KERN HEALTH SYSTEMS POLICY AND PROCEDURES			
Policy Title	Informed Consent	**Policy #**	2.75-P
Policy Owner	Quality Improvement	**Original Effective Date**	08/1997
Revision Effective Date	10/14/2025	**Approval Date**	11/20/2025
Line of Business	☒ Medi-Cal ☒ Medicare ☐ Corporate		

I. PURPOSE

The purpose of this policy is to ensure that all Kern Health Systems (KHS) contracted providers obtain and document informed consent from Members prior to the initiation of any treatment, procedure, or intervention in accordance with federal, state, and accreditation requirements. This policy establishes the standards by which providers must furnish Members with sufficient, understandable information to make voluntary and informed decisions about their care.

The informed consent process is fundamental to respecting Member autonomy, promoting culturally and linguistically appropriate communication, and supporting ethical and legally compliant medical practice across all lines of business, including Medi-Cal and Dual Eligible Special Needs Plan (DSNP) programs.

II. POLICY

A. KHS requires all contracted providers and delegated entities to obtain and document informed consent prior to initiating any elective procedure, invasive intervention, or course of treatment, except in circumstances where emergency medical care is required to prevent serious harm or deterioration of a Member's condition.
B. The informed consent process must ensure that each Member receives clear, complete, and culturally and linguistically appropriate information about the proposed treatment, including its nature, purpose, benefits, risks, alternatives, and potential outcomes of declining care.
C. Members must have the opportunity to ask questions and make voluntary decisions regarding their treatment without coercion.
D. Informed consent must be obtained by the treating provider or other appropriately licensed practitioner responsible for the Member's care.
E. The signed consent form serves as evidence that the process occurred but does not replace the provider's obligation to ensure understanding.
F. Documentation of the informed consent discussion must be maintained in the Member's medical record prior to treatment.

G. All KHS contracted providers, facilities, and delegated entities are expected to comply with applicable federal and state regulations, including Title 22, Title 28, 42 CFR Part 482, Department of Health Care Services (DHCS) All-Plan Letters (APLs), and National Committee for Quality Assurance (NCQA) standards related to Member rights and communication.
H. KHS reserves the right to audit provider records and monitor compliance with informed consent requirements through routine oversight and quality review activities.

III. DEFINITIONS

TERMS	DEFINITIONS
Consent Form	A written document signed by the Member (or legal representative) confirming that the informed consent discussion has occurred. The form serves as evidence of consent but does not replace the provider's responsibility to ensure comprehension and voluntariness.
Emergency	A medical condition manifesting acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expected to result in serious jeopardy to health, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part. In such cases, consent is implied.
Informed Consent	A voluntary agreement by a Member to proceed with a proposed treatment, procedure, or intervention after receiving sufficient information from the provider regarding the nature and purpose of the treatment, expected benefits, material risks and side effects, alternatives, and the likely consequences of refusing or delaying care. Informed consent reflects both the discussion between the provider and Member, and the Member's understanding and decision.
Interpreter	A qualified individual who facilitates communication between a provider and a Member who has limited English proficiency (LEP) or sensory impairment. The interpreter must meet the requirements outlined in DHCS APL 25-005 and related federal cultural and linguistic access standards.
Member	An individual enrolled in a KHS health plan, including those covered under Medi-Cal, Dual Eligible Special Needs Plan (DSNP), or any other KHS line of business.

IV. PROCEDURES

A. Obtaining Informed Consent

1. The treating provider, or another appropriately licensed practitioner responsible for the Member's care, must conduct the informed consent discussion before the initiation of any elective or invasive procedure, treatment, or intervention.
2. The informed consent discussion must include:
    a. An explanation of the nature, purpose, and expected benefits of the proposed

procedure or treatment.
    b. A description of material risks, side effects, and possible complications.
    c. Available alternatives, including the option of no treatment and the potential consequences of refusal or delay.
    d. An opportunity for the Member or representative to ask questions and receive understandable answers.
    e. Identification of the provider who will perform the procedure or direct the treatment.
    f. Information regarding whether the procedure is established or new, when applicable.
    g. Notification that the Member may withdraw consent at any time prior to the procedure without affecting access to future care.
3. If two or more specific procedures are planned concurrently and this is known in advance, each procedure must be described, and consent must be obtained for each.
4. Consent must be obtained in the Member's preferred language, using a qualified interpreter or language assistance service if the Member has limited English proficiency or a communication barrier, in accordance with DHCS APL 25-005 and federal civil rights laws.
5. Informed consent must be obtained voluntarily and without coercion.

B. Documentation of Informed Consent

1. The informed consent discussion and the Member's decision must be documented in the medical record before the treatment or procedure begins.
2. A signed consent form serves as evidence that the informed consent process occurred; however, the form itself is not a substitute for the discussion.
3. The consent form must include:
    a. The name of the procedure or treatment.
    b. The name and credentials of the provider performing or supervising the procedure.
    c. Date and time of the consent.
    d. Member or legal representative's signature (and relationship, if applicable).
    e. Provider signature verifying that the informed consent process was completed.
    f. Interpreter name and signature, if applicable.
4. Consent forms must be maintained in the Member's medical record and made available to KHS upon request for auditing, quality review, or regulatory compliance verification.

C. Medical Emergencies

1. When immediate treatment is necessary to prevent serious harm, deterioration, or death, and the Member is unable to provide consent, care may proceed under the doctrine of implied consent.
2. If possible, reasonable attempts should be made to obtain the consent or concurrence of the nearest available relative or legal representative.
3. If treatment must proceed without prior consent, the provider must document in the medical record:
    a. The nature of the emergency;
    b. The reason obtaining consent was not feasible; and
    c. Any efforts made to contact a representative.

D. Verification of Consent

1. Verification that informed consent has been properly obtained and documented must occur before any elective or invasive procedure.
2. If the Member expresses confusion, hesitation, or uncertainty at the time of signature, the verifying staff must notify the treating provider immediately for clarification before proceeding.
3. Obtaining informed consent is the responsibility of the treating provider; only verification of signatures may be delegated to trained clinical or administrative staff.

E. Oversight and Monitoring

1. KHS will monitor compliance with informed consent requirements through routine chart audits, delegate oversight reviews, and quality of care investigations.
2. Non-compliance identified through audits or Member complaints will result in corrective action.

V. ATTACHMENTS

Attachment A:	N/A

VI. REFERENCES

Reference Type	Specific Reference
Regulatory	Title 22 CCR § 72528: Definition and elements of informed consent, including interpreter use and documentation requirements.
Regulatory	Title 28 CCR § 1300.67.04: Language assistance and interpreter service requirements for health care service plans.
Regulatory	42 CFR § 482.51(b)(2) – Requirement for a properly executed informed consent form before surgical procedures, except in emergencies.
All Plan Letter(s) (APL)	DHCS All Plan Letter 25-005 Standards for Determining Threshold Languages, Nondiscrimination Requirements, Language Assistance Services, and Alternative Formats.

VII. REVISION HISTORY

Action	Date	Brief Description of Updates	Author
Revised	10/14/2025	Ownership of the policy was transitioned from PNM to QI (formerly 4.08-P). The policy was revised and migrated to the updated template format, which now includes a reference to APL 25-005	QI Director
Revised	12/2018	Policy reviewed as part of the Compliance Department internal review. No changes to policy. Signatures and dates revised to be	Provider Relations Director

		current.	
Revised	11/2014	Routine review requested by Compliance Department.	Provider Relations Director
Revised	06/2010	Reviewed by the Director of Claims and Provider Relations, no substantial changes required.	Provider Relations Director
Revised	11/2001	Revised to incorporate suggestions made by DHS during Medical Review YE 08/31/00. Additional clarifying information added to Obtaining Informed Consent.	Provider Relations Director
Effective	08/1997	Original effective date.	Provider Relations Director

VIII. APPROVALS

Committees | Board (if applicable)	**Date Reviewed**	**Date Approved**
Choose an item.		
Choose an item.		