

Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-09-01

**DATE:** October 3, 2008

**TO:** State Survey Agency Directors

**FROM:** Director  
Survey and Certification Group

**SUBJECT:** Advance Copy – End Stage Renal Disease (ESRD) Program Interpretive Guidance  
Version 1.1

**Memorandum Summary**

**ESRD Interpretive Guidance Update:** Attached is an advance copy of the ESRD Interpretive Guidance. This Interpretive Guidance will also be published in an updated Appendix H of the State Operations Manual (SOM).

The attached ESRD Program Interpretive Guidance represents the most recent guidance related to the 42 CFR Part 494 Conditions for Coverage for ESRD facilities. This Interpretive Guidance should replace all previously-released versions.

The Measures Assessment Tool (MAT) is appended to the Interpretive Guidance. The MAT is a reference tool which is mentioned in the Patient assessment Condition, the Plan of care Condition, and the Quality assessment and performance improvement Condition of the regulations and corresponding guidance. The MAT is a guide for current professionally-accepted standards and values for listed clinical elements for each of the Conditions listed above.

- In using the MAT for individual patient assessments and plans of care, patient target levels should be assessed using the MAT. However, each patient should be treated individually and when a specified target is not met, either the plan of care should be adjusted to achieve the community-accepted standard or an explanation should be provided by the interdisciplinary team member of the group. Initially, goals for some patients may need to be different from these targets and then incrementally changed to the standard value as the patient outcomes improve.
- In using the MAT for facility-based quality assessment and performance improvement (QAPI), facilities are expected to use the MAT as a reference guide for community-accepted standards/values associated with clinical outcomes. If the facility has areas of QAPI that do not meet target levels (based upon the MAT), the facility is expected to take action toward improving those outcomes.

**Attachment A** is an advance copy of the interim final ESRD Interpretive Guidance version 1.1. This version has been modified to clarify certain areas and to incorporate feedback from previously-released versions. This guidance will ultimately be published in Appendix H of the State Operations Manual (SOM). Appendix H in the SOM may differ slightly from this advance copy and will be formatted in portrait style, per agency standards.

**Effective Date:** Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

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

If you have additional questions or concerns, please contact Judith Kari through email at [Judith.Kari@cms.hhs.gov](mailto:Judith.Kari@cms.hhs.gov).

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachment

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		<p>responsible for ordering medications and laboratory tests and may or may not use standing orders or an algorithm.</p> <p>The IDT must develop a program for anemia and iron management, and monitor laboratory results, orders for intravenous iron preparations and medication administration records to address values outside the target levels. Laboratory values outside the target levels must be addressed, doses adjusted, and medications administered as ordered.</p> <p>If there is a trend of problems in iron management for an individual patient, the IDT must develop an outcome-oriented plan based on their assessment of the problem and identification of possible barriers to attaining the goals.</p> <p>The requirements for patient assessment of anemia/iron are at V507 and for blood pressure/fluid management at V504.</p>
V550	<p>(5) <i>Vascular access</i>. The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement.</p>	<p>Based on the comprehensive assessment, the facility IDT must develop and implement a plan of care to facilitate each hemodialysis patient receiving and maintaining the most appropriate and optimal vascular access identified for that patient.</p> <p>A well functioning vascular access enables the hemodialysis patient to receive efficient/adequate dialysis treatments, enhancing their quality of life. The determination of which type of vascular access is the most appropriate for the individual patient requires the integration and coordination between the facility IDT, including the patient/designee, and may include referrals for vessel mapping, surgical consult, Doppler studies, etc., enlisting the participation of other entities, such as primary care physicians, surgeons, interventional radiology, and surgical or vascular access centers for access placement and maintenance.</p>

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		<p>To meet this requirement to “achieve and sustain” vascular access, the patient's medical record must include evidence of the evaluation and the basis for the decision for placement of the current vascular access. If the records from the surgeon are not available, the patient’s physician, advanced practice registered nurse or physician assistant is expected to provide this information from communication with the surgeon. If the patient's vascular access is not an arteriovenous fistula, the record should indicate why the patient was determined to not be a candidate for a fistula. If a patient has been dialyzed with a central venous catheter in excess of 90 days, there should be an active plan in process for the placement of a more permanent vascular access or information in the record to demonstrate that a catheter is the most appropriate vascular access for that patient. Some patients may not be candidates for a fistula or graft; each patient has a right to make an informed choice. Patients must be informed and educated about the benefits, risks and hazards of each type of vascular access. Repeated education may be needed. The IDT must involve the patient/designee in the plan for vascular access. The facility social worker should be involved and determine whether psychosocial considerations, such as body image, needle fear or anxiety need to be addressed.</p> <p>Refer to the Measures Assessment Tool (MAT) which lists the current professionally-accepted clinical standards and CMS CPMs for vascular access. The MAT incorporates measures/standards from the Department of Health and Human Services’ Fistula First Breakthrough Initiative. This initiative has joint goals of increasing fistula use in dialysis patients, while also decreasing the inappropriate use of catheters in these patients.</p> <p>Vascular access monitoring is addressed in V551. Requirements for vascular access assessment are at V511.</p>
V551	The patient’s vascular access must be monitored to prevent access failure, including monitoring of	The facility must have an on-going program for vascular access monitoring and surveillance for early detection of failure and to allow

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	arteriovenous grafts and fistulae for symptoms of stenosis.	<p>timely referral of patients for intervention when indications of significant stenosis are present. Patient education should address self-monitoring of the vascular access.</p> <p>“Monitoring” strategies may include physical examination of the vascular access; observance of changes in adequacy or in pressures measured during dialysis; difficulties in cannulation; or in achieving hemostasis. Precipitating events should also be noted, such as hypotension or hypovolemia. Surveillance strategies include device-based methods such as access flow measurements, direct or derived static venous pressure ratios, duplex ultrasound, etc.</p> <p>For patients with grafts and fistulas, the medical record should show evidence of periodic monitoring and surveillance of the vascular access for stenosis and signs of impending failure. The documentation of this may be on the dialysis treatment record, progress notes, or on a separate log. A member of the facility staff must review the vascular access monitoring/surveillance documentation to identify adverse trends and take action if indicated.</p> <p>Refer to the Condition for Infection Control at V147 and V148 and the Condition for QAPI at V633 which also cover monitoring and surveillance of vascular accesses.</p>
V552	(6) <i>Psychosocial status</i> . The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.	To address the patient’s psychosocial needs and “achieve and sustain” an appropriate psychosocial status, each patient's plan of care must reflect the information obtained from the applicable components of the IDT comprehensive assessment under the Condition for Patient assessment at V502-V515, including the psychosocial assessment at V510. The plan of care must include interventions individualized to meet that patient's psychosocial needs and aimed at optimizing the patient’s adjustment to kidney failure and its treatment. The social worker is expected to assist patients in achieving their psychosocial goals. Counseling services to patients and their families should be

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		<p>achieved over consecutive evaluation periods and other factors (e.g., transfers, new admissions, hospitalizations, discharges, recent access surgeries, or acutely ill patients) are not responsible.</p>
V632	(iv) Anemia management.	<p>The intent of QAPI in addressing management of anemia is to maximize the number of patients who achieve the goals for this area. Refer to the Measures Assessment Tool (MAT) which lists the current professionally-accepted clinical practice standards and CMS CPMs in this and other areas.</p> <p>For anemia management, factors which should be tracked monthly for the facility patient population as a whole include laboratory values for hemoglobin and hematocrit. If facility QAPI goals for anemia management are not achieved over consecutive evaluation periods, the facility IDT should conduct a review of transferrin saturation (TSAT) levels, ferritin levels, and other iron indices; erythropoietin stimulating agent (ESA) doses and response to those doses; and any evidence of blood loss, such as repeated episodes of insufficient rinseback of red blood cells or prolonged bleeding post treatment.</p> <p>If the facility uses a standardized anemia management guideline or algorithm, the IDT should evaluate the efficacy of this tool if facility QAPI goals for anemia management are not achieved over consecutive evaluation periods.</p> <p>Home and in-center patient outcomes may need to be reviewed separately by the facility in this area as the factors to be addressed may be different. For example, a home peritoneal patient may be reluctant to inject himself/herself with an ESA, resulting in lower values for this measure in the home population.</p>
V633	(v) Vascular access.	<p>The intent of QAPI in addressing vascular access is first, to improve the rate of use and preservation of fistulas; second, to decrease the inappropriate use of catheters; and finally, to improve the care provided for all types of vascular access.</p>

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		<p>To identify opportunities for improvement and track progress in management of vascular access for its hemodialysis population, the IDT must use a standard that has achieved broadly accepted use in the ESRD community. Refer to the Measures Assessment Tool (MAT), which lists the current professionally-accepted clinical practice standards and CMS CPMs for this and other areas.</p> <p>Fistula survival may be affected by:</p> <ul style="list-style-type: none"> <li>• Cannulation technique problems such as frequent infiltrations related to training issues or individual personnel difficulties;</li> <li>• Episodes of hypotension or hypovolemia; and</li> <li>• Differences in surgical outcomes.</li> </ul> <p>The QAPI program should include efforts to reduce the use of catheters and to reduce the incidence of infection related to catheter use. Requirements related to the care of catheters can be found under the Condition for Infection control, at V146, V147 and V148.</p>
V634	(vi) Medical injuries and medical errors identification.	<p>The intent of QAPI in addressing medical injuries and identification of medical errors is to minimize the number of occurrences and limit the number of patients and staff who are adversely affected by such occurrences.</p> <p>The facility must compile and the QAPI team must review reports and complaints related to any patient or staff injuries, and treatment or medication errors. Part of the QAPI activity is to trend any injuries or errors to identify the prevalence of occurrences, commonalities, and causes.</p> <p>An example of medical injury is a patient fall, which may occur post-dialysis treatment. Information to allow identification of any trends and to detail facility response in terms of risk assessment and precautions in place to prevent future falls should be in evidence.</p>