

**V-TAGS & INTERPRETIVE GUIDANCE REGARDING PATIENT GRIEVANCES**  
**CMS End Stage Renal Disease (ESRD) Program Interim Final Version Interpretive Guidance Version 1.1**

TAG NUMBER	REGULATION	INTERPRETIVE GUIDANCE
V450	§ 494.70 Condition: Patients' rights.	<p>This Condition requires the facility to provide respect, privacy, information, and appropriate services for their patients, as well as an internal grievance mechanism and information about external grievance mechanisms.</p> <p>The survey of this Condition is primarily accomplished by interviews of patients and observations of care delivery and the interactions of staff with patients. Review of medical records and applicable policies for these requirements are indicated if any issues are identified by the observations or interviews.</p> <p>Condition level non-compliance should be considered if there are serious and/or pervasive deficient practices identified that seriously threaten one or more of these rights. Examples of Condition level non-compliance include, but are not limited, to a pattern of:</p> <ul style="list-style-type: none"> <li>•Failure to treat patients with respect and dignity, to provide an opportunity for private communication, or to prevent exposure of private body areas during dialysis causing patients emotional discomfort;</li> <li>•Cognizant patients/designees not being aware of their options for treatment modalities or grievance mechanisms.</li> </ul>
V465	(14) Be informed of the facility's internal grievance process;	<p>Each facility should develop and implement an internal grievance process, as is stated in the Condition for Governance at V765.</p> <p>Facility staff must inform patients about the internal grievance process and the steps to follow for filing an internal grievance. Refer to V765 for the components of the internal grievance process. Use those tags for failure to implement the process. Use this tag for failure to inform patients about the process.</p>
V466	(15) Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency;	<p>The facility must establish a procedure for informing patients about seeking external help to resolve grievances that cannot be resolved internally or if patients are not comfortable using the internal process. The facility staff must inform each patient/designee how to contact the appropriate external entity to file a grievance, including the ESRD Network and the State survey agency.</p>

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		Refer to V470 for the requirement of posting contact information for the Network and State survey agency.
V467	(16) Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of services; and (17) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.	Every patient must be free to file a complaint or grievance within the facility or externally with the ESRD Network or State survey agency. Facility staff should inform patients that they can file a grievance anonymously or through a representative without being afraid that they will be treated differently or denied services. "Reprisal" would include retaliation or revenge and could include perceived punishment, isolation, the intentional infliction of physical pain or emotional distress or involuntary discharge from the facility.
V470	(c) <i>Standard: Posting of rights.</i> The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.	The facility must post all of the rights listed in V452-V469 in a common area of the facility which is routinely available to in-center and home dialysis patients. This posting is meant to augment, not substitute for communicating these rights to each individual patient in a way the patient can understand. Information that must be posted includes the list of patient rights and the mailing addresses and contact information for the applicable ESRD Network and State survey agency, as well as the complaint telephone numbers for each.
V636	(viii) Patient satisfaction and grievances.	The intent of QAPI in this area is to use patient satisfaction surveys and patient grievance investigations as a means to identify opportunities to improve care. The survey should be non-threatening and be conducted in a manner to protect the patient's identity. QAPI discussion of patient satisfaction survey results and patient grievance information should focus on the use of data to inform the care delivery system. If needed changes are identified, there should be evidence of action taken to implement those changes. Facilities must monitor and track patient grievance reports and outcomes as required at V765; use that tag for issues related to responding to individual grievances. An In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS) survey instrument, which is a standardized experience of care assessment tool appropriate for in-center hemodialysis patients, is available for use. Effective 4/1/2008, CMS endorsed the use of this tool to measure in-center hemodialysis patient satisfaction as a CPM. As other measures of patient satisfaction

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		are standardized, refer to the Measures Assessment Tool (MAT) for the current standard of practice.
V750	<b>§ 494.180 Condition: Governance.</b>	<p>This Condition addresses the overall management of the facility. It requires that an identifiable governing body demonstrate responsibility for the operation of the facility, including fiscal management, staff training and coverage, medical staff appointments and coverage, and the QAPI program. This Condition also holds the governing body accountable for establishing an internal grievance process and decreasing the potential for involuntary discharge of patients; for emergency coverage and backup; for electronic data submission; and the relationship of the facility to the ESRD Network. Compliance with this Condition is determined by patient and staff interview, observations, and review of records. Because the governing body is responsible for the total operation of the facility, the responsibility of the governing body must be considered when serious problems in other Conditions are identified.</p> <p>Examples of Condition-level non-compliance include but are not limited to:</p> <ul style="list-style-type: none"> <li>•Major problems with care and safety of patients, patient rights, or operations;</li> <li>•Failure to follow the requirements for involuntary patient discharge;</li> <li>•Failure to respond to Network requests for corrective action plans for problems identified by the Network;</li> <li>•Failure to submit required data electronically; and</li> <li>•Non-compliance with another Condition for Coverage if the governing body has some responsibility for the deficient practices.</li> </ul>
V755	(3) The relationship with the ESRD networks	<p>The ESRD Networks are CMS contractors assigned responsibilities via a Statement of Work to:</p> <ul style="list-style-type: none"> <li>•Collect and analyze data on ESRD patients and their outcomes of care, including the information that allows patients to be enrolled into the ESRD Medicare benefit program</li> <li>•Provide education and oversight to improve the quality of care delivered to dialysis and kidney transplant patients</li> <li>•Support facilities in developing and maintaining an effective QAPI program</li> <li>•Respond to complaints and grievances</li> </ul>

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		<p>At the time of publishing these regulations, there were 18 ESRD Networks, each covering a specified geographic area.</p> <p>A signed agreement between the facility and the applicable Network is required prior to the initial certification survey. The CEO or administrator is responsible to receive and act on correspondence from the ESRD Network and to promptly respond to any request from the applicable Networks.</p> <p>Additional requirements related to Networks are found at V772.</p>
V765	<p><i>(e) Standard: Internal grievance process.</i> The facility’s internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services.</p> <p>The grievance process must include—</p> <ol style="list-style-type: none"> <li>(1) A clearly explained procedure for the submission of grievances.</li> <li>(2) Timeframes for reviewing the grievance.</li> <li>(3) A description of how the patient or the patient’s designated representative will be informed of steps taken to resolve the grievance.</li> </ol>	<p>The facility’s policies and procedures must describe all available grievance procedures to the patient. The facility must inform the patient and/or the patient’s designated representative (also called “designee”) of its internal grievance process. Refer to the requirement at V465 under the Condition for Patients’ rights.</p> <p>Each facility must implement a process to ensure that there will be no reprisal or denial of services for any patient who files an internal grievance and the grievance procedure will be clearly explained to patients. The existence of grievances should not be viewed negatively, as this would be an indication that patients understand the internal grievance process and believe that filing a grievance will not result in reprisal or denial of services. Lack of grievances does not indicate a lack of an internal grievance process.</p> <p>The facility’s grievance process should assure those grievances involving situations or practices that place patients or staff members in immediate danger (e.g. the patient’s grievance brings attention to hazardous environmental conditions) are resolved immediately.</p> <p>The facility’s process must include clearly defined timeframes for a grievance to be acknowledged, investigated, and addressed. Timeframes should be sufficient to conduct an investigation yet ensure that the grievance is addressed in a timely manner. The patient/designee should be informed of the status of the investigation periodically, and when resolution is attained or considered attained by the facility. Each grievance should demonstrate a completed cycle of reviewing the grievance and reporting back to the patient.</p>

Excerpted from the CMS ESRD Surveyor Training Interpretive Guidance (version 1.1) available at [www.cms.gov/Medicare/ProviderEnrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html](http://www.cms.gov/Medicare/ProviderEnrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html)  
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