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, published April 15, 2008, in the Federal Register.

Dear Mr. Hamilton:

California Dialysis Council (CDC) 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. CDC is a statewide organization that continues to address legislative and clinical issues representing the needs of the renal community. CDC has for over 25 years been in the forefront of addressing concerns that affect not only California, but the nation, in managing renal patients and providers.

Upon reviewing the Draft Interpretive Guidance, we would like to offer additional suggestions / comments to those that were submitted by the Kidney Care Partners (KCP) of which CDC is a member. Specifically, CDC encourages CMS to:

- **V128 - Infection Control/Hepatitis B**

  If currently operating facilities who are dialyzing hepatitis B positive patients using the defined "buffer zone" rather than an isolation room are considered in compliance with the Centers for Disease Control & Prevention's 2001 guidelines and that care is considered safe, it is then counter-intuitive to require currently operating facilities that are not dialyzing hepatitis B positive patients, but who later admit hepatitis B positive patients to build an isolation room. The practice is either safe and within guidelines or it is not. If it is considered safe, CMS should apply the same rule, that is, allowing an approved buffer zone for all facilities operating on October 14, 2008. New facilities or facilities with expansion plans after October 14, 2008 may be required to build isolation rooms.

  Recommendation: Allow dialysis facilities operating prior to October 14, 2008, to continue to use the CDC-defined "buffer zone" in lieu of construction of an isolation room, which may be not only costly but literally impossible in many facilities due to space constraints and building configurations.

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- The language in the draft IG creates a contradiction with the 2001 CDC recommendations incorporated into the Conditions of Coverage by addendum.

  The problem involves facilities which already have a separate isolation room (not just a designated area), but are dialyzing vaccinated HBV negative patients in the same room as an HBV+ patient due to capacity limitations in the facility (i.e., a clinic which is full).

  The 2001 CDC recommendations permit this, as long as the machine used is thoroughly disinfected after the HBV positive patient is dialyzed on it and other infection control practices are observed. The new Conditions would make it mandatory that a dedicated machine be used solely for HBV+ patients, which can be done while still allowing the treatment capacity of that room to be used to its maximum.

  However, the language in the draft IG contradicts the CDC recommendations by stating: "If there are current HBV+ patients on census, the isolation area/room cannot be used for HBV- patients on other shifts or days due to the risk of cross-contamination."

  Recommendation: Revise the language in the IG to make it consistent with the 2001 CDC recommendations. Kept as is, the IG may cause access to care problems in some areas where one or more dialysis facilities which have had isolation rooms prior to October 14, 2008, are virtually full.

- **V 692 - V695 Section 494.140(e): Patient Care Dialysis Technicians:**
  California was the first state in the nation to enact a certification requirement for dialysis Patient Care Technicians (PCTs). Since 1984, the California Department of Health Services (DHS, which is also the State Survey Agency) has administered a state-controlled certification program. Legislation has been enacted more than once to refine and improve the program based on accumulating experience.

  In California, the state has dictated the content (curriculum) of what facility-based training programs must address, so there is considerable similarity among them. Every facility training program must first be submitted to DHS for approval, and a state-issued training provider number assigned. The length of the training program (number of hours) and the split between didactic classroom training and clinical preceptorship have been determined by the state. Having once trained and tested a new PCT, the provider must submit paperwork to the state with a recommendation that the individual be granted a PCT certificate. The certificates are issued, tracked, and renewed by the state, not the dialysis facility.

  In sum, California's longstanding state-managed program for PCT certification meets all the requirements in the new Conditions for Coverage without problem.

  However, the draft Interpretive Guidelines (IG), add a requirement that is not in the regulatory language, and thereby may create a problem. Specifically, V695 says: "states…which have a formal certification program (**including standardized tests**, which reflect the content listed in the regulation, **administered in a proctored environment unrelated to any dialysis facility …**" (emphasis added).

California DHS has never required there to be one standardized test used by all dialysis providers in the state. And because individual dialysis facilities are granted approval as a PCT training program, the tests are therefore by necessity administered at the facility.

If the intent of the language in the IG is that the "standardized test" means that all individuals within one training program (i.e., one facility) take an identical test, then the language needs to be clarified so there can be no possible confusion. As presently written, it can be interpreted as a requirement that there be a uniform test taken by all PCTs within each state.
If that is correct, then it also implies that the three national commercial training programs would have to collaborate with each other and all the dialysis providers in each state to arrive at one uniform test that all organizations were using. If all dialysis providers in a state were required to agree to one standardized test, but the national commercial training programs operating in the same state were exempt, this would be inequitable

In the nearly 25-year history of PCT certification in California, there has never been an independent organization which administered a uniform ("standardized") test in a location separate from the training dialysis facility. The only exception would be BONNET or if a PCT went through an independent or commercially offered training program, which costs the individual a considerable sum, whereas if s/he is trained by the hiring dialysis facility, there is no training cost to the PCT.

Recommendations:

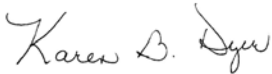
1. If the definition of "standardized test" would include one uniform test used for all trainees within a specific training program, which in turn has been approved by a state certification program, this language needs to be extremely clear. At present it is not.
2. Drop the requirement that the test must be given in "an environment unrelated to any dialysis facility." California's process for certifying PCTs has been working well for over two decades. Retaining this requirement will require a substantial overhaul of the state's current program.
3. If either the requirement for an identical test used statewide, or the giving of the test away from a dialysis facility, or both, is retained in the IG, then more than 18 months will be required to put a new system into place. Major changes in legislation or administrative procedures are currently a lengthy process due to the state's financial challenges and shortages of personnel throughout state agencies. Extend the requirement to at least 24 months if it is retained, and include a provision recognizing the current certification procedure until the new one is put into place.
4. It is our reading of the language in the draft IG that California's estimated 6,000 plus already state-certified PCTs would have to do nothing further if they were certified prior to October 14, 2008. However, to ensure that there can be no confusion, revise the language on page 259 (first full paragraph in the right column) to read: "Patient care dialysis technicians working on October 14, 2008, **but who are not yet certified**, must be certified before April 15, 2010".
5. California has learned from experience that there must be some mechanism to revoke the certification of an unsafe or incompetent PCT in order to protect the public's safety. Provisions for this were incorporated into state legislation. Without it, an unacceptable PCT fired by one California dialysis provider could be hired by another unknowingly (in this era when it is nearly impossible to get a true performance-related job reference). Without any regulatory

requirement that all state and national PCT certification programs have similar provisions, and can share information with one another, dangerous PCTs will simply be able to relocate from one state to another and keep on working. This does not ensure the safety of dialysis patients. We recommend that CMS consider adding a provision that addresses this potential problem.

Conclusion:

CDC 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 Michael Paget, CDC Executive Director at 928-717-1156 if you have questions regarding these comments.

Sincerely,



Karen Dyer
President