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CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-04-36

DATE: **July 8, 2004**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Corrections to Appendix H of the State Operations Manual (SOM) Web Version

Letter Summary

- The Centers for Medicare & Medicaid (CMS) posted a version on its Web site of the SOM that erroneously omits certain parts of Appendix H, Survey Procedures and Interpretive Guidelines for End-Stage Renal Disease Facilities
- CMS is providing the corrections to the above omissions in this memorandum
- Attachments include 1) the omitted guidance for V338, "(11.3.1) – Performance test after each use," and 2) the following V-tags: V482 - V484, and V490, with the accompanying "Guidance to Surveyors."

On May 28, 2004, CMS posted a web version of the SOM. A review of Appendix H of the SOM noted that Appendix H, "Survey Procedures and Interpretive Guidelines for End-Stage Renal Disease Facilities" contained some errors, including omissions of certain V-tags and "Guidance to Surveyors" information.

The attachments to this memorandum contain the omitted V-tags and the "Guidance to Surveyors" for V338. Attachment A contains the omitted guidance for V-338, "(11.3.1) – Performance test after each use." Attachment B contains the following V-tags: V482 - 484, and V490, and the accompanying "Guidance to Surveyors."

Surveyors should continue using the paper version of Appendix H until changes to the Web version of Appendix H are made and SOM change transmittals are published.

Effective Date: This guidance is effective immediately. Nothing in this Memorandum should be construed to require the rescheduling of a recertification review.

Training: The information contained in this announcement should be shared with all surveyors, survey and certification staff, their managers, and the state/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachments:
A – "Guidance to surveyors" for V338
B – V482, V483, V484, V490 and accompanying "Guidance to surveyors"

Attachment A

"Guidance to Surveyors" for V338

AAMI Rationale for the Development and Provision of this Recommended Practice

(11.3.1) Performance test after each use

A measure of solute transport of the hemodialyzers, clearance must be maintained within acceptable limits to ensure that dialysis is adequate to prevent uremic complication. Because of the established clinical importance of lower molecular weight clearance (Lowrie, 1981), the committee decided that the urea clearance should be the recommended criterion for rejecting a dialyzer. The alternative of sodium clearance was included since sodium and urea clearance are similar and the former may be more easily accomplished. The committee agreed that an acceptable tolerance for urea or sodium clearance is +/-10 percent because this amount of variation does not result in a clinically significant change in the BUN of the patient. The committee considered a proposal to include vitamin B_{12} clearance as a criterion for rejection.

The committee recognizes that the clearance of larger molecules may be affected by the type of reuse cycle used, especially the cleaning agent. It was felt beyond the scope of the document to define this effect for all combinations of reuse cycles and dialyzer types.

The committee recognizes that larger molecule clearances, such as that for vitamin B_{12} are largely membrane limited (Collins and Ramirez, 1979; Dorson, et al., 1983) as opposed to small molecule clearances, such as that for urea, which are largely flow-rate limited. Larger molecule clearances will therefore be disproportionately decreased by loss of membrane area or increased membrane resistance due to protein coating of the membrane (Pizziconi, 1985). It was decided not to include vitamin B_{12} clearance as a rejection criterion because of:

a) uncertainty about the significance of protein coating of the membrane in reprocessed hemodialyzers (Gotch, 1985)

b) lack of evidence supporting the clinical relevance of vitamin B_{12} clearance when the change in clearance is within that observed with reprocessed dialyzers; and

c) extensive experience demonstrating the safety of either monitoring urea clearance or using an appropriate indirect test for the urea clearance (Deane and Bemis, 1981).

Although direct clearance measurements fulfill these needs, determining the clearance for each hemodialyzers reprocessed may be impractical; moreover, there are indirect tests that reflect the mass transfer characteristics of the device which may be used in lieu of clearance measurements.

The residual TCV of hollow-fiber hemodialyzers, the most widely used indirect test for clearance, has been found to yield mortality and morbidity results as good or better than those for dialyzers that have not been reprocessed in studies that do not include randomized, controlled trials (Deane & Bemis, 1981).

V482, V483, V484, V490

V482 - §405.2170(b)

Assuring adequate training of nurses in the care of transplant patients.

Survey Procedures and Probes: §405.2170(b)

Interview nursing staff who are responsible for caring for transplant patients. What special monitoring do they do to identify rejection of the transplanted kidney? What teaching do they do for patients regarding signs and symptoms of rejection and side effects of immunosuppressives?

V483 - §405.2170(c)

Assuring that tissue typing and organ procurement services are available either directly or under arrangement.

Survey Procedures: §405.2170(c)

Review transplant recipient records for results of tissue typing and final crossmatches with the donated kidney. The results of this crossmatch should be known before the transplant surgery is begun.

V484 - §405.2170(d)

Assuring that transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon.

Survey Procedures: §405.2170(d)

Review operative reports for documented presence of a qualified transplant surgeon.

V490
§405.2171 Condition: Minimal Service Requirements for a Renal Transplantation Center

Kidney transplantation is furnished directly by a hospital that is participating as a provider of services in the Medicare program and is approved by CMS as a renal transplantation center. The renal transplantation center is under the overall direction of a hospital administrator and medical staff; if operated by an organizational subsidiary, it is under the direction of an administrator and medical staff member (or committee) who are directly responsible to the hospital administrator and medical staff, respectively.