

CAMC Health System, Inc. Communication				
	3/27/2025	Approved: 3/28/2025	Created by: Mary Beth Mullins marybeth.mullins@vandaliahealth.org	
<b>MED STAFF SBAR</b>		Topic Title: <b>REGULATORY AND BYLAW REQUIREMENTS FOR OBTAINING AND DOCUMENTATION OF INFORMED CONSENT</b>		
<b>S</b>	Situation	<b>INFORMED CONSENT DOCUMENTATION DOES NOT CONFORM WITH CMS, DNV AND MEDICAL STAFF BYLAW REQUIREMENTS RESULTING IN A FINDING AND REQUIRED CORRECTIVE ACTION PLAN.</b>		
<b>B</b>	Background	<p>In a recent survey by DNV and as noted in previous medical record audits, the following issues have been found requiring CAMC to submit a corrective action plan to DNV.</p> <ol style="list-style-type: none"> <li>1. Informed consent was not obtained by the provider performing the procedure.</li> <li>2. Documentation that the physician who performed the procedure had a discussion with the patient prior to the procedure.</li> <li>3. Informed consent was not signed by the physician prior to the start of the procedure.</li> </ol>		
<b>A</b>	Assessment	<p>Seven (7) medical records reviewed by DNV surveyors in March 2025 were found to be non-compliant with regulatory and bylaw requirements for obtaining and documentation of informed consents by surgeons/proceduralist.</p> <p>After initial review of contributing factors to these findings, it is noted that:</p> <ul style="list-style-type: none"> <li>• providers may be unaware of the regulatory and bylaw requirements that the physician or APP performing the treatment or procedure is responsible for obtaining informed consent/refusal from the patient, surrogate, or MPOA and they must have clinical privileges to perform the treatment or procedure.</li> <li>• Providers may be unaware that the informed consent must be signed by the physician prior to the start of the procedure.</li> <li>• APPs or physicians cannot consent patients for procedures that they are not privileged to perform.</li> </ul>		
<b>R</b>	<b>Recommendation / Requirement</b>  <b>Effective Date:</b> <b>Upon receipt of education</b>	<p><b>Medical Staff Leadership Council will address outliers from ongoing audits.</b></p> <ul style="list-style-type: none"> <li>• Outliers from monthly chart audit results (performed by Surgical Services Directors) will be communicated to the Medical Affairs Office for review with Medical Staff Leadership and next steps.</li> <li>• Progressive action steps to ensure providers are educated, understand the deficiency found, barriers removed, assistance available where needed and noted improvements will be reported to MEC.</li> </ul> <p><b>Leadership Council will review and address outliers</b></p> <p>1<sup>st</sup> occurrence – Letter requesting input from provider</p> <p>2<sup>nd</sup> occurrence – Meet with Leadership Council to discuss and identify any barriers or system issues</p> <p>3<sup>rd</sup> occurrence – Focused review of records for provider conducted by Medical Staff Quality Specialists.</p>		