



August 18, 2008

Thomas E. Hamilton  
Director  
Survey and Certification Group  
Mailstop S2-12-25  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: Draft Interpretive Guidance for the Survey Process of the New End Stage Renal Disease Conditions for Coverage

Dear Mr. Hamilton:

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on Draft Interpretive Guidance for the Survey Process of the new End Stage Renal Disease (ESRD) Conditions for Coverage. KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care of individuals with irreversible kidney failure, known as ESRD.<sup>1</sup>

This letter supplements our earlier letter dated August 2, 2008. We continue to encourage CMS to adopt the recommendations outlined in that letter. Upon reviewing the Draft Interpretive Guidance, we would like to offer a few additional suggestions. Specifically, KCP encourages CMS to:

- ❖ V420—In light of the substantial cost burden of compliance with the Life Safety Code, CMS should provide flexibility to facilities through the waiver process;
- ❖ V451—CMS should extend the period during which facilities must inform patients of their rights and responsibilities to the first two weeks;

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<sup>1</sup> A list of Kidney Care Partners coalition members is included in Attachment A.

- ❖ V506—CMS should allow chest x-rays to be included as a valid method for tuberculosis screening;
- ❖ V516—CMS should clarify that patients do not need a new assessment when transferring between related facilities when patient records are fully transferred;
- ❖ V560—CMS should clarify the Interpretive Guidance references to non-physician practitioners;
- ❖ V592—CMS should extend the window for completing the patient assessments for home dialysis patients;
- ❖ V692—CMS should grandfather-in patient care technicians who do not have a high school diploma or equivalency;
- ❖ V711—CMS should remove the hours requirement for medical directors from the Interpretive Guidance;
- ❖ V728—CMS should modify the Interpretive Guidance to permit state surveyors and ESRD Networks the right to take copies of medical records off-site only through electronic submission through secure networks; and
- ❖ V733—Patient medical records should be transferred within two working days or before the next treatment for patients who are visiting another facility.

**I. V420—In light of the substantial cost burden of compliance with the Life Safety Code, CMS should provide flexibility to facilities through the waiver process.**

KCP appreciates CMS' flexibility regarding the inclusion of a waiver process for dialysis facilities in relation to the Life Safety Code. We strongly encourage the Agency to provide maximum flexibility when it comes to granting waivers and assessing compliance with the Life Safety Code. As expressed in previous comments, KCP remains concerned that compliance with the Life Safety Code will impose a significant cost burden on dialysis facilities.

**II. V451—CMS should extend the period during which facilities must inform patients of their rights and responsibilities to the first two weeks.**

KCP strongly agrees that facilities should inform patients of their rights and responsibilities when they begin dialysis. The Interpretative Guidance defines "when they begin treatment" to mean within the first three treatments. We are concerned that this window does not take into account that many new dialysis patients are extremely ill and overwhelmed by the amount of information they must learn in these initial sessions. Patients need to be able understand their rights and responsibilities when they are described. Although it would be ideal to assume that all patients

could be in a position to discuss their rights and responsibilities within the first three treatments, the reality is that many cannot. Therefore, we recommend that CMS extend the period during which facilities must inform patients of their rights and responsibilities to encompass the first two weeks after their admission to the facility.

**III. V506—CMS should allow chest x-rays to be included as a valid method for tuberculosis screening.**

KCP recommends that CMS recognize the appropriateness of using chest x-rays to determine whether or not a patient has tuberculosis (TB). In its regulations and draft guidance, CMS has recognized the importance of thorough vaccination records and tuberculosis screening. In conformity with Centers for Disease Control (CDC) recommendations, CMS proposes that all dialysis patients be tested at least once for baseline tuberculin skin test (TST) results and re-screened if TB is detected. Although the TST is an effective and appropriate instrument for achieving this goal, it is not the only available test for detecting TB. Chest x-rays are also effective. Including chest x-rays would provide patients who may not be able to tolerate the TST with a viable alternative. Additionally, it would allow patients who have already had a chest x-ray to avoid an unnecessary test. For these reasons, CMS should allow chest x-rays to be included alongside TST for determining whether a patient has TB.

**IV. V516—CMS should clarify that patients do not need a new assessment when transferring between related facilities when patient records are fully transferred.**

KCP recognizes the importance of completing a comprehensive patient assessment for new dialysis patients. Patient assessments are critically important to providing patients with the appropriate level of care. The Interpretive Guidance, however, does not differentiate between patients who are transferred to facilities related to their original facility and transfers to unrelated facilities. When a patient is transferred to a related facility, the dialysis teams follow the same clinical protocols and guidelines. In addition, the entire patient record is also transferred. Thus, it is appropriate to permit this new team to rely upon the existing patient assessment and update it as appropriate. To ensure resources are used most effectively, a facility should not be required to complete a new comprehensive assessment when the patient has transferred with full medical records from a related facility.

In addition, we recommend that CMS clarify how patients who are traveling should be treated. For example, a number of dialysis patients travel. It does not make sense to require the facility they are visiting to complete a new assessment when the patient will be returning to their “home” facility. In addition, CMS should consider permitting dialysis facilities that treat individuals who travel to temperate areas of the country during the winter months to rely on the patient assessment from their “home” facilities. These patients change dialysis facilities each time they move. Requiring that such patients be given a comprehensive assessment in each facility does little to improve patient care and only adds to the cost of providing care.

**V. V560—CMS should clarify the Interpretive Guidance references to non-physician practitioners.**

The Conditions require dialysis facilities to ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist or physician's assistant at least monthly. CMS should clarify in the Interpretive Guidance that use of the non-physician practitioners is appropriate in meeting the monthly visit requirement. In the interest of clarity and consistent implementation, KCP would like to ensure that all references to medical practitioner include both the physician and the non-physician practitioners. Accordingly, KCP recommends modifying the Guidance language by inserting the language in bold below:

This requirement is to ensure that patients see a medical practitioner (i.e., physician or one of the non-physician practitioners listed) at least monthly. The patient may see the practitioner **(i.e., physician or one of the non-physician practitioners listed)** in the dialysis facility (before, during or after treatment), or in the physician's office if the record of care for that visit is incorporated into the dialysis facility medical record.

**VI. V592—CMS should extend the window for completing the patient assessments for home dialysis patients.**

KCP encourages CMS to provide facilities with a broader window in which to complete home dialysis patient assessments. Home dialysis patients are physically present in the dialysis facility far less than hemodialysis patients. Accordingly, it is difficult to conduct the assessment within the required time frame. Hemodialysis patients receive treatment in a dialysis facility several times a week. Home dialysis patients, by contrast, are treated at home and interact with the dialysis facility less often than hemodialysis patients. A home dialysis patient's initial contact with a dialysis facility focuses on the patient's training. During this time, home dialysis patients are in a facility for an average of four days. This time frame is often not sufficient for performing a comprehensive patient assessment. Coordinating the interdisciplinary team and the patient's schedule to assess the patient and develop a plan of care is extremely challenging. If the assessment is not completed during this time, the beneficiary would be forced to return to the facility within the same 30-day period. This is an unnecessary burden for the home dialysis patient. To avoid burdens to patients and unrealistic requirements to facilities, CMS should allow facilities slightly more time to complete home dialysis patient assessments.

**VII. V692—CMS should grandfather-in patient care technicians who do not have a high school diploma or equivalency.**

KCP agrees with the need to establish consistent training for patient care technicians. As you know, such standards were included in the Kidney Care Quality and Education Act of 2007, introduced by Sen. Kent Conrad (D-ND) and Reps. John Lewis (D-GA) and Dave Camp (R-MI), and which the KCP strongly supports. Current patient care technicians will have the opportunity to meet most of the requirements set forth in the Conditions for Coverage. However, some patient

care technicians who have been employed for many years and provide outstanding patient care may – for various reasons – not have proof of a high school diploma or equivalency. In these cases, we recommend that CMS grandfather-in such patient care technicians. Thus, while any new patient care technician would be required to meet this standard, current patient care technicians who can not show proof of a high school diploma or its equivalent would be permitted to continue to work in facilities so long as they meet the other requirements outlined in the condition.

**VIII. V711—CMS should remove the hours requirement for medical directors from the Interpretive Guidance.**

KCP agrees that facility medical directors must be actively involved in the oversight of patient care delivery and outcomes. However, we believe that facilities should have the flexibility to determine with the medical directors the time required to meet their obligations. We are concerned that a minimum number could lead to a race to the bottom in terms of the amount of time medical directors are expected to spend fulfilling their obligations. Therefore, we recommend that CMS not include a specific hours requirement in the Interpretive Guidance.

**IX. V728—CMS should modify the Interpretive Guidance to permit state surveyors and ESRD Networks the right to take copies of medical records off-site only through electronic submission through secure networks.**

While KCP appreciates the need for state surveyors and ESRD Networks to access medical records offsite, it is critically important that such records be obtained and maintained in a highly secure manner. Under the HIPAA Privacy Rule, covered entities must safeguard protected health information. *See generally*, 45 C.F.R. § 164.501 *et seq.* As part of this duty, any transmission of medical records must be made in a secure manner. KCP acknowledges that state surveyors and ESRD Networks have the right to access and review patient records under certain circumstances. Our concern is that permitting these entities to physically take such records offsite could result in an otherwise avoidable breach of privacy. A more secure means of providing them with offsite access would be to electronically transmit the files as a pdf or other appropriately secure document using a secure transmission. This option would eliminate the possibility of a loss of the physical copies during transit. We strongly encourage CMS to adopt a more secure requirement for accessing and reviewing patient medical records in the Interpretive Guidance.

**X. V733—Patient medical records should be transferred within two working days or before the next treatment for patients who are visiting or switch to another facility.**

KCP agrees that it is critically important to maintain the continuity of care whenever patients transfer between facilities or switch to a new facility. It is important for the receiving facility to have a clear understanding of a patient's medical history and current treatments. The goal of the requirement to transfer files within one day is to ensure that there is such continuity of care. One day, however, places an unnecessary burden on facilities. Rather than set an arbitrary time, we recommend requiring that the transfer be made before the patient's next treatment or within two working days. We recognize that this request will require a change to the policy underlying the

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Conditions for Coverage, but believe it is important to make such a change as soon as possible to reduce the burden on facilities.

**XI. Conclusion**

KCP members appreciate the opportunity to comment on the draft Interpretive Guidance. We look forward to working with the Agency to effectively implement the Conditions for Coverage. Please do not hesitate to contact Kathy Lester at 202-457-6562 if you have questions regarding these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "E. Jones, M.D.", written in a cursive style.

Edward R. Jones, M.D.  
Chairman  
Kidney Care Partners



**Coalition Members:**

Abbott Laboratories  
AMAG Pharmaceuticals  
American Kidney Fund  
American Nephrology Nurses' Association  
American Regent, Inc.  
American Renal Associates, Inc.  
American Society of Diagnostic and Interventional Nephrology  
American Society of Nephrology  
American Society of Pediatric Nephrology  
Amgen  
Baxter Healthcare Corporation  
Board of Nephrology Examiners and Technology  
California Dialysis Council  
Centers for Dialysis Care  
DaVita, Inc.  
Dialysis Patient Citizens  
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Fresenius Medical Care North America  
Fresenius Medical Care Renal Therapies Group  
Genzyme  
Kidney Care Council  
National Association of Nephrology Technicians and Technologists  
National Kidney Foundation  
National Renal Administrators Association  
Nephrology Nursing Certification Commission  
Northwest Kidney Centers  
Renal Advantage Inc.  
Renal Physicians Association  
Renal Support Network  
Renal Ventures Management, LLC  
Satellite Healthcare  
U.S. Renal Care  
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