, California. The hospital will be at the forefront of the new era in US healthcare delivery that seeks to provide personal, compassionate, high quality healthcare at an affordable cost. The mission of the hospital will be to empower local physicians, nurses and support staff to excel in these provisions and to provide patients and their families with a new paradigm of efficiency in healthcare services. The hospital will offer multi-specialty surgical services and post-surgical recovery care in a comfortable, home-like environment, a unique level of personal care and comfort that will distinguish the hospital regionally if not nationally. This prospect makes it an attractive investment opportunity.

CALIFORNIA HEART & SURGICAL HOSPITAL

The new, two-level hospital will be approximately 66,000 square feet and have exterior mission-style architecture with a complementing motif of interior arches and two interior gardens. The upper level will include twenty-four in-patient rooms and four intensive care units. Each of the twenty-four patient rooms will enjoy a patio "healing garden." The lower level will include six operating rooms, twelve post-anesthesia care units, eleven same-day surgery preparation/recovery rooms, two procedure rooms, two catheter laboratories, and eight catheter preparation/recovery rooms as well as a magnetic resonance imaging machine, a computerized axial tomography machine, x-ray machine and ultrasound machine. The facility's amenities will also include a café with "room service" food quality. Patients will benefit from the finest available medical equipment and information systems technology in a modern facility that is physician majority-owned and operated. The hospital is expected to open in the fourth quarter of 2005.

Upper Level	24 in-patient beds; 4 ICUs; 2 Courtyards (one exclusive to patients and their families; Dietary; Coffee Vendor; Waiting/Reception; Emergency; Administrative; Business; Pharmacy; Medical Records; Conference; Security; and Chapel
Lower Level	6 ORs; 12 PACU beds; 11 SDS Prep/Recovery; 1 Exam/Prep; 8 Cath Prep/Recovery; 1 Cath Isolation; 2 Procedure Rooms; 2 Cath Labs; MRI; Nuclear Medicine; Echo/EKG; Ultrasound; Gen. Rad.; R&F; CT; IT; Telephone; Data; Material Management; Maintenance; and Mechanical

INVESTMENT OPPORTUNITY

Loma Linda Properties, L.L.C. is offering up to 900 Units of membership interest in the real estate, building and equipment to be used by California Heart & Surgical Hospital at a per Unit price of \$10,000 to accredited investors as defined under SEC Rule 501(a), or knowledgeable and experienced investors, who are residents of the United States or entities organized in the United States. Loma Linda Properties, L.L.C. will have a fixed lease agreement with California Heart & Surgical Hospital for the exclusive use of all property and equipment. A local investment group, including many prominent Loma Linda physicians and the development group Medical Development Associates, LLC, will operate California Heart & Surgical Hospital. The hospital will be licensed by the California Department of Health and will be subject to the same stringent requirements as any other medical facility.



INVESTMENT RETURN & BENEFITS

Investors in Loma Linda Properties, L.L.C. will enjoy a high, fixed, quarterly return on investment of approximately twenty-four percent (24%) beginning ninety (90) days after the hospital's opening. Investors will also enjoy potential tax benefits from the pro rata share of pass-through equipment depreciation. In addition, the intangible benefits from an investment in the hospital may include satisfaction derived from

- more active involvement in delivery of healthcare in the Loma Linda community and region
- association with a modern and attractive alternative site to existing surgical and cardiac surgical providers
- enabling physicians to control the performance of comprehensive and affordable healthcare services
- stemming the "outmigration" of healthcare services to surrounding areas

MARKET OVERVIEW

Demographic Shifts

Profound demographic shifts over the next twenty-five years will result in significant increases in the demand for hospital inpatient acute care services if current utilization patterns do not change, according to a Solucient white paper, "National and Local Impact of Long-Term Demographic Change on Inpatient Acute Care" published in 2002. An aging baby boom generation, increasing life expectancy, rising fertility rates, and continued immigration will increase the volume of inpatient hospitalizations and significantly alter the mix of acute care services required by patients over the next quarter century. According to Solucient, Nationwide, demographic changes alone could result in a 46 percent increase in acute care bed demand by 2027. Assuming 80 percent occupancy of acute care facilities, the increase in hospital stays could amount to nearly 238,000 additional beds needed for the United States within the next twenty-five years. Total acute care admissions could also increase by almost 13 million cases in the next quarter century—a growth of 41 percent from the current number of national admissions.

"Over the next twenty-five years, seniors (ages 65 and over) will become the dominant patient type needing hospitalization. Currently, seniors nationwide account for about 40 percent of inpatient admissions and about 49 percent of beds. By 2027, senior patients could make up a majority of acute care services—51 percent of admissions and 59 percent of beds," stated Solucient.

While virtually every market in the US may see an increase in hospital inpatient services over the next twenty-five years, the western and southern states will most likely grow the fastest. This rapid expansion of hospitalizations will be due primarily to continued net migration to those areas from other parts of the US and foreign countries. Southern California counties will be among the highest growth markets with demand for acute care beds increasing more than 60% over the next twenty-five years. The mix of services provided during hospitalization will also shift significantly over that time period. The aging US population will expand certain service lines quickly, while others should show relatively slow growth. Cardiology, pulmonary medicine, orthopedics, and gastroenterology will be the fastest growing service lines, adding a combined 6.6 million annual admissions to current utilization—a 50 percent growth rate for those service lines combined. In contrast, annual admissions for obstetrics and delivery will grow at a much slower rate with only a 14 percent expansion of annual admissions, according to Solucient.

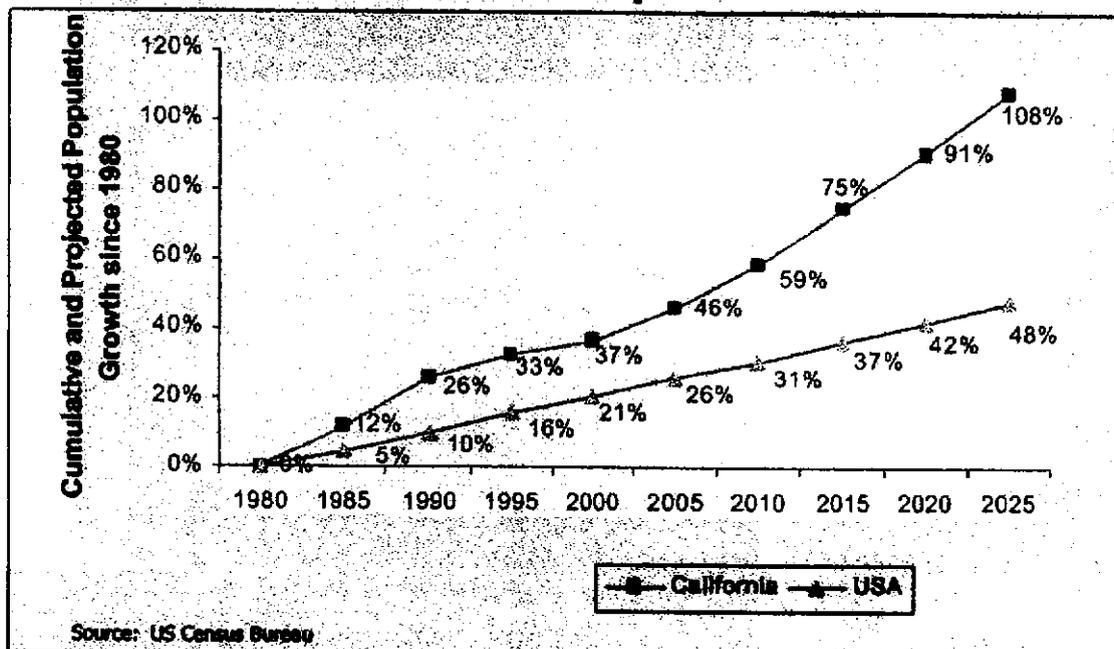
Population

Increases in demand for inpatient hospital care are driven largely by the growth and aging of the population. The US Census predicts that the population will continue to grow and age considerably

over the next quarter century, resulting in potentially much higher volumes of hospitalization (see National Population Projections on the US Census Web site at www.census.gov). Between 2002 and 2027, the overall US population is estimated to grow from approximately 287 million people to over 351 million—a 23 percent increase. California's population is projected to grow at exponential rates, exceeding the overall US population growth rates, as shown below in Table 1.

Table 1

California and US Population Growth



Loma Linda Area

California Heart & Surgical Hospital will be built in Loma Linda, CA., a community directly in the path of progress in the San Bernardino and Riverside Counties area of southern California. The US Census Bureau population estimates for San Bernardino and Riverside Counties in 2002 were 1,816,072 and 1,699,112 respectively. This area is estimated to be among the fastest-growing areas in the United States. The recently announced commercial expansion of San Bernardino Airport (previously Norton AFB) and the housing developments (approximately 4,500 homes) in Oak Valley are just two examples of the exciting new projects occurring in this demographic area.

A prosperous city of approximately 19,000, Loma Linda, CA has been a national center of health and wellness research, and for its size has a decidedly cosmopolitan air. Six and one-third acres of land at Barton Road and New Jersey Street in Loma Linda have been purchased for the construction of California Heart & Surgical Hospital, and plans have been submitted to the city for its review.

COMPETITION

Arrowhead Regional Medical Center
Colton, CA 373 beds

Redlands Community Hospital
Redlands, CA 172 beds

Community Hospital of San Bernardino
San Bernardino 293 beds

Riverside Community Hospital
Riverside, CA 276 beds

Kaiser Foundation Hospital
Riverside, CA 118 beds

Riverside County Regional Medical Center
Moreno Valley, CA 364 beds

Loma Linda University Medical Center
Loma Linda, CA 900 beds

San Bernardino County Medical Center
San Bernardino, CA 293 beds

Moreno Valley Community Hospital
Moreno Valley, CA 101 beds

St. Bernardine Medical Center
San Bernardino, CA 433 beds

Parkview Community Hospital Medical Center
Riverside, CA 193 beds

Most hospitals in the Loma Linda area are older facilities with stressed operating room capacities. California Heart & Surgical Hospital believes that referring physicians and prospective patients will welcome the new hospital's efficient, high quality care and modern facility.

SEISMIC COMPETITIVE ADVANTAGE

California's hospitals are struggling to address government regulations that impose expensive requirements upon hospitals but do not provide the funding to meet them. The most expensive of these "unfunded mandates" is the state's Senate Bill 1953 concerning seismic safety. This California law requires that all hospitals guarantee by 2008—or by 2013 if the buildings are expected to remain in use 26 years from now—that their buildings will not collapse in a significant earthquake. By 2030, hospitals must be able to withstand a major earthquake and continue functioning immediately afterward. Current estimates of the cost of complying with Senate Bill 1953 are at least \$24 billion, which is equal to

- the total existing assets of all California hospitals
- \$250,000 per bed
- a tax of \$233 on every discharge over the next 30 years

According to makeitright™ Hospital Building Design Professionals, there are nearly 43 million square feet of California hospitals that will need significant corrective construction by 2008. Over 75% of the State's hospitals will undergo seismic strengthening of their internal equipment and utility systems bracing.

While other hospitals are forced to invest significant time and money to bring their older facilities into compliance with Senate Bill 1953, California Heart & Surgical Hospital with its state-of-the-art facility will be able to focus 100% of its financial resources on providing quality healthcare, not facility development. While other hospitals are forced to pay attention to safety-related issues, California Heart & Surgical Hospital will have the strategic advantage of being able to pay attention to better patient care.

TRENDS IN HEALTHCARE CONSUMERISM

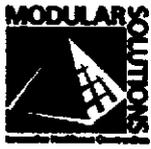
As consumers are asked to shoulder a larger portion of rising healthcare costs, they are taking greater control of their health, seeking out important information before making significant decisions, and playing an active role in the decisions that are ultimately made. This increasingly proactive consumer behavior signifies a change in the way hospitals must approach their strategic planning and business development efforts.

Several key trends in the way these proactive consumers approach the healthcare system and make decisions about their health were identified in a proprietary research report published by Solucient in 2003, after collecting responses from more than 100,000 households annually for several years:

- As consumers win greater access to and choice of healthcare providers, they are becoming increasingly concerned with the cost of care, the benefits they receive, and the convenience/accessibility of services
- For many consumers, physicians no longer play the central role in the hospital decision that they once did. Rather, consumers have displayed an increased willingness to ask their physicians to send them to the hospital that they most prefer.
- In selecting a hospital, consumers tend to rely much more on a hospital's reputation for providing the service needed than on a physician's recommendation to use a certain hospital.
- The number of consumers who sought out information about hospitals has nearly doubled over the past three years, indicating an increasing consumer need to support decisions related to hospital selection.
- For younger consumers, the Internet has replaced physicians as the most often used source for consumer-oriented healthcare information while printed materials are an increasingly important source of information for older adults.
- Consumers indicate a high propensity to give hospitals permission to use their personal health information for marketing and educational purposes—a fact that should provide reassurance in the still murky world of HIPAA marketing regulations.
- Consumer responsiveness to print marketing for hospital and physician services—especially direct mail—has increased significantly over the last several years, while responsiveness to mass advertising has declined.

Because California Heart & Surgical Hospital is committed to providing personal, compassionate, high quality healthcare at an affordable cost and in a state-of-the-art facility, the hospital believes that it will be significantly advantaged by the current trends in healthcare consumerism and in winning the loyalty of healthcare consumers in Southern California.

MANAGEMENT & DEVELOPMENT TEAM

	<p>Development Medical Development Associates, LLC 615 W. Carmel Dr. Suite 100 Carmel, IN 46032</p>
	<p>Design Professional Makeitright, Inc. 55 E. Huntington Dr. Suite 277 Arcadia, CA 91008</p>
	<p>Architect Marshall Erdman & Associates 5117 University Avenue Madison, WI 53705</p>
	<p>Construction Modular Solutions, LLC 615 W. Carmel Dr. Suite 100 Carmel, IN 46032</p>
	<p>Bank Security Savings Bank 317 S. Santa Fe Salina, KS 67401</p>
	<p>Legal Morris, Laing, Evans, Brock, & Kennedy, Chtd. Old Town Square 300 N. Mead, Suite 200 Wichita, KS 67202</p>
	<p>Board Advisor Arsenault Consulting 12020 Fenimore Drive Moreno Valley, CA 92555</p>

FINANCIAL OVERVIEW

CALIFORNIA HEART & SURGICAL HOSPITAL EQUIPMENT AND REAL ESTATE INVESTMENT ANALYSIS

		Year 1	Year 2	Year 3	Year 4	Year 5
EQUIPMENT LEASE RATE TO OPERATING CO.	14.50% **	\$3,828,502	\$3,828,502	\$3,828,502	\$3,828,502	\$3,828,502
EQUIPMENT PAYMENT TO BANK	11.25% **	(\$3,292,006)	(\$3,292,006)	(\$3,292,006)	(\$3,292,006)	(\$3,292,006)
		\$536,497	\$536,497	\$536,497	\$536,497	\$536,497
LAND & BLDG. LEASE RATE TO OPERATING CO.	11.25% **	\$2,447,513	\$2,447,513	\$2,447,513	\$2,447,513	\$2,447,513
LAND & BLDG. PAYMENT TO BANK	7.25% **	(\$1,843,720)	(\$1,843,720)	(\$1,843,720)	(\$1,843,720)	(\$1,843,720)
		\$603,793	\$603,793	\$603,793	\$603,793	\$603,793
RETURN ON CASH	11.25%	\$1,848,977	\$1,848,977	\$1,848,977	\$1,848,977	\$1,848,977
TOTAL CASH ON CASH RETURN		\$1,989,276	\$1,989,276	\$1,989,276	\$1,989,276	\$1,989,276
RETURN ON INVESTMENT						
Annual cash on cash return		24%	24%	24%	24%	24%
Annual (cash + residual) return	29.00% **	33%	34%	36%	36%	37%

Investment = \$8,331,117

Annual Return = \$1,989,276

	Year 1	Year 2	Year 3	Year 4	Year 5
Equipment Costs					
IMAGING EQUIPMENT	7,100,000				
HOSPITAL EQUIPMENT	6,000,000				
INFO TECH EQUIPMENT	2,800,000				
TOTAL	15,900,000	0	0	0	0
Equipment Cost	15,900,000	0	0	0	0
Building Cost					
Land **	1,813,359				
Building **	3,021,606				
Construction	22,036,346				
Total Land and Building Cost	27,770,301				
Total Land and Building Cost Financed through RE/ E Partnership	27,770,301				
Portion Financed by Debt	70% **	19,439,274			
Portion Financed by Equity	30% **	8,331,117			

See Private Placement Memorandum
for details and risks

HOSPITAL VISION

INSIDE THIS ISSUE:

<i>Hospital Design</i>	1
<i>Land Purchased</i>	1
<i>What's in a Logo?</i>	2
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Special points of interest:

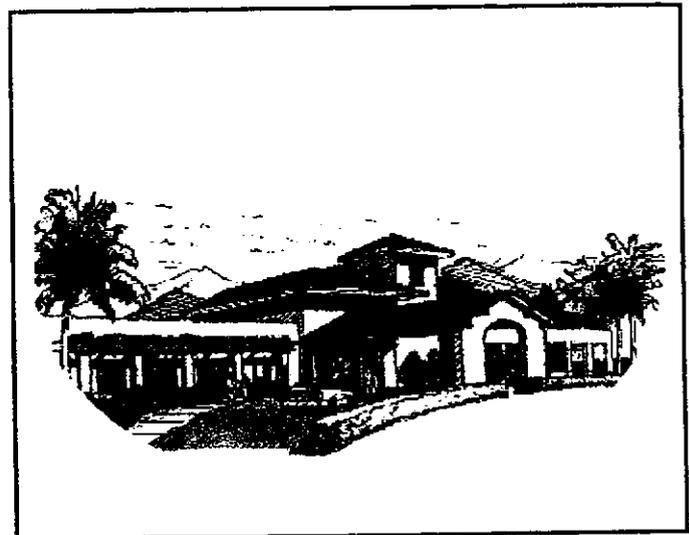
- California mission-style architecture distinguishes new hospital
- 6.3 acres purchased at Barton Road and New Jersey Street
- Hospital located in Historic Mission Overlay District
- Hospital looks to recreate the Zanja Trail

HOSPITAL DESIGN NEARING COMPLETION

As befitting the complex task of designing a new hospital, there have been many intense hours invested in the process. The staffs of Marshall Erdman and Associates which has design/build responsibilities along with Makelright which is the design professional have been working at a non-stop pace to complete the project.

Several meetings have been held during which walls have been repositioned, whole departments moved, and at one point, the hospital itself relocated. Out of this dynamic process has emerged a very exciting design that will be completed for an OSHPD submittal at the end of June.

A key component of the new hospital is its elegant exterior design. As can be seen from the accompanying rendering, the hospital will have a California mission-style architecture. This exterior design will complement the San Gabriel Mission Asistencia that is just up the street from the hospi-



The hospital's bell tower is a focal point of its mission-style architecture.

tal on Barton Road. Additionally, the design fits within the City of Loma Linda design guidelines established for the Historic Mission Overlay District.

A prominent feature of the new hospital is its 45-foot-high bell tower that is part of the hospital's chapel. A tile

roof, lattice covers and arch accents add to the mission theme. The theme is further reinforced within the facility with a complementing motif of interior arches and two interior gardens. The overall effect is that of an inviting hospitality center rather than a cold hospital setting.

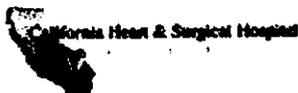
HISTORIC LAND PURCHASED FOR HOSPITAL

After extending the escrow period several times to complete the due diligence required on the property, the hospital group completed the purchase in late 2003. The 6.33 acre property is located on the Northeast corner of Barton

Road and New Jersey Street. The hospital was fortunate to close on the property that was selected as the best of many sites reviewed by the Board.

The size of the property will allow a medical office building to be included in the overall

project. As can be seen from the below drawing, initial site plans have been developed in conjunction with input from the City of Loma Linda. While the medical office building will not be directly related to the hospital, it is anticipated that many of the physicians in-





California Heart & Surgical Hospital

L O M U

Volume 1, Issue

July 2004

HOSPITAL VISION

INSIDE THIS ISSUE

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<i>Design and Construction</i>	1
<i>Engineering Challenges</i>	2
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Special points of interest:

- California mission-style appointments characterize facility's interior design.
- Hospital design and construction plans expected to be submitted to OSHPD in July
- Hospital looks for creative ways to address civil engineering challenges.

HOSPITAL INTERIOR COMPLEMENTS MISSION-STYLE ARCHITECTURE

The exterior mission theme of California Heart & Surgical Hospital is complemented inside the facility by a motif of interior arches, wood beams and interior gardens. Visitors to the new hospital enter a spacious central atrium that serves as a hub for amenities that include a café, coffee bar, chapel, courtyard and reception desk. Natural materials, such as tile and wood

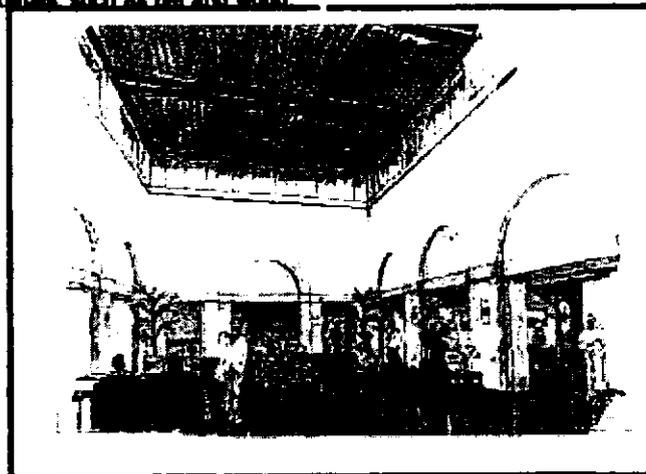
were selected to provide a warm, hospitable environment. The use of interior mission-style appointments creates a smooth transition from the facility's exterior design.

Registration desks in key locations allow patient rooms to be located on the perimeter of the facility. This design provides each patient access to natural lighting, a patio garden and landscape views,



Patient hallway

which studies have proven enhance the healing process. In patient hallways refined mission-style elements combine with tile and deep accent colors to provide patients and visitors with an attractive surrounding. Indirect light from ceiling fixtures is combined with light from accent wall sconces that also serve to identify room entrances. The overall effect is a soft, comforting ambience. Nurse stations are decentralized and located near patient rooms, providing the staff more immediate access to clinical information and allowing more time with patients.



Central atrium of California Heart & Surgical Hospital

EXPECT THE BEST IN DESIGN AND CONSTRUCTION

California Heart & Surgical Hospital will reflect a vision of superior patient care and be built by leaders who expect the best in facility design and construction.

Hospital design and construction are known to be challeng-

ing and often time-consuming processes. Acute care hospitals built in California are required by law to be plan-reviewed, approved, permitted and inspected by the Office of Statewide Health Planning and Development (OSHPD). With unprece-

dent demands currently placed on OSHPD for hospital construction review, the leaders of the new hospital were determined to complete a design of exceptional quality that would result in a smoother, more efficient OSHPD review process. First

California Heart & Surgical Hospital

c/o Arsenault Consulting
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Healthcare for the future

Development



Design Professional

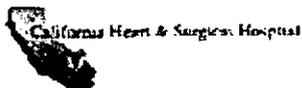


Design/Build



Marshall Erdman & Associates

Program Management



and foremost, hospital leaders looked to include OSHPD in the very initial phases of the design process. Not just team members but the entire hospital development team met with OSHPD representa-



tives in April 2004 for consultation regarding the project and early insight and feedback regarding OSHPD expectations. Hospital leaders then made the strategic decision to invest time upfront in the development of complete plans for OSHPD without any deferred issues that can lead later to increases in review time.

Design elements such as fire protection system, imaging center equipment, elevators and nurse call system that are routinely deferred by most design professionals until construction has begun have been designed early and completely. Extreme attention has been paid to room and department functions and the equipment that must be available for the best possible patient care.

The hospital's design and development plans are scheduled for submittal to OSHPD during this month, and the project team believes that the submittal will receive an efficient review. From the project's inception, the hospital's leaders have cast a vision to "expect the best." Everyone involved in the development process has responded to the need for cooperation and synergy to help realize this vision.

Harriet Beecher Stowe wrote "Common sense is the knack of seeing things as they are, and doing things as they ought to be done." From physicians to design engineers, the California Heart & Surgical Hospital project team has shown creativity and common sense in addressing the hospital's design and development challenges. Everyone on the team has been committed to excellence so that all who come to depend upon the hospital can expect the best.

CIVIL ENGINEERING CHALLENGES

In processing a site plan through the City of Loma Linda, California Heart & Surgical Hospital is prepared to meet a number of civil engineering challenges. Some of the challenges are general in nature such as gaining approvals from several different city departments: not only the planning department but the public works/engineering department and the building and safety department. Plans are also coordinated with all utility companies and the fire department. Working with the different personalities within all the departments represents an opportunity for creative solutions.

Hurdles that are more specific to the hospital project include:

the absence of a storm drain in the street at the hospital site: since the hospital



is responsible for accommodating rain water and excess water from irrigation, it has proposed a retention basin based upon the size of the site and percentage that is impervious.

the export of dirt: since the hospital's lower level will require the excavation and export of a significant

amount of dirt, the hospital is evaluating means of controlling costs, for example, by working with adjacent sites that need fill dirt.

recreation of the Zanja Trail: the hospital believes that recreating the trail on the property line will add to the aesthetics of the landscaping, and the city is excited about the prospect of a "rustic and authentic" historic landmark.

typical civil engineering challenges: handicap access, grading, sewer system, utilities and the improvements required by the city for Barton Road.

The hospital is prepared to meet these and other challenges as they arise.

Thank you for the opportunity to comment.

1. A separate condition of participation must be developed for beneficiaries residing in nursing homes (aka facilities: Long term care facilities, Skilled Nursing Facilities):

Section 1919 of the Social Security Act (the law) provides this definition of nursing facility: (a) NURSING FACILITY DEFINED.—In this title, the term “nursing facility” means an **institution** (or a distinct part of **an institution**) which—

(1) is primarily engaged in providing to residents—

(A) skilled nursing care and related services for residents who require medical or nursing care

Section 440.155 of Code of Federal Regulation 42 provides this definition of nursing facility:

Nursing facility services -

(a) “**Nursing** facility services, other than in an institution for mental diseases” means services provided in a facility that--

(1) Fully meets the requirements for a State license to provide, on a regular basis, health-related services to individuals who do not require hospital care, but whose mental or physical condition requires services that--

(i) Are above the level of room and board; and

(ii) Can be made available only through **institutional facilities**

CMS has supported the provision of home dialysis to residences of institutional facilities recognizing the hardship involved in transporting these most vulnerable beneficiaries out of their institutional residences to a hemodialysis center. However, 2004 CFR Title 42 Sec. 405.2102 Defines home dialysis as:

(3) Home dialysis. Dialysis performed by an appropriately trained patient at home.

(c) Self-dialysis and home dialysis training. A program that trains ESRD patients to perform **self-dialysis** or home dialysis with **little or no professional assistance**, and trains other individuals to *assist patients* in performing self-dialysis or home dialysis.

Home hemodialysis was intended for the capable, independent beneficiary or the beneficiary that required **some, but not total assistance** from a traditional home caregiver.

It is widely acknowledged that nursing homes face huge challenges with staff turnover and low skilled patient care assistants.. Though beneficiaries residing in nursing homes should continue to benefit from the convenience of receiving hemodialysis in their residential environments, CMS is obligated to assure that this special population is receiving safe, quality care. CMS must develop a separate condition of participation that outlines specific minimum requirements for staff, water, infection control, pre and post

care and dialysis adequacy. Oversight of the care of nursing facility residents is different than oversight of care of the traditional beneficiary who elects home hemodialysis. While the population of ESRD patients is projected to grow, the population of the aged is growing more rapidly and we can expect that a higher percentage of nursing home residents will have end stage renal disease and require hemodialysis to be delivered in their residential facilities.

2. Clinical Outcome Standards

The proposed regulation requires providers to use “community accepted standards” to guide quality of care and set benchmarks for improvement of care. Though the vast majority of the renal community shall comply with the intent of this statement, it leaves opportunity for individual interpretations. The community understands the intent of the statement to be the K/DOQI guidelines; however, an individual may elect to interpret this differently. Therefore, CMS should define the minimum clinical outcome standards by referring to K/DOQI guidelines in the regulation.

In addition, CMS is developing systems to support the concept of ‘payment for performance.’ It is not logical to pay a provider who demonstrates “improvement” from an individually defined “community accepted care standard” the same as the provider who demonstrates improvement in care as defined by the intent of the statement – K/DOQI. Therefore, CMS must affirmatively define the minimum clinical outcome standard in the regulation.

3. Use of Updated Water/Dialysate AAMI Standards

AAMI RD52 is the current water/dialysate AAMI standard. The regulation must incorporate this standard to define limits of toxin and preparation of dialysate. Water/dialysate is one of the largest potential threats to patients safety as negative outcomes associated with inappropriate water/dialysate are often fatal. The condition for “water quality” should be expanded to include “water/dialysate quality.”

4. Carbon Tanks

The regulations must state that the water treatment system include the use of 2 carbon tanks as a minimum. Hemolysis, the result of a blood exposure to chlorine/chloramines, is extremely dangerous. Daily testing for chlorine/chloramines does not provide safeguards for patients should the daily testing reveal the presence of chlorine/chloramines. Daily testing does not protect those patients exposed between the last negative test and the test revealing the presence of chlorine/chloramines if chloramines self generates since last tested (as we know it can).



National Council of State Boards of Nursing, Inc.
111 E. Wacker Drive, Suite 2900
Chicago, IL 60601-4277
312.525.3600
312.279.1032 fax
www.ncsbn.org

May 5, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8012
Baltimore, MD
21244-8012

Re: CMS-3818-P

Dear CMS:

The language proposed in § 494.140(b)(3)(i) is not clear and open to misinterpretation. A Licensed Practical Nurse (LPN) cannot be in charge of a unit without specific authority from a state board of nursing nor can a LPN supervise a Registered Nurse (RN).

The proposed rules need to clearly articulate and reference the authority of the individual state board of nursing in order to determine a safe and legal scope of practice.

Sincerely,

Kathy Apple, RN, MS, CAE
Executive Director

Cc: Kristin Hellquist, Director of Policy & Government Relations

122 3818 8

**Congress of the United States
Washington, DC 20515**

May 5, 2005 15:06 PM 2:35

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator McClellan:

We are writing in response to the proposed rule for the Medicare program conditions of coverage for End Stage Renal Disease (ESRD) facilities published by the Department of Health and Human Services (HHS) in the Federal Register on February 4, 2005. (42 CFR Parts 400, 405, 410, et. al.) First, we would like to congratulate you on this accomplishment. The changes in medical technology and clinical practice that have taken place in the twenty-nine years since the last conditions of coverage were established make this update to the ESRD program a welcome and necessary change. We offer the following initial thoughts on the proposed rule and respectfully request the ability to provide additional comments on the conditions for coverage and other ESRD-related issues as we learn more about the practical implications of these changes.

We are particularly pleased that the proposed rule significantly improves quality assessment and performance improvement requirements for dialysis facilities. Requiring each facility to develop and implement an on-going quality assessment and performance improvement program using evidence based, well-recognized clinical measures will greatly improve the quality of patient care delivered in dialysis facilities. In addition, requiring the electronic submission of data will enable CMS to monitor a facility's performance and to compare performance across facilities. These steps are a natural prelude to the next generation of Medicare payment policy - linking reimbursement to more efficient, quality care. We also support the Department's continued requirement that facilities cooperate and share data with the renal Networks.

The proposed rule appears to address several problems identified by the Government Accountability Office (GAO) regarding patients' rights, including increased protection of physical and informational privacy, an improved grievance process (internal and external), and improved protection for patients from being transferred or discharged without adequate reason. The rule also expands and brings patient assessment requirements up to date, including defining the minimal elements of an assessment and the nature of the assessment team.

Staff qualifications and competencies are also updated and outlined, including minimal qualifications for the renal technicians. Infection control and water quality standards have been updated and significantly improved based on well-recognized industry guidelines. Emergency

The Honorable Mark McClellan
May 5, 2005
Page Two

preparedness expectations have been enhanced, including requiring CPR training and availability.

While these long awaited changes to the ESRD conditions of coverage are a substantial improvement over the existing conditions, enforcement mechanisms are still lacking. We remain concerned that the rule does nothing to address the following concerns raised in previous GAO and OIG reports:

- 1) State surveys are infrequent, poorly targeted, and inadequate.
- 2) Short of terminating a facility from the Medicare program, there is no provision for sanctions against facilities that have repeat deficiencies.
- 3) State survey staff do not specialize in ESRD facilities and do not receive adequate training to inspect ESRD facilities.

Although the proposed rule references recommendations in the OIG's Report of 2000 in *External Quality Review of Dialysis Facilities: A Call for Greater Accountability* (pp. 6218), it does not adopt the OIG's recommendations for oversight. The quality improvements you propose will be meaningless if there are no mechanisms in place to hold facilities accountable for the care they provide. We believe the proposed rule will lead to significant improvements in the care of persons with ESRD. Nonetheless, without adequate oversight and enforcement mechanisms, changes to the conditions of coverage are not sufficient to ensure that persons with ESRD receive the optimal level of care.

We look forward to hearing how HHS intends to address these concerns. Please provide your response by 3 June 2005. Should you have any questions regarding this matter, please do not hesitate to contact Diann Johnson (Senator Grassley) at (202) 224-4515 or Deborah Veres (Representative Stark) at (202) 225-4021. All correspondences should be sent via facsimile to (202) 228-2131 and (202) 226-4969. All original material should be sent via USPS mail.

Sincerely,



Charles E. Grassley
Chairman
Senate Committee on Finance



Pete Stark
Ranking Member
Committee on Ways and Means
Subcommittee on Health

CHARLES E. GRASSLEY IOWA, CHAIRMAN

ORRIN G. HATCH, UTAH
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DIANNE L. LINCOLN, ARKANSAS
RON WYDEN, OREGON
CHARLES E. SCHUMER, NEW YORK

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL
RUSSELL SULLIVAN, DEMOCRATIC STAFF DIRECTOR

FACSIMILE TRANSMITTAL

204 HART SENATE OFFICE BUILDING

PHONE 202-224-4515

FAX 202-228-2131

To: Dr. Marc McClellan

Fax: (202) 690-8168

From: Senator Charles E. Grassley & Representative Pete Stark

Date: May 5, 2005

Number of pages transmitted, including cover sheet: 3

Notes: Please call Tom Novelli at 202-224-6447 for problems with transmissions

SHARP[®] Coronado Hospital

May 2, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: CMS-3818-P; Medicare Program; Conditions for Coverage of End Stage Renal Disease Facilities; Proposed Rule

To Whom It May Concern:

Sharp Coronado Hospital and Medical Center appreciates the opportunity to comment on the proposed rule regarding conditions for coverage of end stage renal disease (ESRD) facilities.

Dialysis of ESRD Patients in Skilled Nursing Facilities

Background

We are concerned about the provisions regarding dialysis in skilled nursing facilities (SNFs). We are seeing an increasing number of patients who have complex medical needs and require dialysis, but are otherwise stable. These patients could be cared for by nursing facilities.

We appreciate the Centers for Medicare and Medicaid Services' (CMS) recognition of this problem as set forth in the proposed rule. Allowing SNF residents to access home dialysis, however, does not solve the problem. We urge CMS to revise its position and make it financially feasible for nursing facility patients to receive dialysis at the bedside from a dialysis facility or the SNF.

Provision of Home Dialysis to SNF Patients Is Inappropriate

Nursing home patients who typically require dialysis are extremely fragile. The stability of their health status is precarious and can change at a second's notice. The home dialysis benefit, on the other hand, is designed for dialysis patients who are healthier and heartier than the average dialysis patient. Thus, home dialysis is not medically appropriate for the vast majority of SNF patients who require dialysis.

In addition, for these patients their stay in the SNF is a short break in the midst of on-going dialysis treatment. Rarely, if ever, are these patients on home dialysis prior to or after the SNF stay. Requiring these patients to switch from chronic dialysis to home dialysis and back again within a one-month timeframe is unrealistic. The current system cannot support demands for such quick benefit coverage decisions. Thus, patients' continuity of care is jeopardized by the proposed rule.

SHARP® Coronado Hospital

For these reasons, use of home dialysis in nursing homes is inappropriate for the vast majority of nursing home residents.

Bedside Dialysis Services Provided by Dialysis Facility or Nursing Facility Covered by Medicare Statute
Currently, the vast majority of nursing home patients requiring dialysis receive such services at an off-site dialysis clinic. This situation has significant drawbacks. First, it necessitates use of an ambulance – and Medicare resources – to transport the patient to and from the clinic. Second, being transported to/from the clinic and sitting up in a dialysis chair are extremely taxing on residents whose health is already seriously compromised. Third, it requires the patient to be out of the nursing facility for a significant amount of time, missing medication administration, treatment regimens, meals and planned activities. Fourth, it is not uncommon for the resident to require accompaniment of a SNF nurse, which pulls resources away from other SNF residents.

We believe that Medicare should cover dialysis provided at the bedside in the nursing facility when provided by a dialysis facility or the nursing facility. Doing so would create a win-win situation. Nursing facility residents requiring dialysis would receive better care. Medicare would save ambulance costs. And many hospitalized dialysis patients would move sooner from the hospital to a lower level of care, thus providing for more effective and efficient use of our nation's limited healthcare resources.

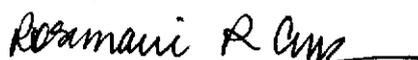
Not only do we believe these options are the right thing to do, we believe that they are consistent with existing Medicare law. As set forth in more detail in the comment letter from the California Hospital Association (CHA), the applicable statutory provisions provide leeway for interpretation. **Thus, we urge Medicare to interpret existing law so as to make it financially feasible for SNF residents to receive dialysis services at the SNF, whether under a Part A stay or Non-Part A stay and whether performed by a dialysis provider or by the SNF.**

Conclusion

The number of patients who require dialysis, but could otherwise be cared for in a nursing facility are increasing. Home dialysis is inappropriate for the vast majority of nursing home residents because of their medical fragility. We urge CMS to interpret existing law in such a manner as to make it financially feasible for SNF residents to receive dialysis services from dialysis providers and SNFs at the bedside.

If you have any questions or comments, please contact Rosemarie R. Cruz at 619-522-3937.

Sincerely,



Rosemarie R. Cruz
Manager Villa Coronado



NATIONAL RENAL ADMINISTRATORS ASSOCIATION

April 20, 2005

The Honorable, Mark McClellan, Administrator
Attn: CMS 3818-P
Centers for Medicare and Medicaid Services
U.S. Dept of Health and Human Services
Room 445-5
Hubert Humphrey Building
200 Independence Ave. S.W.
Washington, D.C. 20201

Dear Dr. McClellan:

The National Renal Administrators Association is a voluntary organization representing professional managers of dialysis facilities and centers throughout the United States. NRAA represents a broad cross section of the dialysis industry, including for-profit, not-for-profit, free-standing and hospital based facilities in urban, suburban and rural areas across the country.

NRAA is very concerned about the proposed Hematocrit Management Audit Guidelines published in the fall of 2004. NRAA members have worked diligently to improve the anemia outcomes for dialysis patients. This is evidenced by the continuing improvement in achieving KDOQI hemoglobin levels.

In order to continue improvement or even maintain current hemoglobin levels, it is imperative that facilities have a reasonable expectation of reimbursement for medication administered to achieve those goals. Due to human variability in dose response to medications, it is impossible to be precise with outcomes even when dosing is comparable between like patients. Therefore at any point in time, even the same patient can have a different response to the same dose of medication based on an acute illness, infection or other complications. A realistic expectation of dose limits would be for providers to take a very conservative approach to Epogen® dosing and thus adversely affect patient outcomes. No provider can afford to provide unreimbursed medications.

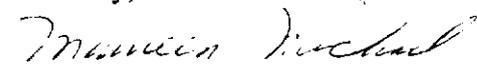
The proposed HMA would limit doses or deny payments for Epogen® in patients with hematocrits over specific levels. Limiting doses without consideration of patient weight or concurrent illnesses does not follow the instructions for dosing in the FDA approved package insert. Underdosing could become a litigation issue for the physician, provider and even CMS.

NRAA recommends reasonable guidelines such as the following:

1. Use Hemoglobin levels versus hematocrit levels
 - a. Rationale: Hematocrit levels can be affected by patient fluid weight gains and are not as accurate a measurement of anemia as hemoglobin levels
2. Allow for occasional temporary excursions over max hemoglobin levels
 - a. Rationale: Takes into consideration human dose response variability
3. No fixed maximum dose or arbitrary dose audits
 - a. Rationale: Does not follow FDA package insert dosing guidelines
 - b. Consider a per -kilo-per week dose for oversight purposes
 - c. Exempt home patients from any fixed maximum dose or reduction in Epogen® reimbursement based on hemoglobin or hematocrit levels as
 - i. Home patients receive a month's worth of Epogen® during their monthly recheck visit when their lab work is drawn.
 - ii. Results may not be available immediately so an estimated monthly allotment of Epogen is provided to the patient. Dosing may later be reduced based on lab results, but the supply of Epogen is billed in total when dispensed according to CMS billing guidelines.
 - d. Allow for medical justification from physicians for those patients who need higher hematocrits due to justifiable medical reasons. A technical expert panel could determine these approved reasons .
4. Update UB 92 claim form to allow coding to note reduction in dosing when hemoglobin is greater than 13 g/dl
 - a. Rationale: This will alert CMS that the high hemoglobin has been addressed with a reduction in dose of Epogen®
5. Allow reporting of the first hemoglobin of the month instead of the last
 - a. Rationale: This allows for dose adjustments within the same month of billing and annotation on the claim form if item 4 above is implemented.

NRAA respectfully requests CMS consider the NRAA recommendations mentioned above in any future HMA guideline. Please direct inquiries to Maureen Michael, at 407 843-6110 or email at mmichael@cfkc.net.

Sincerely,



Maureen Michael
President, NRAA

1904 Naomi Place • Prescott, AZ 86303-5061

(928) 717-2772 • Fax: (928) 441-3857 • e-mail: nraa@nraa.org • www.nraa.org

125
APR 25 2005



4470 Redwood Hwy, Suite 102
San Rafael CA 94903-1905

The TransPacific Renal Network provides leadership for chronic dialysis and transplantation professionals to promote delivery of the highest quality care to people with end stage renal disease.

April 20, 2005

Centers for Medicare & Medicaid Services
Department of Health Services
PO Box 8012
Baltimore, Md 21244-8012

Re: File Code CMS-3818p

This comment concerns emergency coverage and a requirement that there be an agreement with a hospital to provide backup.

I believe this requirement does not go far enough in terms of providing mutual aid in the event of a large disaster. For the most part, dialysis patients, because of the chronic nature of their disease, do not receive priority or even acknowledgement from emergency planners and civil defense authorities. One can also assume in the event of a wide-scale disaster, hospitals too would be compromised in their ability to provide backup services, and perhaps they too might be rendered inoperable.

Our Network has done extensive research and planning into the implications of an area-wide disaster affecting dialysis patients. We believe that every facility should have one or more mutual aid agreements with other facilities both near and far. Our recommendations have been incorporated into two CMS publications on Emergency Preparedness for Dialysis Facilities and for People on Dialysis.

We also believe that education and training of patients is paramount to the success of this policy, and you have somewhat addressed this in other sections of the proposed Conditions.

Sincerely,

A handwritten signature in dark ink, appearing to read "Arlene Sukolsky", is written over the typed name.

Arlene Sukolsky
Executive Director



April 18, 2005

Centers for Medicare & Medicaid Services
Department of Health Services
PO Box 8012
Baltimore, Maryland

Re: FILE CODE CMS 3818p

To Whom It May Concern:

The following comments represent my opinion as a member of the Medical Review Board or the Board of Directors of the TransPacific Renal Network regarding the proposed Conditions of Participation.

Patient Safety: The Board supports the proposal that new facilities must have an isolation room. We further recommend consideration of required testing for Hepatitis C upon admission to a dialysis facility and periodically thereafter. We further recommend that existing laws regarding reimbursement for this procedure must be changed, and that CDC Guidelines must be followed, including reimbursement for testing for Hepatitis C. The Board also supports the recommendation of a Hepatitis B positive separate area in existing facilities, unless the facility is so small that a separate area is not feasible.

Water Quality: There are no data available to support the proposed requirement for ultra pure dialysate, and this also adds significant costs to the facility.

Physical Environment: The Board supports all of the recommendations for emergency preparedness and feels there should be no exemptions for defibrillators in rural facilities. Personnel should be certified in CPR and AED.

Patient Assessment: The Board feels that 30 days AFTER ADMISSION to a dialysis facility is more appropriate for patient assessment, followed by a 6-month comprehensive review. The Board also supports the elimination of the long term care program and signature of a transplant surgeon. The requirement for seeing patients on a monthly basis may be unduly burdensome for geographically-isolated facilities or those with severe nephrologist shortages. The Board questions the reasonableness of holding the facilities responsible for assuring that physicians would be required to see patients while on dialysis.

Patients Rights: We seek clarification of "appropriateness of discharge". The Board supports the concept that patients may not be discharged for not following staff recommendations. The Board is pleased to see a requirement that patients be informed of their right to complete an advance health care directive.



Dialysis in skilled nursing facilities: There is no financial incentive for these facilities to undertake dialysis unless changes are effected in licensure. SNFs should not have to be responsible for equipment, staffing, and transportation. We have concerns about quality, safety, and accountability.

Priority of Improvement Activities: The Clinical Performance Measures initiative should provide the data necessary to guide facility quality improvement. Billing data, usually submitted by clerical staff, would be questionable as to accuracy. We question the use of minimum standards, since standards change over time. Minimum standards might actually restrict patients to accessing care if the patients are labeled as unacceptable.

Medical Director Qualifications: We object to the lowering of standards for this important position, except on a case-by-case basis.

Social Worker Qualifications: We strongly support the recommendation that social workers should be freed of clinical tasks, and advocate that a masters level should be the community standard, and licensing required.

Dialysis Technicians: The Board supports this language.

Adequate number of trained staff: The minimum requirement for one registered nurse per shift does not take into consideration the large number of patients in a given facility and makes for questionable patient safety.

Discharge and Transfer Policies: The Board supports the proposed language.

Sincerely,

Hamoudi Al-Bander, MD