KAISER PERMANENTE®

12. Quality & Patient Safety Programs/Informed Consent and Who May Consent

The KP Quality Program includes many aspects of clinical and service quality, patient safety, behavioral health, accreditation and licensing, and other elements. The KP quality improvement program assures that quality improvement is an ongoing priority for the organization. Information about our quality program is available in the "Quality Program at KP" document, including:

- Awards and recognition for our quality program
- Programs and systems within KP that promote quality improvement
- Quality improvement structure
- Areas targeted by our quality goals

To obtain a copy of this document, call Member Services at **1-800-464-4000** or **1-800-777-1370** (TTY). Alternatively, you can view and print the document by visiting kp.org/quality. Click on "measuring the quality and safety of health care at Kaiser Permanente" then click on "Hawaii's Quality Program at KP"

Additionally, we send an annual Quality Summary to provide you with the best quality support and communication. Topics covered in the summary include:

- Utilization Management
- Pharmaceutical Management
- Member Rights and Responsibilities
- Cultural Competency Plan
- Quality Program and quality-related efforts
- Clinical Practice Guidelines
- Medical Record Documentation Standards

Should you need additional information or have any questions regarding the policies or key processes described in the Quality Summary, please contact our Quality Management Department at (808) 432-3610.

Patient safety is a central component of KP's care delivery model. We believe our distinctive structure as a fully integrated health care delivery system provides us unique opportunities to design and implement effective, comprehensive safety strategies to protect our Members. Providers play a key role in the implementation and oversight of patient safety efforts.

If you would like independent information about KP's health care quality and safety, the following external organizations offer information online:

The National Committee for Quality Assurance (NCQA) works with consumers, purchasers of health care benefits, state regulators, and health plans to develop standards that evaluate health plan quality. KP is responsible to manage, measure, and assess patient care in order to achieve NCQA accreditation, which includes ensuring that all Members are

entitled to the same high level of care regardless of the site or provider of care. The focus of NCQA is on care provided in the ambulatory setting.

KP received accreditation by NCQA, and we periodically undergo re-accreditation. KP Hawaii Region provides the appropriate information related to quality and utilization upon request, so that KP may meet NCQA standards and requirements and maintain successful NCQA accreditation. You can review the report card for KFHP Hawaii at www.ncqa.org.

The Leapfrog Group is a group of Fortune 500 companies, including nonprofit and large private companies, that encourages purchasers and consumers to use their health care buying power as leverage to create quality and safety standards in the U.S. The group gathers information about aspects of medical care and patient safety relevant to urban hospitals via an annual Leapfrog Survey. All KP hospitals in Hawaii, as well as most contracted hospitals, participated in the most recent survey. To review survey results, visit www.leapfroggroup.org/cp.

The Joint Commission is a health care accreditation organization recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards. To earn and maintain its accreditations, KP must undergo an on-site survey by The Joint Commission survey team at least every three years. KP has adopted a set of The Joint Commission compliance expectations for contracted practitioners coming into our facilities. Learn more at www.jointcommission.org.

12.1. QUALITY ASSURANCE AND IMPROVEMENT (QA & I) PROGRAM OVERVIEW

KP's Quality Assurance and Improvement Program uses a multidisciplinary and integrated approach that focuses on opportunities for improving operational processes, health outcomes, and Member and Provider satisfaction.

The quality of care Members receive is monitored by KP's oversight of Providers. You may be monitored for various indicators and required to participate in some KP processes. For example, we monitor and track the following:

- Patient access to care
- Patient complaint and satisfaction survey data for administrative and quality of care issues.
- Compliance with KP policies and procedures.
- UM statistics.

- Quality of care indicators and provision of performance data as necessary for KP to comply with requirements of NCQA, Medicare, The Joint Commission, and other regulatory and accreditation bodies.
- Performance standards in accordance with your Agreement.
- Credentialing and re-credentialing of Providers.

In any of the above situations, when KP reasonably determines that the Provider's performance may adversely affect the care provided to Members, KP may take corrective actions in accordance with your Agreement. As a Provider, you are expected to investigate and respond in a timely manner to all quality issues and work with KP to resolve any quality and accessibility issues related to services for Members. Each Provider is expected to remedy, as soon as reasonably possible, any condition related to patient care involving a Member that has been determined by KP or any governmental or accrediting agencies to be unsatisfactory.

12.2. PROVIDER CREDENTIALING AND RE-CREDENTIALING

As an important part of KP's Quality Management Program, all credentialing and re-credentialing activities are structured to assure applicable Providers are qualified to meet KP, NCQA, TJC, AAAHC and other regulatory standards for the delivery of quality health care and service to Members.

The credentialing and re-credentialing policies and procedures approved by KP are intended to meet or exceed the managed care organization standards outlined by the NCQA, TJC and the AAAHC.

KP has developed and implemented credentialing and re-credentialing policies and procedures for Providers. Practitioners include, but are not limited to, MDs, DOs, oral surgeons, podiatrists, chiropractors, advanced practice nurses, behavioral health practitioners, acupuncturists, and optometrists. Organizational Providers (OPs) include, but are not limited to, hospitals, SNFs, home health agencies, hospice agencies, dialysis centers, congregate living facilities, behavioral health facilities, ambulatory surgical centers, clinical laboratories, comprehensive outpatient rehabilitation facilities, portable x-ray suppliers, federally qualified health centers, and community-based adult services centers. Services to Members may be provided only when the Provider meets KP's applicable credentialing standards and has been approved by the appropriate Credentials and Privileges Committee.

Providers must also submit, upon renewal, ongoing evidence of current licensure, insurance, and accreditation/certification as applicable, along with other credentialing documents subject to expiration.

12.3. PRACTITIONERS

KP requires that all practitioners within the scope of KP's credentialing program be credentialed prior to treating Members and must maintain credentialing at all times. Re-credentialing will occur at least every 24 months in a hospital setting, at least every 36 months in an ambulatory (medical office) setting and may occur more frequently.

Requirements for initial credentialing and re-credentialing for practitioners include, but are not limited to:

- Complete, current, and accurate credentialing/re-credentialing application.
- Current licensures, certifications, and/or permits as required by law.
- Evidence of appropriate education, clinical training, and current competence in practicing specialty.
- No history of state or federal sanctions/limitations/exclusions.
- Evidence of current insurance, in amounts as required by KP.
- Complete clinical work history.
- Complete malpractice claim history.
- Evidence practitioner is not currently opted out of Medicare.
- No significant events as identified through KP performance data (at re-credentialing only).

KP adheres to the NCQA and TJC standards for credentialing and re-credentialing of hospitalists. Hospitalists who provide services exclusively in the inpatient setting and provide care for Members only as a result of Members being directed to the hospital setting are deemed appropriately credentialed and privileged in accordance with state, federal, regulatory, and accreditation standards when credentialed and privileged by the hospital in which they treat Members.

The appropriate KP Regional Credentials and Privileges Committee will communicate credentialing determinations in writing to practitioners. In the event the committee decides to deny initial credentialing, terminate existing credentialing, or make any other adverse decision regarding the practitioner's ability to treat Members, appeal rights will be granted in accordance with applicable legal requirements and KP policies and procedures. The practitioner will be notified of those rights when notified of the committee's determination.

All information obtained by KP during the practitioner credentialing and re-credentialing process is considered confidential as required by law. For additional information regarding credentialing and re-credentialing requirements and policies, please contact Quality and Operations Support.

12.3.1. Practitioner Office Site Quality

KP adheres to the NCQA standards for practitioner office site quality. Practitioner office site visits will be conducted when Member complaints exceed established thresholds for accessibility, physical appearance, adequacy of waiting room, and adequacy of examining room space. Actions will be instituted to improve offices that do not meet established thresholds. Effectiveness of improvement actions will be evaluated at least every six months until all deficiencies are corrected.

KP will complete a site visit utilizing the Practitioner Office Site Review tool within 60 days of the threshold being met, or sooner if severity warrants. Threshold criteria may be waived altogether when issues of patient safety are at risk.

KP OFFICE SITE REVIEW STANDARDS

Category	Description
Physical Accessibility	• Handicap parking is clearly designated • Facility is handicap accessible externally and internally • All exits are clearly labeled and free of obstruction
Appearance and Cleanliness	• Interior surroundings are clean; carpets and tiles are secure • Public areas are free from food, beverages, and food containers • Public areas are free from personnel belongings • Office hours are clearly posted
Adequacy of Waiting Area	• Waiting room is well lit • Waiting room has adequate patient seating (i.e., seating accommodates 3-4 patients per practitioner per hour) • Furniture is clean, secure, and free of rips and tears • Patient registration area ensures confidentiality
Adequacy of Exam Room	• Exam room is well lit and has adequate space for patient scheduling (i.e., at least two available exam rooms for each provider; each exam room can accommodate 3-4 patients per hour) • Exam room ensures patient privacy and confidentiality • Trash containers have appropriate liners (red for regulated waste) • Sharp containers are present and not overfilled • Exam room, table, and equipment are clean, secure, and free of rips and tears

12.3.2. Practitioner Rights

12.3.2.1. Practitioner Right to Correct Erroneous or Discrepant Information

The credentials staff will notify the practitioner, orally or in writing, of information received that varies substantially from the information provided during the credentialing process. The

practitioner must correct the erroneous or discrepant information in the time-frame set forth by the credentialing staff. The notice will state to whom, and in what format, to submit corrections.

12.3.2.2. Practitioner Rights to Review Information

Upon written request, and to the extent allowed by law, a practitioner may review information submitted in support of their credentialing application and verifications obtained by KP that are a matter of public record. The credentials file must be reviewed in the presence of KP credentialing staff. Upon receipt of a written request, an appointment time will be established during which practitioners may review the file.

12.3.2.3. Practitioner Right to be Informed of the Status of the Credentialing Application

The credentialing staff will inform the practitioner of their credentialing or re-credentialing application status upon request. Requests and responses may be written or oral. Information regarding status is limited to:

- Information specific to the practitioner's own credentials file.
- Current credentialing status.
- Estimated committee review date, if applicable and available.
- Outstanding information needed to complete the credentials file.

12.3.2.4. Practitioner Right to Credentialing and Privileging Policies

Upon written request, a practitioner may receive a complete and current copy of KFHP Hawaii Region Credentialing and Privileging Policies and Procedures. For those hospitals where the practitioner maintains active privileges, the practitioner may also request and receive complete and current copies of Professional Staff Bylaws and the Rules and Regulations of the Professional Staff of Kaiser Foundation Hospital.

12.3.3. Organizational Providers (OPs)

KP requires that all OPs within the scope of its credentialing program be credentialed prior to treating Members and maintain credentialing at all times. Re-credentialing will occur at least every 36 months and may occur more frequently. Requirements for both initial and re-credentialing for OPs include, but are not limited to:

- Completed credentialing/re-credentialing application.
- Hawaii license in good standing, as applicable.
- Medicare and Medicaid certification, if applicable.
- Accreditation by a KP-recognized accreditation body and/or site visit by KP.

- Evidence of current professional and general liability insurance, in amounts as required by KP.
- Other criteria specific to organizational specialty.

12.3.3.1. Corrective Action Plan or Increased Monitoring Status for OPs

Credentialing and re-credentialing determinations are made by the KP Regional Credentialing and Privileges Committee. At the time of initial credentialing, newly operational OPs may be required to undergo monitoring.

Newly operational OPs are typically monitored for at least six months. These Providers may be required to furnish monthly reports of applicable quality and/or clinical indicators for a minimum of the first three months of the initial credentialing period. This monitoring may include on-site visits.

If deficiencies are identified through KP physicians, staff, or Members, the OP may be placed on a corrective action plan (CAP) or performance improvement plan (PIP) related to those deficiencies.

The OP will be notified in writing if deficiencies are identified. The notice will include the reason(s) for which the CAP or PIP is required, the monitoring time frames, and any other specific requirements that may apply regarding the monitoring process. Within two weeks of such notice, the OP must create, for KP review, a time-phased plan that addresses the reason for the deficiency and their proposed actions toward correcting the deficiency. KP will review the draft CAP or PIP and determine whether it adequately addresses identified issues. If the plan is not acceptable, KP representatives will work with the OP to make necessary revisions to the plan. OPs subject to a CAP or PIP will be monitored for six months or longer.

For additional information regarding credentialing and re-credentialing requirements and policies, please contact Provider Relations.

12.4. MONITORING QUALITY

12.4.1. Compliance with Legal, Regulatory, and Accrediting Body Standards

KP expects all applicable Providers to be in compliance with all legal, regulatory, and accrediting requirements, to have and maintain accreditation as appropriate, to maintain a current certificate of insurance, and to maintain current licensure. If any entity takes any adverse action with regard to licensure or accreditation, this must be reported to KP's Credentialing Department, along with a copy of the report and the action plan to resolve the identified issue or concern, within 90 days of the receipt of the report.

12.4.2. Infection Control

KP requests the cooperation of Providers in monitoring their own practice for reporting of communicable diseases, preventing transmission of communicable diseases, and efforts aimed at prevention of hospital associated infection (HAI) including, but not limited to multi-drug resistant organisms such as MRSA, VRE, and C.difficile; postoperative surgical site infections; central line associated bloodstream infections; and catheter-associated urinary tract infection. When a potential infection is identified, notify the local Infection Preventionist to determine if it meets National Healthcare Safety Network's (NHSN) definition. Confirmed HAI should be tracked and rates determined and entered into NHSN for trending. When a trend is identified by the affiliated practitioner or Provider, this should be shared with Regional Infection Control Committee (RICC) and a collaborative approach should be undertaken in order to improve practices related to infection prevention and control. All HAI summary reports and analysis should be submitted for review on an ongoing basis to the KP RICC and Quality Management (QM) departments. Results of this review should then be shared with the affiliated practitioner or Provider. The IP and QM Departments will request certain actions and interventions be taken to maximize patient safety, as appropriate.

12.4.3. Practitioner Quality Assurance and Improvement Programs

KP ensures that mechanisms are in place to continually assess and improve the quality of care provided to Members to promote their health and safety through a comprehensive and effective program for practitioner peer review and evaluation of practitioner performance. This policy supports a process to conduct a peer review investigation of a health care practitioner's performance or conduct that has adversely affected or could affect the health or welfare of a Member.

12.5. QUALITY OVERSIGHT

The peer review process is a mechanism to identify and evaluate potential quality of care concerns or trends to determine whether standards of care are met and to identify opportunities for improvement. The process is used to monitor and facilitate improvement at the individual practitioner and system levels to assure safe and effective care. Peer review provides a fair, impartial, and standardized method for review whereby appropriate actions can be implemented and evaluated. The peer review process includes the following:

- Practitioner performance review and oversight – Practitioner profiling for individual re-credentialing as well as oversight and evaluation of the quality of care provided by practitioners in a department.

- Practitioner peer and system review – Quality of care concern.
- Focused practitioner review and practice improvement plan – Provides an objective evaluation of all or part of a practitioner's practice when issues are identified around the performance of that practitioner.

The primary use of the information generated from these activities is for peer review and quality assurance purposes. Such information is subject to protection from discovery under applicable state and federal law. All such information and documentation will be labeled "Confidential and Privileged," and stored in a separate, secured, and appropriately marked manner. No copies of peer review documents will be disclosed to third parties unless consistent with applicable KP policy and/or upon the advice of legal counsel. Information, records, and documentation of completed peer review activity (along with other information on practitioner performance) shall be stored in the affected individual practitioner's confidential quality file.

Individuals involved in the peer review process shall be subject to the policies, principles, and procedures governing the confidentiality of peer review and quality assurance information.

When a peer review investigation results in any adverse action reducing, restricting, suspending, revoking, or denying the current or requested authorization to provide health care services to Members based upon professional competence or professional conduct, such adverse actions will be reported by the designated leaders of the entities responsible to make the required report (e.g., the chief of staff or hospital administrator) to the National Practitioner Data Bank, and/or regulatory agencies, as appropriate.

12.5.1. Quality Review

Criteria that trigger a referral for Quality Review are identified through multiple mechanisms. Some sources include, but are not limited to:

- Allegations of professional negligence (formal or informal)
- Member complaints/grievances related to quality of care
- Risk management (significant events, potentially compensable events)
- Medical legal referrals
- Inter- or intra-departmental or facility referrals
- Issues identified by another practitioner
- UM
- Member complaints to external organizations

Cases referred for quality review are screened for issues related to the professional competence of a practitioner, which may be subject to peer review. These may include, but are not limited to:

- Concerns regarding the possibility of any breach of professional judgment or conduct towards patients.
- Concerns regarding the possibility of failure to appropriately diagnose or treat a Member/patient.
- Adverse patterns of care identified through aggregate review of performance measures (e.g., automatic triggers).

To assist in review, the reviewer will use appropriate information from sources that include, but are not limited to:

- Nationally recognized practice standards, preferably evidence based.
- Professional practice requirements.
- KP and other CPG.
- KP policies and procedures, including policies related to patient safety.
- Regulatory and accreditation requirements.
- Community standard of care.

12.5.2. OPs' Quality Assurance & Improvement Programs (QA & I)

Each OP must maintain, at all times, a QA & I program, described in a written plan approved by its governing body that meets all applicable state and federal licensure, accreditation, and certification requirements. When quality problems are identified, the OP must show evidence of corrective action, ongoing monitoring, revisions of policies and procedures, and changes in the provision of services. Each OP is expected to provide KP with its QA & I plan and a copy of all updates and revisions.

12.5.3. Sentinel Events/Reportable Occurrences for OPs (Applicable to Acute Hospitals, Chronic Dialysis Centers, Ambulatory Surgery Centers, Psychiatric Hospitals, and SNFs)

All Providers must report sentinel events and reportable occurrences as defined below. OPs must report events and occurrences at its facilities covered by its Agreement.

12.5.3.1. Definitions: Sentinel Events and Reportable Occurrences

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof, to a Member. The phrase "the risk of" includes any process variation for which an occurrence (as in "close call" or "near miss") or recurrence would carry a significant chance of a serious adverse outcome. Sentinel events are inclusive of all the Joint Commission's sentinel events and National Quality Forum's serious reportable events.

Reportable occurrences include, but are not limited to, all of the following:

- Patient fall resulting in serious injury, which require subsequent medical intervention.
- A cluster of nosocomial infections (cohort of three or more).
- Outbreaks of infectious disease reportable to the County Health Department.
- Official notice concerning revocation (requested or actual) of Medicare/Medicaid Certification or suspension of Medicare/Medicaid admissions.

12.5.3.2. Notification Timeframes

Practitioners and OPs will report sentinel events and reportable occurrences within 24 hours of becoming aware of the event or occurrence. The report will be made to Kaiser Permanente as follows:

Provider	KP Contact	Timeframe
Practitioner	Referral Coordinator	Within 24 hours
Acute Hospital	Care Coordinator	Within 24 hours
Chronic Dialysis Center	Care Coordinator	Within 24 hours
Ambulatory Surgery Center	Care Coordinator	Within 24 hours
Psychiatric Hospital	Care Coordinator	Within 24 hours
SNF	Care Coordinator	Within 24 hours

12.5.4. Sentinel Event/Reportable Occurrences - Home Health and Hospice Agency Providers

12.5.4.1. Report Within 24 Hours

Immediately upon discovery, verbally report the following sentinel/significant events to the referring KP home health agency, hospice agency, or facility. The verbal report must be followed by a written notification sent within 24 hours or by the end of the next business day by certified mail, return receipt.

- The event is not related to the natural course of the patient's illness or underlying conditions and results in an unanticipated death or major permanent loss of function (sensory, motor, physiologic), or intellectual impairment not present at the initiation of the care episode that requires continued treatment or lifestyle change.
- The event is a significant adverse deviation from the usual process(es) for providing health care service or managing health care operations.
- The event or related circumstances has the potential for significant adverse media (press) involvement.

- Any process variation from which a reoccurrence would carry a significant chance of a serious adverse outcome.
- Significant drug reactions.
- Medication errors resulting in actual or potential harm to the patient.
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.
- Member/patient is either a perpetrator or victim of a crime or reportable abuse while under home health or hospice care.
- Loss of license, certification, or accreditation status.
- Release of any toxic or hazardous substance that requires reporting to a local, state, or federal agency.

12.5.4.2. Report Within 72 Hours

You must report the following events involving Members that may impact the quality of care and/or have the potential for a negative outcome to the referring KP home health agency, hospice agency, or facility during KP business hours. Such reports should be made within 72 hours of the occurrence. These include but are not limited to the categories below.

- Reportable, communicable diseases, outbreaks of scabies or lice, and breaks in infection control practices.
- Falls resulting in injury.
- Re-admission to a hospital.
- Medication errors (wrong patient, wrong drug, wrong dose, wrong route, wrong time, wrong day, or an extra dose, or an omission of an ordered drug).
- Disciplinary action taken against a practitioner caring for a KP Member that requires a report to the applicable state board or the National Practitioner Data Bank.
- Noncompliance with regulatory and/or accreditation standards requiring CAP.

12.5.5. DNBEs/Reportable Occurrences for Providers

As part of its required participation in KP's QI Program and in addition to the claims submission requirements in this Provider Manual, and to the extent permitted by law, the Provider must promptly notify KP and, upon request, provide information about any DNBE (as defined in Section 5.18.6) that occurs at its location or locations covered by its Agreement in connection with services provided to a Member. Notices and information provided pursuant to this section shall not be deemed admissions of liability for acts or omissions, waiver of rights or remedies in litigation, or a waiver of evidentiary protections, privileges or objections in litigation or otherwise.

Notices and information related to DNBEs should be sent to:

3288 Moanalua Rd, Honolulu, HI 96819, Attn: Risk Management 808 432-7826

At a minimum, Providers should include the following elements in any DNBE notice sent to KP:

- KP medical record number
- Date(s) of service
- Place of service
- Referral number or emergency claim number
- General category description of DNBE(s) experienced by the Member

12.6. QA & I REPORTING REQUIREMENTS FOR HOME HEALTH PROVIDERS

Quality monitoring activities will be conducted at each individual home health agency.

12.6.1. Annual Reporting

On an annual basis, Providers of home health and hospice services, and licensed/certified Providers who manage Members' plan of care on referral, must submit to KP:

- Copies of current license and insurance.
- Reports of any accreditation and/or regulatory site visits occurring within the last 12 calendar months.
- Results of most recent patient satisfaction survey.
- Action plans for all active citations, conditions, deficiencies and/or recommendations.

12.6.2. Site Visits and/or Chart Review

A site visit and/or chart review may be requested by KP at any time to monitor quality and compliance with regulations. When on-site reviews are requested by the referring KP home health agency, your agency will make the following available:

-
- Documentation for Member complaints and follow-up.
- Member medical records.
- Other relevant quality and compliance data.

12.7. QA & I REPORTING REQUIREMENTS FOR SNFs

The KP QA & I plan includes quality indicators that are collected routinely. KP will collect some of these indicators, while others will be collected by the SNF Providers. These indicators will be objective, measurable, and based on current knowledge and clinical experience. They reflect structures, processes, or outcomes of care. KP promotes an outcome-oriented quality assessment and improvement system and will coordinate with SNF Providers to develop reportable outcomes.

12.7.1. Quarterly Reporting

Quarterly SNF quality assessment indicator trend reports will include, at a minimum, the following:

- Patient falls
- Pressure sores
- Medication errors
- Any CMS deficiency with a CAP or Hawaii Department of Public Health (HDPH) deficiency or citation with a CAP
- Reports to HDPH of unusual occurrences involving KP Members

12.7.2. Medical Record Documentation

KP procedures regarding medical record documentation for SNF Providers are detailed below. Any contradiction with a SNF Provider's own policies and procedures should be declared by the SNF, so that steps can be taken to satisfy both the SNF Provider and KP.

All patient record entries shall be written (preferably printed), made in a timely manner, dated, signed, and authenticated with professional designations by individuals making record entries.

Medical record documentation shall include at least the following:

- Member information, including emergency contact and valid telephone number
- Diagnoses and clinical impressions
- Plan of care
- Applicable history and physical examination
- Immunization and screening status when relevant
- Allergic and adverse drug reactions when relevant
- Documentation of nursing care, treatments, frequency, and duration of therapies for Member, procedures, tests, and results

- Information/communication to and from other Providers
- Referrals or transfers to other Providers
- Recommendations and instructions to patients and family members
- Date, purpose, and updated information for each visit
- Advance directive

12.8. QA & I REPORTING REQUIREMENTS FOR CHRONIC DIALYSIS PROVIDERS

12.8.1. Reporting Requirements

Providers who deliver chronic dialysis services are expected to send, on a monthly basis via hard copy or electronic file, a Patient Activity Report form containing the following information for patients who are:

- Dialyzing for the first time
- Transferring into the contracted dialysis center from another dialysis center
- Returning after transplant
- Recovering renal function
- Receiving a transplant
- Transferring to another dialysis center
- Deceased
- Changing treatment modality

Providers must also submit the above information for patients who were on dialysis prior to joining Kaiser Permanente.

12.8.2. Vascular Access Monitoring (VAM)

Pursuant to your Agreement, the chronic dialysis Provider is responsible for monitoring the blood flow in all grafts and fistulas of Members at the levels prescribed by the assigned nephrologist. Your Agreement will specify whether you are obligated to perform VAM services either using the Transonic Flow QC System® or the Fresenius K+ machine, or a combination of the two modalities.

Desirable levels for flow rates are >400 ml/min for fistulas and >600 ml/min for grafts. When blood flow rates fall below the desirable targets, notify the nephrologist and/or KP renal case manager so that an appropriate intervention to prevent the access from clotting can be planned.

12.8.2.1. Surveillance Procedure for an Established Access

Obtain an access monitoring order from the nephrologist. The Provider performs monthly access flow measurements once prescribed blood flow and optimal needle size are achieved at the intervals described below:

Grafts

- ✓ VAM services testing frequency
  - Transonic Flow QC System® — monthly*
  - Fresenius K+ machine — monthly
  - As otherwise prescribed by a nephrologist
- ✓ Graft flow > 600 ml/min — continue to test at monthly intervals and trend results
- ✓ Graft flow rate 500 to 600 ml/min — review test results and trend. If trending indicates that flows are decreasing, refer the patient for angiogram and evaluation.
- ✓ If trends remain constant and are not decreasing, repeat the test at the scheduled time.
- ✓ Graft flow rate < 500 ml/min — refer for angiogram and evaluation.

Fistula

- ✓ VAM services testing frequency
  - Transonic Flow QC System® — every other month*
  - Fresenius K+ machine — monthly
  - As otherwise prescribed by a nephrologist
- ✓ Fistula flow rate >400 ml/min — continue to test at monthly intervals and trend results.
- ✓ Fistula flow rate 300 to 400 ml/min — review test results and trend. If trending indicates that flows are decreasing, refer the patient for angiogram and evaluation.
- ✓ If trends remain constant, use slower blood flows and perform a clinical evaluation to verify the adequacy of the treatments at a lower pump speed.
- ✓ Fistula flow rate < 300 ml/min — refer for angiogram and evaluation.

*In the case of the Transonic Flow QC System®, recirculation should be 0 percent when testing the vascular access.

The Provider performs access flow measurements at frequencies other than those outlined above under the following conditions:

- ✓ After a surgical procedure to create a new vascular access.
- ✓ Within a week following an access intervention, including but not limited to a fistulogram, declotting, angioplasty, or a surgical revision.
- ✓ As ordered by a nephrologist or KP renal case manager.

12.8.3. Performance Target Goals/Clinical Indicators

12.8.3.1. Chronic Dialysis Patients

The following performance targets are the clinical indicators for KP Members on hemodialysis and peritoneal dialysis and shall be reported by the Provider to KP within 15 calendar days from the end of the calendar quarter. The submission of the indicators shall be in a format acceptable to KP via an electronic file or other method designated by KP. Each contracted dialysis company must report the indicators on a quarterly basis for each of its participating dialysis centers in their Agreement:

REGIONAL RENAL ESRD QUALITY IMPROVEMENT PROGRAM DIALYSIS FACILITY SPECIFIC TARGETS			
MODALITY	**MEASUREMENT**	**DESCRIPTION**	**TARGET**
In-Center HD	Vascular Access	Percentage of patients in a given reporting period with a central venous catheter in place. If fistula or graft in use, but CVC in place, CVC will count.	Monitoring only with plan to develop target by January 2014.
	Adequacy of Dialysis	Percent of all patients at clinic whose last valid Kt/V of the month ≥ 1.2	≥ 95%
	Positive Blood Cultures	Report all positive blood cultures according to NHSN guidelines.	100% of known positive blood cultures are reported.
	Patients with Flu Vaccination	Includes vaccines administered at the unit and if patient reports that they received a vaccine elsewhere September through March. Patients who are contraindicated, refused or who are allergic are counted as "No." Data not included on reports April through August.	N/A (Data provided if available)
	Patients with Pneumo Vaccination	Includes patients who received one dose within the last five years or two doses, five years apart within a lifetime. Either administrated at the unit or reported by the patient. Patients who are contraindicated, refused or who are allergic are counted as "No."	N/A (Data provided if available)

REGIONAL RENAL ESRD QUALITY IMPROVEMENT PROGRAM DIALYSIS FACILITY SPECIFIC TARGETS			
MODALITY	**MEASUREMENT**	**DESCRIPTION**	**TARGET**
PD	Adequacy of Dialysis	Percent of all patients at clinic whose last valid Kt/V of the month ≥ 1.7.	≥ 85%
	Peritonitis Rates	12-month rolling peritonitis rate.	Peritonitis not more frequent than 1 infection in 36 patient months.
	Patients with Flu Vaccination	Includes vaccines administered at the unit and if patient reports that they received a vaccine elsewhere September through March. Patients who are contraindicated, refused or who are allergic are counted as "No." Data not included on reports April through August.	N/A (Data provided if available)
	Patients with Pneumo Vaccination	Includes patients who received one dose within the last five years or two doses, five years apart within a lifetime. Either administrated at the unit or reported by the patient. Patients who are contraindicated, refused or who are allergic are counted as "No."	N/A (Data provided if available)

12.9. MEDICAL RECORD REVIEW AND STANDARDS

KP recommends that all Providers maintain their medical records following standards applicable to their specialty to comply with various regulatory and accreditation organizations with regards to clinical documentation and to assure the consistency and completeness of patient medical records.

KP may review medical records for conformance to the standards:

KP MEDICAL RECORD DOCUMENTATION STANDARDS

I. **General Guidelines**
   A. Entries must be completed at the time of visit or by end of day
   B. Entries must be charted using SOAP (Subjective, Objective, Assessment, Plan) guidelines which provides standard format.
   C. Entries must be documented in the ambulatory electronic health record. During downtime, handwritten notes are acceptable. All handwritten entries must be accurate, timely, and documented on valid medical record forms.
   D. All medical records are maintained in a detailed and comprehensive manner that conforms to good professional medical practice

E. All medical records are maintained in a manner that permits effective professional medical review and medical audit processes
F. All medical records are maintained in a manner that facilitates an adequate system for follow-up treatment
G. All medical records shall be legible, signed and dated

II. Demographics

A. Each page of the paper or electronic record includes the patient's name or ID number
B. All medical records contain patient demographic information, including age, sex, address, home and work telephone numbers, marital status and employment, if applicable

III. Content

A. Contain information on any adverse drug reactions and/or food or other allergies, or the absence of known allergies, which are posted in a prominent area on the medical record
B. All forms or notes have a notation regarding follow-up care, calls or visits, when indicated
C. Contain the patient's past medical history that is easily identified and includes serious accidents, hospitalizations, operations and illnesses. For children, past medical history including prenatal care and birth
D. All pediatric medical records include a completed immunization record or documentation that immunizations are up-to-date
E. Include the provisional and confirmed diagnosis(es)
F. Contain medication information
G. Contain information on the identification of current problems (i.e., significant illnesses, medical conditions and health maintenance concerns)
H. Contain information about consultations, referrals, and specialist reports
I. Contain information about emergency care rendered with a discussion of requirements for physician follow-up
J. Contain discharge summaries for: (1) all hospital admissions that occur while the member is enrolled; and (2) prior admissions as appropriate
K. All medical records for members eighteen (18) years of age or older include documentation indicating whether the member has or has not executed an advance directive, including an advance mental health care directive
L. All medical records shall contain written documentation of a rendered, ordered or prescribed service, including documentation of medical necessity
M. All medical records shall contain documented patient visits, which includes, but is not limited to:
    - A history and physical exam
    - Treatment plan, progress and changes in treatment plan
    - Laboratory and other studies ordered, as appropriate
    - Working diagnosis(es) consistent with findings

- Treatment, therapies, and other prescribed regimens
- Documentation concerning follow-up care, telephone calls, emails, other electronic communication, or visits, when indicated
- Documentation reflecting that any unresolved concerns from previous visits are addressed in subsequent visits
- Documentation of any referrals and results thereof, including evidence that the ordering physician has reviewed consultation, lab, x-ray, and other diagnostic test results/reports filed in the medical records and evidence that consultations and significantly abnormal lab and imaging study results specifically note physician follow-up plans
- Hospitalizations and/or emergency department visits, if applicable
- All other aspects of patient care, including ancillary services.

IV. Dictated / Transcribed Documentation

A. Data to be dictated on the day of the encounter
B. Stat dictation to be transcribed within 24 hours
C. Hospital operative reports, history & physical, consults, discharge summaries to be transcribed within 24 hours
D. Clinic consults and progress notes to be transcribed within 7 days

V. Ancillary Service Results

A. Laboratory, Diagnostic Imaging, and Pathology results are available in the electronic medical record
B. Non-electronic reports / interpretations of other ancillary services are scanned into the ambulatory electronic health record

VI. Advice / Messages Related to Patient Care

A. An entry is to be made in the ambulatory electronic health record of all communication relating to patient care including, but not limited to:
   - Medication refills
   - Any new illness or change in health status
   - All messages (communications) to and from the patient, except for patient request for an appointment which is honored
   - Any medical or professional advice which is given
   - Abnormal laboratory results or requests to return for additional testing procedures

VII. "No Show" Appointments

A. When a patient fails to appear for the appointment (no show), it must be clearly indicated in the ambulatory electronic health record and efforts to contact the patient with subsequent actions documented

VIII. Late Entries

A. Documentation of late entries written out of chronological order must begin with "LATE ENTRY FOR (date/time)".

IX. Correcting Entries

A. Federal and State statutes require that when correcting the inaccuracy of a medical record entry, information must not be eradicated (white out) or removed

X. Forms

A. The Regional Forms Committee, Medical Records Administration, and Health Information Management Committee must approve all forms to be used in the medical record

XI. Copy and Paste

A. Clinicians documenting in the Ambulatory Electronic Medical Record must avoid indiscriminately copying and pasting another clinician's progress note, discharge summary, electronic mail communication, and redundant information provided in other parts of the health record.

12.10. INFORMED CONSENT AND WHO MAY CONSENT

Kaiser Permanente recognizes the right of every patient with decision making capacity to be informed about the care, treatment, services, proposed diagnostic and therapeutic procedures, and the risks and benefits of and alternatives to proposed plan. Kaiser Permanente shall permit only those aspects of care, service and treatment for which the patient/representative has given consent, unless the emergency medical treatment exception to consent applies. The right of a patient or the patient's personal representative to decide whether or not to consent to medical treatment includes the right to refuse such care, service, treatment or procedure.

INFORMED CONSENT POLICY

Every patient has the right to make his or her own health care decisions. Where a patient is incapable of providing consent to health care and treatment, the patient's personal representative must provide consent. The determination of who has the legal right to consent to medical care for the patient involves consideration of the patient's legal status, the particular treatment involved, as well as the patient's physical and mental condition at the time.

WHO MAY CONSENT POLICY

INFORMED CONSENT

1. Purpose

The purpose of this policy is to define the scope of the informed consent process, the process used to obtain informed consent, how informed consent is to be documented in the medical record, when someone other than the patient may give informed consent, and when procedures, care, treatment or services normally requiring informed consent may be given without informed consent. The intent is to ensure the Region respects the rights of patients to participate in decisions about their care, including the right to refuse, in accordance with Hawaii law.

2. Scope

This policy applies to all employees of Kaiser Foundation Health Plan, Inc. (KFHP), Kaiser Foundation Hospitals (KFH), and the Hawaii Permanente Medical Group, Inc. (HPMG), collectively "Kaiser Permanente Hawaii Region," and contractors or other individuals who provide care to patients and are involved in the consent process, regardless of the location.

3. Definitions

- **Implied consent**: Consent provided when a patient acts in such a way that leads a reasonable health care provider to assume the treatment option chosen is acceptable to the patient and the risks, and benefits, and alternatives are commonly understood. This category of treatment would include venipunctures and chest x-rays.
- **Emancipated minor:** A person who is not an adult under state law, but can make his/her health care decisions as if he/she were an adult.
- **Express consent:** Consent provided when the patient states verbally or in writing that she/he is willing to undergo the proposed treatment.
- **Informed consent:** A process which allows the patient/representative to participate fully in decisions about his/her care, treatment and services by establishing a mutual understanding between the patient/representative and the physician who provides care, service and treatment. The documentation of informed consent typically is on a form and within the progress notes of the medical record.
- **Minor:** Any person under eighteen (18) years of age.
- **Personal Representative:** A person who has legal authority to act for a member or patient for health care decisions.
- **Legal surrogate:** An agent designated in a power of attorney for health care or surrogate designated or selected in accordance with Chapter 327E.

- **Protected Health Information (PHI):** PHI is individually identifiable information (oral, written or electronic) about a member/patient's physical or mental health, the receipt of health care, or payment for that care. PHI includes individually identifiable member/patient payment, dues, enrollment and disenrollment information. Individually identifiable health information in KP employment records is not PHI: however, it may be subject to other state and federal privacy protections.

4. Policy

Kaiser Permanente recognizes the right of every patient with decision making capacity to be informed about the care, treatment, services, proposed diagnostic and therapeutic procedures, and the risks and benefits of and alternatives to proposed plan. Kaiser Permanente shall permit only those aspects of care, service and treatment for which the patient/representative has given consent, unless the emergency medical treatment exception to consent applies. The right of a patient or the patient's personal representative to decide whether or not to consent to medical treatment includes the right to refuse such care, service, treatment or procedure. (See Guidelines for examples of care/ treatment/ service/ procedures requiring informed consent.)

The best evidence of express consent is a consent form signed by the patient. A physician's notation in the chart that the patient has consented is also evidence of express consent, especially when referencing specific concerns or part of the discussion with that particular patient.

4.1. The responsibility for obtaining informed consent rests with the attending physician or appropriate qualified healthcare practitioner performing the procedure.

4.2. In accordance with Hawaii Revised Statute, Section 671-3 ,the following information must be supplied to the patient or the patient’s guardian or surrogate prior to obtaining consent:

- The condition being treated or diagnosed;
- The description of the proposed care, treatment, services, medications, interventions or procedures,
- The intended and anticipated result;
- The potential benefits, risks or side effects, including potential problems that might occur with the proposed treatment or procedure;
- The recognized material risks of serious complications or mortality associated with the proposed treatment or procedure;
- The recognized alternative treatments or procedures; and

- The potential risks, benefits, side effects of not undergoing any treatment or procedure;
- The likelihood of achieving the desired result/goal; and
- When indicated, any limitations on the confidentiality of information learned from or about a patient.

4.3. The information may be presented in writing, orally, or by means of audio/visual aids, and must be in a language that the patient his/her personal representative can reasonably be expected to understand. Consent forms need not be in a language other than English. An interpreter may be needed. Please refer to the internal document "Interpreter Services, Guidelines for Requesting Language Assistance" (Form # 1027-3552) for instructions on scheduling an interpreter for an informed consent discussion.

4.4. Therapeutic privilege: Information should be presented in a way that patients can understand and use in giving an informed consent decision. Clinical judgment may be required to determine the appropriate means for communicating relevant information, taking patients' personalities and clinical histories into account when possible.

4.5. After the patient has received information to make an informed decision, the patient may give **consent** to the procedure.

4.6. Adults with decision making capacity must consent to their own medical treatment. A personal representative may consent for the patient in cases where the patient lacks decision making capacity, which may be due to, but is not limited to senility, mental deficiency, head injury, unconsciousness, or substance abuse. (See **Guidelines** for information related to consent for treatment of a minor.)

4.7. Consent for medical or surgical treatment may be obtained by telephone or fax only if the patient's personal representative is not otherwise available. (See **Guidelines** for instructions on obtaining consent by telephone or fax.)

Documentation:

4.8 The informed consent process should be documented in the progress notes, and may also be documented on a specifically designed consent form." It is preferable to document any information presented in the discussion, any questions from the patient and the agreement of the patient to have this procedure. In addition, the progress note should indicate that risks, benefits and alternatives to the procedure have been discussed, in accordance with HRS, Section 671-3.

4.9 When a consent form is used, the patient, the qualified healthcare practitioner performing the service and a witness must sign the form with a signature, date

and time. (See Guidelines for what to do if the patient is unable to sign his/her name). The signature must be voluntary and free from coercion. The witness verifies that the patient signature was voluntary.

4.10 The original consent form shall be scanned into the patient's medical record in accordance with charting policy. A copy shall be given to the patient.

Emergency situations:

4.11 Where treatment appears to be immediately necessary to prevent deterioration or aggravation of the patient's condition treatment may proceed without the patient's consent if the patient, his/her parent, if the patient is a minor, or his/ her personal representative are unable to give consent. Please refer to policy # 6226-05-B2, "Who May Consent" for guidance in these circumstances

Duration of Consent

4.12 Consent is generally valid for a reasonable time commencing from the date the informed consent is given to the date of the procedure, unless other time limits are specified, or until a change in circumstance presents different risks, benefits, or alternatives to the treatment. In no event shall it be effective for a time period exceeding thirty (30) days. Change in circumstance includes:

- Each admission to the hospital;
- Each instance of surgery, even if the same or similar surgery was performed earlier in the admission;
- Each instance of a procedure, even if the same or similar procedure was performed earlier in the admission (exception: blood transfusions)
- Any instance where there is a patient change that alters the risks, benefits, or alternatives of the surgery or treatment.

Refusal

4.13 Patients have the right to refuse specific treatments, care, procedures or medications without affecting other aspects of his or her care. (See **Guidelines** for information and procedure for refusal.)

5. Responsibility

The Clinical Risk Management Department, in consultation with Regional Legal Counsel, and the Director of Accreditation, Licensing and Regulation, is responsible for ensuring that this policy is accurate, relevant, and current.

6. Maintenance

Chapter 671-3 of Hawaii Revised Statutes shall be reviewed on a regular basis to ensure the policy is in compliance with any statutory amendments. Title 16, Chapter 85 of Hawaii Administrative Rules shall be reviewed on a regular basis to ensure the policy is in compliance with any regulatory amendments. The Joint Commission standards shall be reviewed on a regular basis to ensure compliance with accreditation requirements. Policy content shall be reviewed on a regular basis and revised as needed.

7. References

- Hawaii Administrative Rules and Hawaii Revised Statues
- The 2017 Joint Commission Comprehensive Accreditation Manual for Hospitals, Chapter: Rights and Responsibilities of the Individual; Standard RI.01.03.01
- AMA's Code of Medical Ethics. *AMA-ASSN.* Retrieved April 7, 2015, from http://www.ama-assn.org

8. Implementation

8.1. Effective Dates – This policy becomes effective upon approval.

8.2. Distribution

- Upon approval, the one page summary of H&P requirements, as well as this policy, shall be distributed to all process stakeholders and the affected entities and departments.
- As applicable, affected entities, departments, and individuals may prepare and implement procedures consistent with this policy and as necessary conduct appropriate education to assure consistent and uniform implementation.
- This policy shall be accessible on the KP Intranet after approval.

9. Review and Approval

Contact Person:	Linda Puu VP Quality, Safety, and Service	
Reviewed By:	Laura Sherill Privacy and Security Officer	Date: 08/03/2017
Reviewed By::	Craig Nakamoto Legal Counsel	Date: 08/02/2017
Approved By:	Risk/Legal Workgroup Regional Quality Council KFH Medical Executive Committee Wailuku ASC Medical Executive Committee Mapunapuna ASC Medical Executive Committee	Date: 02/01/2012 Date: 03/19/2012 Date: 04/16/2015 Date: 08/05/2013 Date: 08/17/2017
Next Review Date:	08/03/2020	
Replaced:	n/a	

10. Appendix – Informed Consent Guidelines

INFORMED CONSENT GUIDELINES

1. **Examples of care/treatment/services/procedures requiring informed consent include but are not limited to:**
    - Operative and invasive procedure and special procedures;
    - Endoscopic procedures;
    - Experimental drugs or treatments;
    - Radiologic procedures such as:
        - Angiocardiogram;
        - Aortogram;
        - Arteriogram;
        - Bronchogram;
        - Cardiac catheterization;
        - Cerebral angiogram
        - Emobolization or occlusion of vascular structures;
        - Lymphangiogram;
        - Myelogram and discogram;
        - Pacemaker insertion and adjustment;
        - Percutaneous abscess drainages, nephrostomy, biliary drainage;
        - Percutaneous biopsy;
        - Percutaneous removal of gallstone or ureteral stones;
        - Percutaneous transhepatic cholangiogram;
        - Pneumoencephalogram;
        - Splenoportogram;
        - Venogram;
        - Ventriculogram;
    - HIV testing.

2. **In the event the person required to sign a permit is unable to write his/her name, his/her mark may be obtained.** The patient's or his/her personal representative's name is written in full above the line for his/her signature. The signing party makes his/her mark by placing an "X" on the signature line.

3. **The signature of the patient or his/her personal representative must be witnessed by a competent adult**. If the consent form calls for more than one witness, the form shall be witnessed by the number indicated. Kaiser Permanente employees may act as witnesses to the signing of consent forms.

4. Informed Consent by Telephone or Fax

4.1. For consents received by telephone, identifying information from the person believed to be the patient's personal representative is obtained. The discussion between the patient's personal representative and physician should be witnessed by a Kaiser Permanente employee. Inform the patient's personal representative that another Kaiser Permanente employee will be listening t o the conversation. The discussion, the circumstances surrounding the need for telephone consent, and the date, time and nature of the consent given, should be carefully documented in the patient's medical record by both the physician and Kaiser Permanente employee.

4.2. A confirmation of consent by fax or letter should be obtained as soon after the telephone discussion as possible. Such confirmation should be in the following general form: "This confirms oral permission to treat [insert name of patient] given [insert date] on the basis of discussion with Dr(s). [insert name(s)]." The confirmation should also contain the name of the person giving the consent and his/her relationship to the patient. The confirmation shall be placed into the patient's medical record.

4.3. When circumstances necessitate obtaining consent by fax, the following shall apply:

- Consent for basic hospital services and medical treatment not requiring informed consent may be obtained by requesting a fax in the following general form: "Permission is granted to provide hospital services and medical treatment for [insert name of patient]," followed by the name of person giving consent and his/her relationship to the patient.
- When informed consent is required, the responsible physician should make the request for consent by sending a message, insofar as is practical, stating the reason and nature of the treatment, and the risks, benefits, and alternatives. The consent should be in the following general form: "Permission is granted to treat [insert name of patient] on the basis of the message from Dr(s). [insert name(s)]." Follow this statement with the name of the person giving consent and his/her relationship to the patient. A copy of the message from the physician and the original fax from the patient's personal representative shall be placed in the patient's medical record.

5. Consent for Treatment of A Minor

5.1. **C**onsent for treatment of a minor, with the exception of emancipated minors, must be obtained from the parent or a personal representative with the power to make medical treatment decisions for the minor.

5.2. Circumstances under which a Minor has Legal Capacity to Consent.

- An emancipated minor may consent to his/her medical care and treatment and release of information. A minor is "emancipated" if he/she is legally married, including a minor who is now divorced, or totally self-supporting. A copy of the minor's certified marriage certificate or other documentation of his/her emancipated status should be included in the medical record. (See Policy No. 414-03-021, *Verification of Identity and Authority for Disclosures of Protected health Information*).
- A minor who is a parent and has not surrendered custody of the child may consent to the medical care and treatment, or release of information, for his/her child.
- A minor may consent to counseling services for alcohol or drug abuse without consent of spouse, parent, custodian or guardian.
- Minors who are 14 through 17 years of age may consent if seeking treatment for venereal disease, pregnancy or family planning, but may not consent to surgery or any procedure to induce abortion. PHI regarding the care may be provided to the patient's parent, spouse, personal representative, or custodian at the discretion of the treating physician after consultation with the patient.
- For minors who are 14 through 17 years of age, the right to authorize release of PHI may be exercised by the minor or the parent or the personal representative. If the minor and parent or personal representative do not agree, the minor's authorization shall control.

6. Refusal of Care, Treatment and Services

- If a patient parent, or personal representative refuses medically indicated therapy, withdraws or withholds blood or medication, or refuses to consent to specific treatment or surgery, the attending physician shall be notified.
- The physician shall inform the patient, parent or personal representative of the risks and complications that may result from refusal of treatment.
- If the patient, parent or personal representative continues to refuse treatment despite attempts to convey the potential risks and complications, a complete statement shall be documented in the patient's medical record. The statement should include a detailed description of the patient's wishes and the explanation(s) provided by the

physician. The statement should be signed by the patient or his/ personal representative.

- A staff person such as a physician, and other than the attending physician, a nursing supervisor, or social worker, shall act as staff witness to the discussions involving the patient's refusal and explanations given by staff. In addition to the signature of the attending physician, any notations or statements entered into the patient's medical record should be cosigned by the staff witness.
- If the patient or his/her personal representative is unwilling to endorse the statement, the person's refusal to sign the statement should be noted.
- If refusal of treatment may result in death or severe disability, or the patient is a minor or incompetent adult, the attending physician has the prerogative to remedy the situation through legal intervention.

Policy Title: Healthcare Decision Making: Who May Consent	Policy Number: 6226-05-B2
Owner Department: Risk Management	Effective Date: 07/01/1984
Custodian: Regional Risk Manager	Page: 1 of 11

1.0 Policy Statement

Every patient has the right to make his or her own health care decisions. Where a patient is incapable of providing consent to health care and treatment, the patient's personal representative must provide consent. The determination of who has the legal right to consent to medical care for the patient involves consideration of the patient's legal status, the particular treatment involved, as well as the patient's physical and mental condition at the time.

2.0 Purpose

The purpose of this policy is to provide guidance regarding who may provide consent for health care and treatment in accordance with federal and state laws and regulations.

3.0 Scope

3.1 Except as otherwise provided below, the provisions of this policy apply to the following persons:

3.1.1 All workforce members of Kaiser Foundation Hospitals (KFH), Kaiser Foundation Health Plan, Inc. (KFHP), and their respective subsidiaries;

3.1.1.1 And professional staff members of KFH hospitals;

3.1.2 All physicians, employees, and other workforce members of the Hawaii Permanente Medical Group, Inc. (HPMG);

4.0 Definitions

4.1 **Advance Health Care Directive (AHCD):** An individual's instruction or direction concerning health care decisions for the individual and/or a power of attorney for health care.

4.2 **Agent:** An individual designated under a power of attorney for health care to make health care decisions for the individual granting the power. A power of attorney for health care may take effect immediately, while the patient still has capacity, or may become effective only when the patient lacks capacity.

4.3 **Caregiver *(e.g., Hānai caregiver)*:** A person who is at least eighteen (18) years of age and:

(a) Is related by blood, marriage, or adoption to a Minor, including a person who is entitled to an award of custody of a Minor by the court when the court deems it necessary or proper and in the best interest of the Minor, even though said person is not the legal custodian or Guardian of the Minor; or

(b) Has resided with a Minor continuously during the immediate preceding period of six (6) months or more.

4.4 **Decision-making Capacity:** A patient's ability to understand the significant benefits, risks and alternatives to proposed health care and to make and communicate a health care decision by any means.

4.5 **Emancipated Minor:** Under Hawaii State law, a minor who is legally married, (including a minor now divorced) or totally self-supporting.

4.6 **Incapacitated:** A condition in which the patient is unable to understand the significant benefits, risks and alternatives to proposed health care and/or is unable to make and communicate a health-care decision by any means including verbal, written, electronic or expressive means. Incapacity may be due to senility, mental deficiency, head injury, unconsciousness, altered cognitive ability or alcohol/drug abuse and may be permanent or temporary.

4.7 **Guardian:** A person appointed by the court to act on an individual's behalf. Guardians may or may not have authority to make health care decisions on a patient's behalf.

4.8 **Minor:** A person who has not yet reached legal majority age of 18.

4.9 **Minor without Support:** A person at least fourteen (14) years of age, but less than eighteen (18) years of age, who is not under the care, supervision, or control of a parent, custodian or legal Guardian (for example a runaway or a Pacific Island minor who has immigrated to Hawaii without his/her parents).

4.10 **Personal Representative:** A person who has legal authority to act for a patient in regards to health care decisions.

4.11 **Power of Attorney for Health Care:** Document in which an individual designates an agent to make health care decisions for the individual granting the power.

4.12 **Surrogate:** Adults with decision making capacity who have not executed an AHCD or power of attorney for health care may designate or disqualify any individual to act as a surrogate decision-maker. A surrogate's authority to make health care decisions for the patient takes effect only when the patient has been determined to lack capacity.

4.11.1 **Designated Surrogate:** A person other than the patient's Agent or Guardian, who is designated by the patient to make health care decisions on his/her behalf should he/she become incapacitated.

4.11.2 **Non-Designated Surrogate:** A person, other than a patient's Agent, Guardian or Designated Surrogate, selected to make health care decisions on behalf of an incapacitated patient. Non-Designated Surrogates are selected when an incapacitated patient has made no advance determinations as to who will act on his/her behalf in terms of health care decisions *(see policy "Advance Health Care Directives" 6020-0220 Section 4.5 for a description of the process to appoint a non-designated surrogate).*

5.0 Who may consent to medical care and treatment

5.1 Adults

Except in an emergency or where treatment is court ordered, the following persons, in order of priority, may provide consent for health care decisions for or on behalf of an adult patient.

5.1.1 Adults with decision making capacity

Adult patients with decision-making capacity have the right to consent to their own medical care and treatment. This includes patients in police custody.

5.1.2 Personal Representative of an Incapacitated Adult

If it is determined that the patient is incapacitated, consent must be obtained from the patient's personal representative. However, where an incapacitated patient has a validly executed AHCD and the treatment involves decisions regarding end of life care, the healthcare team may proceed in accordance with the terms of the AHCD.

The scope of a personal representative's powers may be specified and/or limited by the patient or the issuing court. If the documents do not specifically limit the personal representative's authority to consent, the personal representative may consent to any treatment or procedure which the patient would be able to consent to if capable of granting consent subject to limitations set forth in section 5.1.2.3.

Unless otherwise specified in an AHCD, authority to consent for an incapacitated patient ends upon return of the patient's decision-making capacity.

5.1.2.1 **Personal Representatives.** In Hawaii, personal representatives for the purpose of providing consent (in order of priority) include:

Guardian:

- A guardian's authority to make medical decisions on behalf of the patient must be specified by letters of guardianship or a court order.

  NOTE: Guardianship of the person includes authority to make medical decisions on behalf of the individual.

- A guardian, without authorization of the court, may not revoke any health care directions set forth in an AHCD or health care power of attorney

- The appointment of a guardian automatically terminates the authority of any agent or surrogate designated in an AHCD or health care power of attorney.

Agent:

- An agent shall make decisions consistent with the patient's instructions, if any, and other wishes to the extent known to the agent.
- Otherwise, the agent shall make decisions consistent with the agent's determination of the patient's best interest

Designated Surrogate:

- A surrogate designated by the patient may make health-care decisions for the patient that the patient could make on the patient's own behalf.

Non-Designated Surrogate:

- A non-designated surrogate may make all health-care decisions for the patient that the patient could make on his/her own behalf except for decisions about withdrawal artificial nutrition and hydration (see section 5.1.2.3.2)

Authorized Third Party Medical Consent

- Under certain circumstances, a third party may present a medical consent form signed by the personal representative which authorizes the third party to consent to treatment of an incapacitated adult. The scope of the third party's authority may be specified and/or limited by the consent form. If the document does not specifically limit the authority to consent, the authorized third party may consent to any treatment or procedure to which the personal representative may consent.

5.1.2.2 **Documentation and Scope of Authority.**

A copy of the court order or letters of guardianship, the power of attorney for health care, or documentation of the designation of a surrogate decision-maker should be included in the medical record.

5.1.2.3 **Limitations on Consent for Incapacitated Patients**

5.1.2.3.1 **Sterilization**

In the absence of a court appointed guardian with specific written court ordered authority to consent to sterilization of an incapacitated adult, no personal representative may consent to sterilization of the incapacitated adult except in

an emergency. The personal representative seeking sterilization for the incapacitated adult is the appropriate party to petition the court for authority to consent to sterilization.

If authority to consent for the sterilization of an adult who lacks decision-making capacity has been granted by the court, a copy of the court order or letters of guardianship must be placed in the medical record before any procedure is performed.

5.1.2.3.2 **Artificial Nutrition and Hydration**

A non-designated surrogate may make health care decisions regarding artificial nutrition and hydration only when the primary physician and a second independent physician certify in the patient's medical record that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to have any neurological response in the future.

5.1.2.4 **Conflicts with Patient's Best Interests.**

If the personal representative's consent or refusal to consent appears to be in conflict with the patient's previously expressed wishes or not in the patient's best interests, the case should be referred to the Legal Department and/or the Ethics Committee for further recommendations.

5.2 Minors

A minor is not an adult under state law and, therefore, generally does not have the right to consent to medical care and treatment except in certain circumstances (See Section 5.2.5 below).

5.2.1 **Parental Consent**

5.2.1.1 **Minor with Married Parents**

In general, either parent can consent to treatment of a minor. However, when the parents are in disagreement and there is no court decision or written agreement concerning control or custody of the child, treatment should be delayed unless such treatment appears to be immediately necessary to prevent deterioration or aggravation of the minor's conditions (See emergency exception to consent, Section 5.3.3 in policy Informed Consent/Consent to Treat).

5.2.1.2 **Minor with Divorced Parents**

In the case of minors of divorced parents, consent shall be obtained from the parent with court ordered legal custody of the child. If both parents have joint legal custody of the child, the consent of either parent is sufficient. However, when the parents are in disagreement and there is no court decision or written agreement concerning control or custody of the child, treatment should be delayed unless such treatment appears to be immediately necessary to prevent deterioration or aggravation of the minor's conditions (See emergency exception to consent, Section 5.3.3 in policy Informed Consent/Consent to Treat).

5.2.1.2 **Minor with Stepparent**

A stepparent who has not legally adopted a minor may provide consent for the minor's treatment only upon presentation of a third-party medical consent form signed by a parent with legal custody of the minor (e.g., authorization to treat a minor form) or a notarized Caregiver affidavit.

5.2.1.3 **Minor with Unmarried Parents**

If parents are unmarried, the minor's mother may provide consent. The minor's father may provide consent if paternity may be presumed under the Uniform Parentage Act. If the child's birth certificate includes the name of the father, then paternity is presumed. Other evidence supporting a reasonable presumption under the Uniform Parentage Act includes, but is not limited to, listing of the individual in the child's medical record as the father, presence of the mother and individual together with the child at prior visits, the child referring to the individual as the child's father and the individual holding himself out as the father, etc.

5.2.2 **Guardian Consent**

5.2.2.1 If a guardian with power to make medical treatment decisions has been appointed for the minor, the guardian must consent to the medical care and treatment or on behalf of the minor.

5.2.2.2 If the letters of guardianship or court order do not specifically limit the guardian's authority to consent, the guardian may consent to any treatment or procedure for which the parent would be able to consent.

5.2.3 **Limitations on Parental/Guardian Consent**

5.2.3.1 No parent, personal representative or guardian may consent to the sterilization of any minor, unless a court has specifically addressed the issue and granted a guardian the authority to consent as set forth in the letters of guardianship.

5.2.3.2 Family Court may order that a physician, surgeon, psychiatrist, psychologist examine a minor who is the subject of a petition, and it may order treatment of a minor who has been adjudicated by the court. Except in cases of authority, the Probation Officer is given the duty of locating the parents of the minor. Should the parents object, Family Court can order the treatment.

5.2.3.3 If a minor aged 14 or older objects to treatment for which the parent, guardian, or caregiver has consented, the case should be referred to the Legal Department and/or the Ethics Committee for further recommendations.

5.2.4 **Minors: Special Situations**

5.2.4.1 **Caregiver**

Upon presentation of a notarized caregiver affidavit that meets the requirements of §HRS 577-28 (Appendix A), a caregiver may consent on behalf of a minor to primary and preventative medical and dental care and diagnostic testing, and other medically necessary health care and treatment.

5.2.4.2 **Authorized Third Party Medical Consent**

Under certain circumstances, a third party may present a medical consent form signed by the parent, guardian or Caregiver which authorizes the third party to consent to treatment of a minor. The scope of the third party's authority may be specified and/or limited by the consent form. If the document does not specifically limit the authority to consent, the authorized third party may consent to any treatment or procedure which the parent, guardian or Caregiver may consent.

5.2.4.3 **Adoption**

Adopted Minor: If a minor has been legally adopted by order of the court, the adoptive parents may consent to the minor's treatment.

Minor in Process of Adoption: If the minor has been placed for adoption and the adoptive parents have not yet been given legal custody by the court, either the birth mother, placing attorney/agency or adoptive parents may consent to the minor's treatment, depending on the legal documents that have been signed by the birth mother.

5.2.4.4 **Minor born of Minor Parents**

A minor mother, married or unmarried, may consent to her child's treatment. A minor father may only consent to the child's care if he is the legal father through marriage or paternity where it is reasonable to presume that the minor is the father of the child. Evidence supporting a reasonable presumption includes, but is not limited to, listing of the individual in the child's medical record as the father, presence of the mother and individual together with the child at prior visits, the child

referring to the individual as the child's father and the individual holding himself out as the father, etc.

However, where the minor parent's ability to understand the proposed medical treatment is in question, it is advisable to seek the additional consent of the parent or legal guardian of the minor parent.

5.2.4.5 **Minor under Child Welfare Services and Child Protective Services (CPS)**

Unless otherwise ordered by the court, a child's parent or family member shall retain the right and responsibility to consent to the child's care and shall provide consent except as indicated below:

- If the parent or family member is unable or has refused to consent, the Department of Human Services may provide consent for any medical care or treatment, including, but not limited to, surgery, if the care or treatment is deemed necessary for the child's physical or psychological health or welfare by two physicians or two psychologists, as appropriate, who are licensed or authorized to practice in the State.

5.2.4.6 **Minor in Foster Custody**

Foster parents may consent to ordinary medical and dental care, immunizations and well-baby and well-child medical services.

5.2.4.7 **Minor in Custody of the Police or Probation Officer**

Consent for medical treatment must be obtained from a parent or legal guardian.

5.2.4.8 **Minor under the Jurisdiction of the Family Court or the Hawaii Youth Correctional Facility**

The parents, legal Guardian, or the representative of the authorized institution to which legal custody has been awarded must provide consent to treatment.

5.2.5 Circumstances under which a Minor has Legal Capacity to Consent.

5.2.5.1 **Minor on Active Duty with the US Armed Forces**

Any minor on active duty with any branch of the US Armed Forces may consent to his or her own treatment.

5.2.5.2 **Emancipated Minors**

An emancipated minor may consent to his/her medical care and treatment.

5.2.5.3 **Minor without Support**

A minor, age 14 – 17, who is not under the care, supervision or control of a parent, custodian or legal guardian (i.e., abandoned minor or

runaway) may consent to his/her primary medical care and services if a physician reasonably believes that:

- The minor is a minor without support as defined above;
- The minor understands the significant benefits and risks of the proposed care and can communicate an informed consent; and
- The proposed services are for the minor's benefit.

Primary medical care and services, for the purpose of this section, are defined as health care services that include screening, counseling, immunization, medication, and treatment of illnesses and medical conditions customarily provided in an outpatient setting. It does not include invasive care such as surgery that goes beyond standard injections, lacerations, or treatment of simple abscesses.

5.2.5.4 **Minor Consent for Certain Types of Treatment**

Minors age 14 – 17 may consent to their own treatment for the following:

- Family Planning Services
- Pregnancy related care
- Treatment for sexually transmitted diseases
- Substance abuse counseling

If a minor requests the above services and the provider determines that the minor is not capable of providing informed consent, the provider should contact legal services for assistance and guidance as to whether or not consent should be sought from the parent or legal guardian or the courts.

Information regarding the care may be provided to the patient's parent, spouse, personal representative, legal guardian or custodian at the discretion of the treating physician after consultation with the patient.

5.2.5.4 **Minor Consent to Mental Health Services**

Minors age 14 – 17 may consent to mental health treatment or counseling services if, in the opinion of a licensed mental health professional, the minor is mature enough to participate intelligently in the treatment or counseling services. However, consent of the minor's parent or guardian is required to prescribe medications or to place the minor in an out-of-home or residential treatment program.

Where a minor consents to mental health treatment or services, the mental health professional should include involvement of the minor's parents or legal guardian unless, after consulting with the minor, the mental health professional determines such involvement is inappropriate.

The mental health professional must document in the minor's medical record attempts to contact the minor's parent or legal guardian about the services or, should the mental health professional determine involvement of the parent or legal guardian is inappropriate, the reason for that determination.

If there is disagreement between the minor and the parent or legal guardian with respect to consent for the services, contact legal services for assistance and guidance.

5.3 Documentation and Scope of Authority.

KP shall verify the authority of a personal representative, where necessary, by obtaining a copy of documentation that supports the personal representative's right to make health care decisions on the patient's behalf. Such document should be filed in the patient's medical record.

5.4 Legal Assistance

Obtain assistance, legal interpretation and clarification from the Legal Department as needed.

8.0 References

- Hawaii Revised Statutes, Chapter 327E Uniform Health-Care Decisions Act
- Hawaii Revised Statutes, Chapter 551D Uniform Durable Power of Attorney Act
- Hawaii Revised Statutes, Chapter 560: Part 6 Incapacitated Persons Sterilization Rights
- Hawaii Revised Statutes, Chapter 560: 5-208 Powers of a Guardian
- Hawaii Revised Statutes, Chapter 577-3 Natural Guardian
- Hawaii Revised Statutes, Chapter 577-25 Emancipation of Certain Minors
- Hawaii Revised Statutes, Chapter 577-26 Alcohol or drug abuse relating to minors; diagnosis, counseling and related activities
- Hawaii Revised Statutes, Chapter 577-28 Affidavit of Caregiver Consent for Minor's Health Care
- Hawaii Revised Statutes, Chapter 577A-2 Legal Capacity of Minor Regarding Medical Care
- Hawaii Revised Statutes, Chapter 577D Primary Medical Care for Minors without Support
- Hawaii Revised Statutes, Chapter 577-29 Mental Health Services relating to Minors
- Hawaii Revised Statutes, Chapter 584-4, Uniform Parentage Act
- Hawaii Revised Statutes, Chapter 587A, Child Protective Act, Sections 15 and 42
- Hawaii Revised Statutes, Chapter 671-3 Informed Consent

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8.0 Hawaii Region Endorsement and Approval:

Contact Person:	Linda Puu, VP Quality, Safety and Service	
Reviewed by:	Laura Sherrill, Privacy & Security Officer Craig Nakamoto, Counsel George Apter, HPMG VP & General Counsel	Date: 04/18/16 Date: 04/18/16 Date: 12/13/16
Endorsed by:	Hospital Compliance Committee HPMG Executive Committee	Date: 12/22/16 Date: 05/03/17
Approved by:	Hawaii Regional Compliance Committee HPMG Board of Directors	Date: 01/27/17 Date: 05/04/17
Adopted by:	KFH Medical Executive Committee KFH Hospital Executive Committee Mapunapuna ASC Medical Executive Committee Wailuku ASC Medical Executive Committee Quality Committee	Date: 08/03/17 Date: 07/10/17 Date: 08/17/17 Date: 08/11/17 Date: 05/11/17
Last Review:	05/04/2017	
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9.0 Policy Life History

Original Approvals	Revision Approvals	Update Approvals
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