Northwest Kidney Centers

Coordinated Quality & Safety Improvement Program (CQSIP) Plan

September 2020

700 Broadway
Seattle, WA 98122

WAC 246-50-020 Cross Reference

	WAC #	WAC Requirement	Page	Lines
1	WAC 248-50-020 (1)(a)	A governing body	2 5	15-34 22-33
2	WAC 248-50-020 (1)(b)	A committee, appointed by the governing body, with a broad representation of the services offered, responsible for:	4 5	7 – 40 1-20
3	~WAC 248-50-020 (1)(b)(i)	~Reviewing services rendered, both retrospectively and prospectively, to improve the quality of health care by measuring key characteristics such as effectiveness, accuracy,	4	12-19
4	~WAC 248-50-020 (1)(b)(ii)	~Reviewing categories and methodologies of services rendered and to be rendered with the goal of improving health care outcomes;	4	12-19
5	~WAC 248-50-020	~Overseeing and coordinating the program;	4	8-10
6	~WAC 248-50-020 (1)(b)(iv)	~Ensuring information gathered for the program is reviewed and used to revise health care policies and procedures;	4	17-18
7	~WAC 248-50-020 (1)(b)(v)	~Reporting to the governing body, at least semiannually, on program activities and actions taken as a result of those activities	4	18-19
8	WAC 248-50-020 (1)(c)	Periodic evaluation of each provider under the purview of the program, including mental and physical capacity, competence in delivering health care, and verification of current	8 9 10 11	23-39 12-42 1-37 1-35
9	WAC 248-50-020 (1)(d)	A procedure for promptly resolving all complaints pertaining to accidents, injuries, treatment and other events that may result in claims of health care malpractice	19 20	31-40 1-7
10	WAC 248-50-020 (1)(e)	A method for continually collecting and maintaining information concerning:	20 21	9-46 1-35
11	~WAC 248-50-020	~Experience with negative health care outcomes and injurious incidents	20	9-46
12	~WAC 248-50-020 (1)(e)(ii)	~Professional liability premiums, settlements, awards, costs for injury prevention and safety improvement activities	21	1-35
13	WAC 248-50-020 (1)(f)	A method for maintaining information gathered under the purview of the program concerning a provider in that provider's personnel or credential file, assuring patient confidentiality	14	1-10
14	WAC 248-50-020 (1)(g)	A process for reporting accidents, injuries, negative health outcomes, and other pertinent information to the quality improvement committee	15 16 17 17 20	11-15 28-42 1-10 19-21 19-34
15	WAC 248-50-020 (1)(h)	A process assuring compliance with reporting requirements to appropriate local, state and federal authorities	15	5-25

	WAC #	WAC Requirement	Page	Lines
16	WAC 248-50-020 (1)(i)	A method for identifying documents and records created specifically for and collected and maintained by the quality improvement committee	5	19-20
17	WAC 248-50-020 (1)(j)	Educational activities for personnel engaged in health care activities, including, but not limited to:	11 12 13	37-39 1-44 1-40
18	~WAC 248-50-020	~Quality improvement	6 12	27-35 4-10
19	~WAC 248-50-020 (1)(j)(ii)	~Safety and injury prevention	12 12 13	11-18 43-44 1-40
20	~WAC 248-50-020	~Responsibilities for reporting professional misconduct	12 12	23-26 40-42
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1. INTRODUCTION

The Northwest Kidney Centers' Coordinated Quality and Safety Improvement Program (CQSIP) is designed to maintain and improve the quality and safety of all services. This CQSIP plan is a summary of that program's current and planned processes and activities. Its purpose is to ensure program alignment with Board of Trustee expectations, employee and patient needs, management responsibilities, regulatory requirements and the organization's overall strategic plan.

2. BACKGROUND, MISSION AND GOALS

a. Background

The Northwest Kidney Center (NKC) was originally established in 1962 as the Seattle Artificial Kidney Center, the first organization in the world established to deliver dialysis treatments outside of a hospital. Starting with three beds that served nine dialysis patients, NKC now provides dialysis services throughout King, Clallam, Pierce, and Snohomish Counties through its 20 outpatient dialysis clinics, a home dialysis support program and a hospital services program. The outpatient programs provide over 251,000 dialysis treatments per year for 1,825 patients who dialyze in one of our clinics or at home. The NKC Hospital Services Program is certified by The Joint Commission as a healthcare staffing agency and provides over 13,000 dialysis treatments per year to patients in nine hospitals in King and Snohomish Counties. NKC is currently among the 10 largest dialysis providers in the United States.

In addition to these direct service programs, NKC also operates an outpatient pharmacy, researches chronic kidney disease through the Kidney Research Institute (a collaboration with the University of Washington Department of Medicine), provides numerous community educational programs, and fosters philanthropic gifts to allow the organization to improve kidney care. NKC also collaborates with numerous other kidney care organizations through relationships with other nonprofit dialysis clinics, providers, hospitals and transplant centers, as well as through the Northwest Kidney Care Alliance, a federal CMS end-stage renal disease seamless care organization (ESCO), which functions as an accountable care organization focused on integrated care for people on dialysis. NKC is a founding member of the Northwest Healthcare Response Network, a collaborative emergency response program in Western Washington: a coalition of private and public partners working together to develop the relationships, plans and tools necessary for effective, coordinated

regional response to healthcare emergencies.

The hospital services program has a coordinated quality improvement plan (CQIP) approved by the Washington Department of Health in 2015. This current coordinated quality and safety improvement program CQSIP plan has been developed for all NKC programs and services, including the hospital services program. Going forward, the hospital services program will no longer have a stand-alone DOH approved CQIP.

b. **Mission**

The mission of the NKC Coordinated Quality and Safety Improvement Program (CQSIP) is to set, practice, and continuously improve upon the highest quality and safety standards for a continuum of services focused on individuals with kidney disease.

This supports NKC's overall mission to "promote the optimal health, quality of life and independence of people with kidney disease through patient care, research and education" as set forth in the organizations 2016- 2021 strategic plans (See

c. **Goals**

Among the organizational goals described in the strategic plan, are perform better and care better. These are supported by the goals of the CQSIP:

i. Perform Better in quality and safety. Be the region's leader in high-value healthcare services demonstrated by high quality and safety, exceptional patient experience, and competitive overall cost.
ii. Care Better through care model transformation and community health improvement.

Actions being taken to achieve these goals are summarized in a set of strategies and tactics that are reviewed and revised on an annual basis. See Attachment B for FY21 (July 2020-June 2021) strategies and tactics.

3. AUTHORITY AND ACCOUNTABILITY FOR QUALITY AND SAFETY

NKC has established a governance and committee/work group structure that supports the maintenance and improvement of quality and safety through clear lines of authority, accountability, reporting, decision-making and communications.

a. Governance and leadership

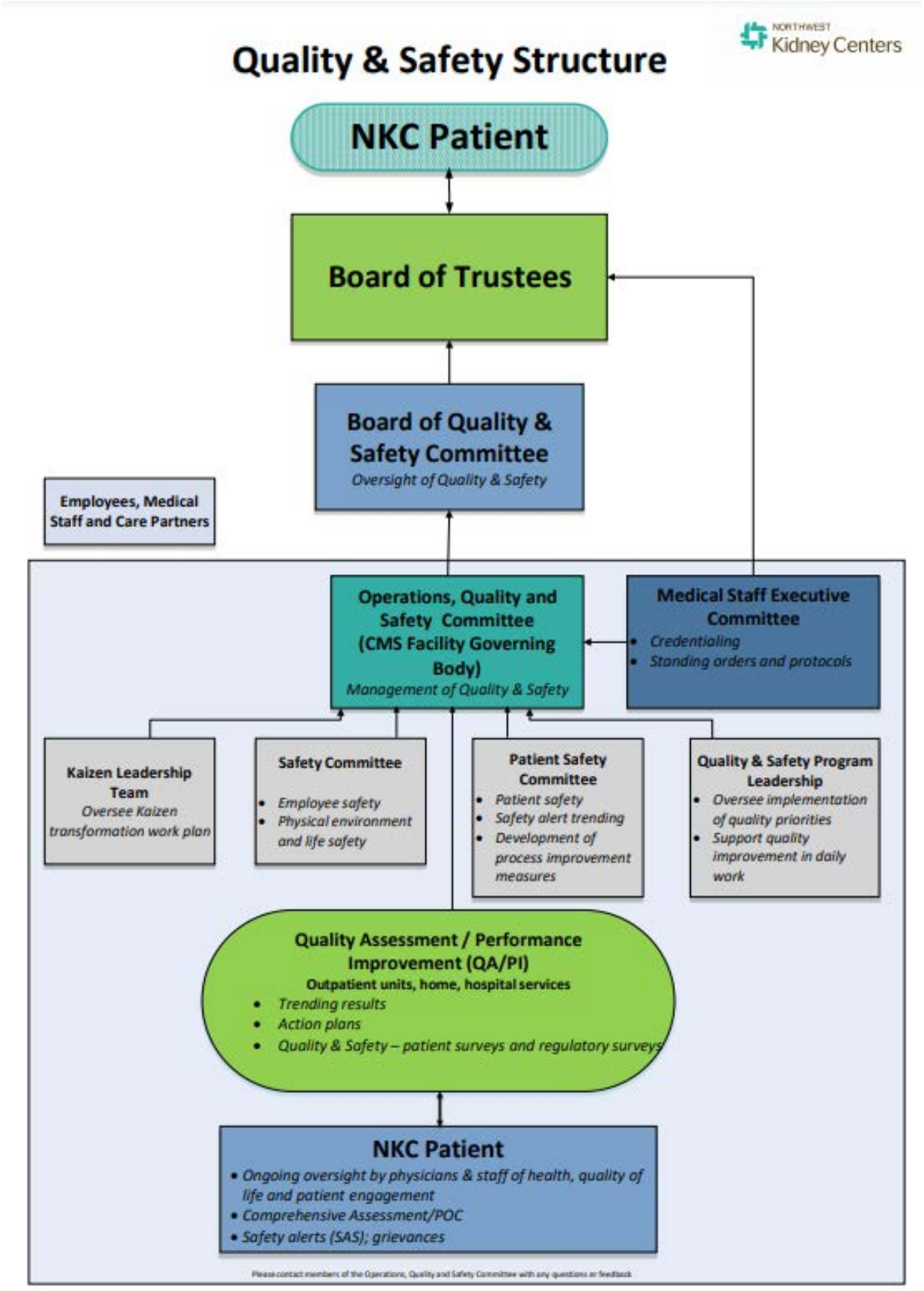
The Northwest Kidney Center's Board of Trustees has overall accountability for quality and safety within the organization. In support of this, the Board, per the organization's by-laws (see Attachment C, p. 9), established and authorized the Board Quality and Safety Committee as a standing committee. They play a central role in monitoring and improving the quality and safety of health care services provided. The Committee is chaired by a member of the Board of Trustees and consists of trustees, patients and quality and safety executives.

The Board of Trustees also authorized and designated the Chief Executive Officer (CEO) as the individual responsible for the implementation of the CQSIP. With support of the Board, the CEO or his/her designee leads the management of the Operations, Quality and Safety Committee (OQSC) as the focal point for the oversight and guidance of quality and safety activities within NKC. In addition to the CEO, the Chief Medical Officer and key physician, nursing and other executives and management, participate on the OQSC.

Internal quality and safety activities and programs report to the OQSC for review, guidance, and decisions. The OQSC then reports and makes recommendations to Board Quality and Safety Committee, as well as the full Board itself. Reporting to the Operations, Quality and Safety Committee are the Safety Committee, the Quality Assessment and Performance Improvement (QA/PI) Team from each clinic and program (currently 20 teams), the Medical Staff Executive Committee, and the NW Kidney Care Alliance. The Quality and Safety Program Leadership reports monthly to the OQSC. These are all shown in Figure 1 and described below

FIGURE 1

1


Quality & Safety Structure
NORTHWEST Kidney Centers
NKC Patient
Board of Trustees
Board of Quality & Safety Committee
Oversight of Quality & Safety
Employees, Medical Staff and Care Partners
Operations, Quality and Safety Committee (CMS Facility Governing Body)
Management of Quality & Safety
Medical Staff Executive Committee
Credentialing
Standing orders and protocols
Kaizen Leadership Team
Oversee Kaizen transformation work plan
Safety Committee
Employee safety
Physical environment and life safety
Patient Safety Committee
Patient safety
Safety alert trending
Development of process improvement measures
Quality & Safety Program Leadership
Oversee implementation of quality priorities
Support quality improvement in daily work
Quality Assessment / Performance Improvement (QA/PI)
Outpatient units, home, hospital services
Trending results
Action plans
Quality & Safety – patient surveys and regulatory surveys
NKC Patient
Ongoing oversight by physicians & staff of health, quality of life and patient engagement
Comprehensive Assessment/POC
Safety alerts (SAS); grievances
Please contact members of the Operations, Quality and Safety Committee with any questions or feedback

b. Roles and responsibilities in quality & safety

The clear roles and responsibilities of different committees and work groups greatly facilitate the tracking, reporting and managing of quality and safety throughout the organization. This structure empowers all employees to play a role in identifying improvement opportunities, communicating them to leadership and participating in the implementation.

i. Operations, Quality and Safety Committee (OQSC)

This management committee oversees and coordinates the organization's quality and safety program, and acts as the "facility governing body," as described in the CMS Conditions for Coverage for end-stage renal disease (ESRD). The OQSC functions to ensure the adequacy of all activities and programs related to quality and safety (see Attachment D for the OQSC policy).

The OQSC meets monthly and reviews quality and safety data/reports and information from a variety of sources. This includes information on performance and outcome metrics basic to the services provided, such as infection rates, catheter rates, safety issues and sentinel events. This also includes information on quality and safety initiatives, operational processes, and current action plans. Using this, the OQSC provides direction and guidance to improve the quality and safety of services delivered and health outcomes; it reviews recommendations received, adjusts policies and procedures, and implements programmatic changes. The OQSC reports key data and updates on activities to the Board Quality and Safety Committee, and often to the entire Board. Specifically, the OQSC does the following:

- Identify and oversee the clinical directors (identified by CMS as "facility administrators"), to whom they delegate numerous responsibilities related to quality and safety:
    - Oversight of processes relating to the quality assessment and improvement program
    - Implementation of the internal grievance process per policy
    - Compliance with patient discharge and transfer policies
    - Compliance with emergency coverage policies
    - Cooperation with the ESRD network and participation in ESRD network activities

- Allocate resources necessary for the Quality Assessment and Performance Improvement Program
- Review quality and safety metrics from throughout the organization, including those following both remediation and action plans

- Report on regulatory compliance and identified survey issues with corrective action plans as reported to the OQSC from the Clinical Director of Regulatory Compliance

- Implement all medical staff appointments and credentialing for physicians and their advanced practice practitioners after approval by the Medical Executive Committee and the Board of Trustees

- Communicate expectations to the medical staff regarding participation in improving the quality of medical care provided to patients

- Secure agreements with hospitals for emergency coverage

- Ensure data and information is provided to CMS as required

- Receive and take action upon recommendations from the ESRD network

- Provide resources (time, staff and/or funding) for audits, employee education, and direction to support correction of identified problems.

- Review information related to identified significant problems and their causes, and provide guidance and support for proposed needed corrections, including revisions to organizational policies and procedures

- Report on quality and safety issues to the Board Quality and Safety Committee at their bi-monthly meetings

The members of the Operations, Quality and Safety Committee are a mix of leaders who have a deep understanding of both clinical and administrative processes, access to key information, authority to make organizational decisions and can allocate resources to support those decisions. The committee membership is as follows:

- President and CEO
- Chief Medical Officer
- Chief Nursing Officer (Chair)
- Patient Safety and Quality Officer

- Vice President of Human Resources
- Chief Financial Officer

Minutes are taken at all OQSC meetings and housed on the organization's K-net system along with documents presented or reviewed at these meetings.

ii. Board of Trustees

The Board is made up of medical, business, civic and patient leaders who have fiduciary powers and accountability for the management and administration of NKC affairs, including quality and safety.

The quality & safety activities of the Board include:

- Review and approve the Coordinated Quality and Safety Improvement Program plan on an annual basis (this is delegated to the Board Quality and Safety Committee).

- Review quality and safety data and information, as presented by the Board Quality and Safety Committee and management. This includes key performance metrics, progress on the strategies and tactics of the CQSIP, and assessments of sentinel events

- Review and approve appointment/credentialing recommendations from the Medical Staff Executive Committee

- Incorporate consideration of quality and safety in Board decisions

iii. Board Quality and Safety Committee

This is a standing Board committee, chaired by a Board Trustee, that has a minimum membership of ten and meets at least six times per year. This Committee receives data and reports from the Operations, Quality and Safety Committee, provides guidance and direction and, in turn, reports key information to the entire Board of Trustees. In addition, this Committee participates annually in local education provided by WSHA and others regarding the board's role in quality and safety oversight.

The NKC bylaws (see Attachment C, p. 9) identify the responsibilities of the

Board Quality and Safety Committee to be:

- Oversee clinical performance of policies and programs regarding appropriate care, best outcomes and services in a safe and cost-effective manner

- Cause NKC to incorporate philosophy, methods and tools of quality to meet these goals

- Advise the Board on activities that affect clinical operations including compliance with regulations, standards of clinical practice, and satisfaction of patients, physicians and employees.

In addition, the Board Quality and Safety Committee annually reviews and approves the Coordinated Quality and Safety Program plan.

iv. Safety Committee

The Safety Committee, led by the organization's Safety Officer, is made up of management and non-management employees. This committee focuses on creating a safe environment for patients, employees and visitors, as well as is responsible for emergency preparedness. This ongoing basis, the Safety Committee provides data and recommendations to the OQSC and, on an annual basis, the Safety Officer prepares and presents a summary of Safety Committee achievements and planned strategies and tactics.

Specifically, the Safety Committee's focus is on:

- Evaluation of the employee, visitors or facility safety event investigations conducted to determine if the cause of the unsafe acts or unsafe condition(s) involved are properly identified and corrected.

- Evaluation of the employee safety event and illness prevention program and review of recommendations for improvement where indicated.

- Review of safety suggestions submitted by employees.

- Review of disaster drills including recommendations and actions.

- Review of safety surveys including recommendations and actions.

- Oversees the completion of the CMS required Emergency Management Plan

including Hazard Vulnerability Assessment for all units

v. Kaizen Process Improvement

Since August 2016 the organization has adopted a continuous performance improvement system named Kaizen (see strategic plan – Attachment A). Kaizen is continuous improvement with front line employee involvement. The intent is to standardize processes to reduce the burden of work, cut waste, support growth and improve quality and safety, of the patient experience. NKC has a senior process improvement consultant who works collaboratively with NKC Executives on FY21 tactics to improve quality and safety at NKC.

vi. Quality Assessment and Performance Improvement (QA/PI) Teams

Each clinic and program has a QA/PI team. These are interdisciplinary teams that provide performance data and work collectively towards measureable3 improvements in a patient's health and prevention of medical errors. Each QA/PI team meets monthly to analyze rotating patients, identify problem areas, conduct root cause analyses, identify and prioritize improvement, and develop, implement and evaluate a work plan for such improvement.

The QAPI team is responsible for regulatory compliance and preparedness for CMS and other surveys; in addition, they implement a response plan for citations which then may result in policy and programmatic changes throughout NKC. These efforts are led by the Clinic Medical Director and facilitated by the Nurse Manager (who is the "facility administrator"). Activities are reported to the Operations, Quality and Safety Committee, which reviews key findings and provides guidance and decisions as needed. In some cases, the improvements seen by one QA/PI team leads the OQSC to implement policy and programmatic changes throughout the organization.

vii. Quality and Safety Program Leadership

This group of leaders supports quality improvement in their daily work and oversees the implementation of quality priorities. For some of these priorities, specific task forces or Kaizen work groups are organized to research issues, determine root causes and identify, test and assess possible solutions. When a solution with measurable favorable results is identified, recommendations

for change and/or implementation throughout the organization are made to the OQSC.

viii. Medical Staff Executive Committee (MEC)

The medical staff consists of physicians and advanced practice providers (Advanced Registered Nurse Practitioners and Physician Assistants) who have admitting privileges to the clinics for their patients to receive dialysis services. They are led by the five-member Medical Staff Executive Committee (MEC), which is elected every other year by active medical staff members (active medical staff are those who are regularly involved in the care of five (5) or more NKC dialysis patients on a continuing basis).

Per the Medical Staff bylaws, the medical staff is "responsible for the quality of medical care provided at and through NKC." (see Attachment E, p. 1). Towards this end, specific activities of the Medical Staff Executive Committee include the following (see Attachment E, pp 34-35):

- Approve, review periodically, and modify standing orders utilized for patients followed by Medical Staff members

- Oversee pharmacy and therapeutic functions, including evaluation of appropriateness, safety and effectiveness of drugs administered or prescribed to patients

- Establish rules and policies pertaining to clinical and operational matters (including, without limitation, rules pertaining to matters such as credentialing, medical records documentation and confidentiality)

- Fulfill the medical staff's accountability for the quality of care provided to patients by undertaking and causing medical staff to undertake, ongoing quality assessment and improvement activities, including evaluation of performance data and implementation of quality improvement measures based upon the data, in compliance with applicable licensing, certification or accreditation requirements.

- Review the credentials of all applicants and make recommendations to the Board of Trustees on appointments, reappointments and delineation of privileges.

- Take all reasonable steps to ensure professionally ethical conduct and competent clinical performance on the part of medical staff physicians and other practitioners

- Initiate and participate in peer review and corrective action activities, which include recommending, implementing and enforcing disciplinary action as warranted

- Participate in organizational performance improvement activities

- Represent and act on behalf of the medical staff, as well as Implement the bylaws, rules and policies of the medical staff

- Make recommendations to the Board of Trustees, based on reports of subcommittees or ad hoc groups, or as deemed necessary

ix. NW Kidney Care Alliance

NKC participates in the NW Kidney Care Alliance, an ESRD Seamless Care Organization (ESCO) set up as a Medicare demonstration accountable care organization. This is a group of health care organizations, physicians and other health care professionals who work together to collaborate, share information and provide better-coordinated care for patients. The aim is to improve the patient's experience of care and reduce the total cost of their healthcare. Through the NW Kidney Care Alliance, NKC conducts and shares data analyses and collaborates with Alliance partners on quality and safety improvement activities. This program is set to expire on March 31, 2021.

4. THE QUALITY AND SAFETY PROGRAM

Quality and safety are built into all NKC clinical and managerial activities, and the program itself has numerous components. Those activities that have a direct or indirect impact on patient care are designed and monitored to ensure the organization functions at the highest levels of quality and safety possible. This includes clinical activities of care delivery, patient interaction, and documentation, as well as management activities such as hiring, credentialing, training, and performance reviews.

a. Hiring

Quality and safety start with people. NKC takes great care to hire employees who are capable and willing to understand and adhere to high levels of quality and safety in all they do. Administrative and employed clinical employees are hired following a standard application and hiring process (see Attachment F). To hire the most qualified candidates, the process starts with management collaborating with Human Resources (HR) to understand job requirements and qualifications, review and update the job description, complete an employment requisition, post the position, receive applications from internal and external candidates, as appropriate, and screen applications/resumes. Interviews are scheduled with select candidates and conducted by HR, the hiring manager and, as needed, a team. Background checks are conducted on all candidates interviewed and references are checked for position finalists. Clinical employees, such as dialysis nurses and technicians, undergo a thorough credentialing process. The hiring director, manager or supervisor has ultimate responsibility for making a hiring decision.

The clinic Medical Director candidates must be members of the medical staff in practice as nephrologists. Candidates respond to a position posting, go through a

reference check and are interviewed by the CEO, CMO, Clinical Director and others as needed. The CMO has ultimate responsibility for making the hiring decisions. The initial compensation of a clinic Medical Director is approved by a group of disinterested parties, which is the Board of Trustees.

b. Medical Staff appointments

To admit patients to an NKC clinic for dialysis, providers must be appointed to the medical staff. There is an application process that includes in-depth credentialing. Applicants are reviewed by the CMO and then considered by the Medical Staff Executive Committee (MEC) at their monthly meeting. The MEC makes recommendations to the Operations, Quality and Safety Committee and also to the Board of Trustees. The OQSC, and then the Board, subsequently take action to approve or deny the appointment. Initial appointments to the Medical Staff consist of a three year period. Re-appointment, including re-credentialing occurs every three years. (See Attachment E, Articles V, VII and VIII of the Medical Staff bylaws and Attachment G for the medical staff credentialing application)

c. Credentialing and re-credentialing

Verifying credentials prior to hiring clinical employees is a key process related to quality and safety. Both hired clinical employees and appointed medical staff undergo a credentialing process prior to starting work at NKC.

i. Hired Clinical Employees

With the exception of Dialysis Technicians, all clinical employees who require licensing or certification by state agencies and/or ESRD Medicare regulations, must have their credential prior to hiring. Dialysis Technicians may be hired conditional, upon participation in NKC training and submitting an application for the Washington State certification, after completion of NKC orientation program. Additionally, Dialysis Technicians must be nationally certified within 17 months of the date of hire. All clinical employees are required to keep their credential status current and in effect. Failure to do so could lead to termination.

Other credentialing background and credentialing information includes valid identification, education and work history, criminal background checks and other relevant information. (See Attachment H for the employee credentialing policy).

Human Resources maintains a file that includes name, credential, credential number and state, and credential expiration date of each employee holding a professional license.

ii. Medical Staff

Physicians undergo an extensive credentialing process as outlined in the Medical Staff bylaws (see Attachment E, Article V). This includes the following:

- A current, valid, license to practice in the State of Washington;
- A current valid DEA license;
- Training and experience relevant to dialysis;
- Current professional competence, as determined by the Medical Staff Executive Committee;
- Physical and mental health adequate to exercise the privileges requested;
- Minimum $1M/$3M medical professional liability with an insurer deemed satisfactory by a delegate of the Board of Trustees;
- A record free of felony convictions related to or impacting patient care and any exclusion from Medicare, Medicaid or any other federal health care program;
- Physicians may be exempt from this requirement at the discretion of the Medical Staff Executive Committee
- Other qualifications and conditions deemed by the medical staff to be relevant.

iii. Advanced Practice Providers (APP's and PA's)

APP's are credentialed using a set of requirements very similar to those of medical staff physicians, which are detailed in the Medical Staff bylaws (see Attachment E, Article VIII). Full credentialing must be completed before the APP is allowed to see patients in NKC facilities. APP's without previous dialysis experience are required to provide evidence of dialysis education six months after initial credentialing. Until that time, APP's are granted "temporary" provisional privileges that includes limitations on their activities at NKC.

d. Performance reviews and corrective actions

Ongoing performance evaluations are an important component of the quality and safety program. They provide a formal opportunity for discussions in which high quality and safety practices are identified and reinforced. At the same time, they are an opportunity to identify concerns about quality and safety and how they may be improved.

i. Administrative and Clinical Employees

NKC recognizes the importance of formal performance evaluation sessions, as well as informal feedback conferences between supervisors and employees. NKC requires that all employees receive regular performance evaluations. Factors considered in performance evaluation include, but are not limited to: the quality, safety and quantity of work; attendance; job knowledge; initiative; clinical competency and the employee's ability to work with others (see Attachment I for the performance evaluation policy).

As appropriate for each position, evaluations may include consideration of competencies in specific activities or techniques where quality and safety are of great importance, such as:

- New or changing policies, procedures and technologies.
- Infection control / blood borne pathogen (OSHA)
- Water quality
- Fire Safety
- Body mechanics
- Hazardous chemicals
- National patient safety goals (Joint Commission)
- Age specific competencies
- Hemodialysis emergencies
- Clinical skills checklists

- Validation of licensure, registration, and certification (where applicable)

- Validation of biennial BLS certification (Healthcare Provider)

- Health screening for tuberculosis

A written performance evaluation is given to each employee by his/her supervisor at the end of the employee's probationary period and at each annual anniversary date. Clinical employees also have an assessment of their clinical competency as part of their annual evaluation. Additional written evaluations may be given at other times as deemed necessary by the supervisor or as requested by the employee. The original evaluation is maintained by Human Resources in the employee's personnel file.

When an employee fails to perform job duties in a high quality and safe manner, or engages in a practice inconsistent with established policies, or ordinary, reasonable or common-sense rules of conduct, NKC responds with required disciplinary action. (see Attachment K). This is a progressive process that may include a verbal warning, written reprimand, written warning, suspension without pay, and termination. Steps may be skipped based on the severity and/or frequency of infractions when immediate action, up to and including termination, are warranted.

ii. Medical Staff

The Medical Staff bylaws outline an approach for performance improvement and corrective actions. (see Attachment E, Article IX). Practitioners granted Medical staff membership are subject to evaluation based on Medical Staff peer review, or external review if deemed appropriate by the Medical Staff Executive Committee (MEC). Such evaluation results may be used in recredentialing, performance and system improvement, and when warranted, corrective action.

Any person may provide information to the MEC about the conduct, performance, or competence of any practitioner. When reliable information indicates that the activities or professional conduct of any practitioner are not consistent with the standards of the Medical Staff or are unethical,

unprofessional, disruptive to NKC operations, or detrimental to patient safety or the delivery of quality patient care,
investigation or remedial action or corrective action may be requested by any Medical Staff member, Board of Trustees member, the CEO or CMO. In such cases, the MEC follows a formal process that includes investigation, an interview with the Medical Staff member in question, and determination of appropriate remedial and/or corrective action.

This is all communicated to the Board of Trustees. If the MEC declines to act when the Board feels it should, the bylaws provide for a conflict resolution process, after which the Board may take action. NKC also will provide medical staff with performance "dashboards" twice a year, through which they can assess their quality outcomes for their patients' performance and compare with that of their peers on the medical staff.

e. Training and education

NKC has an extensive training and education program for both administrative and clinical employees, as well as Medical Staff. Quality and safety are a key focus of initial and ongoing training/education.

i. Training and Education Focus

Employee training and education includes some specific topics related to quality and safety that receive particular attention:

- *Quality improvement*: Much of the quality improvement training takes place during clinic quality assurance and performance improvement (QA/PI) monthly meetings. This is when clinic staff review monthly statistics, identify opportunities for improvement and make action plans. In many cases, the action plans include an educational component. The Clinical Director of Quality Initiatives is very often involved in these sessions and brings in quality improvement concepts and tactics. NKC has also introduced Kaizen methodologies as an approach to teach and practice process improvement for both administrative and clinical processes and workflows.
- *Safety and injury prevention*: The orientation for new employees includes presentations from the Safety Officer on both safety and injury prevention and overviews of emergency/disaster preparedness. There are also presentations from nurses on employee and patient safety and injury prevention during the provision of clinical services. When there is an ongoing safety issue identified on the

Safety Alert System (SAS) that indicates the need for additional employee training, The Clinical Director of Quality Initiatives is responsible for conducting follow-up to provide information or conducting training sessions. In addition, clinical employees learn safety and injury prevention in hands-on, one-on-one training with preceptors during an intensive 8-week job skills training.

- *HIPAA and patient confidentiality*: Orientation for new employees includes a presentation from the Compliance Officer about HIPAA and confidentiality policies. Each year, all employees are required to take an online course on these topics through the online learning system Relias Learning. The HIPAA training includes testing for knowledge and understanding.
- *Compliance and reporting*: Orientation for new employees includes a presentation from the Compliance Officer on such legal and compliance topics as conflict of interest, CMS fraud, waste and abuse, as well as reporting information about breeches and professional misconduct. This also retaken annually by all employees using the online Relias learning system.
- *Communicating with patients*: There is ongoing training available on patient communications. NKC has a contract with a behavioral health specialist which provides mandatory training on such topics as trauma informed care behavioral/mental health and communicating with respect and professionalism with all patients. In addition, there are educational sessions offered or available on professionalism that include working and communicating with patients.

Training on these topics not only helps employees function well on their jobs, but also helps them identify and avoid actions and situations that could lead to liability risks and malpractice claims.

ii. Administrative and Clinical Employee Orientation

All new employees, regardless of position, participate in a mandatory three-day orientation. This NKC education includes information on the following:

- *Administrative topics*, such as: the employee handbook, introduction to units, job roles, professionalism and time clock expectations, etc.
- *Compliance and regulatory topics*, such as: HIPAA and

protection of personal health information, conflicts of interest, fraud, waste and abuse, etc. This includes a review of policies and procedures, as well as case study discussions.

- *Quality and Safety topics*, such as: hand washing, employee and patient safety, blood borne pathogens, additional infection control and prevention topics, emergency preparedness, etc.

iii. Clinical Employee In-depth Training and Continuing Education

In addition to the mandatory three-day orientation, nurses and dialysis technicians participate in an eight-week in-depth training specific to the provision of high quality and safe dialysis services and kidney care. This is a combination of classroom education and "on the job" training in the unit by preceptors. Depending on prior training and experience, this in-depth training may be modified for specific employees. This training also varies depending on where the employee provides care: clinic, home or hospital.

Both nurses and dialysis technicians require ongoing continuing education credits to retain their clinical credentials. NKC supports this through providing on-site continuing education with contact hours, Paid-Time-Off (PTO) for education, as well as registration support for each employee to attend local off site meetings each year.

iv. Medical Staff

Medical staff are well trained and experienced nephrologists and advanced. When they start work at NKC, they have an orientation that addresses medical staff policy and standing orders as well as administrative topics (e.g., computer usages, bylaws, etc.). When they are appointed by NKC, the credentialing process includes an attestation that they have received HIPAA, patient confidentiality and other compliance training. On an ongoing basis, the Chief Medical Officer provides education sessions on clinical topics at medical staff meetings, many of which touch on quality and safety for patients.

For those medical staff members who serve as clinic Medical Directors, there is a more detailed onboarding process that includes a

review of policies, the QA/PI process and water treatment purification. At each monthly meeting of Medical Directors there are topics relating to quality and safety, including case studies, sentinel event reviews, and clinical protocols are discussed.

v. New Managers and Supervisors

Whether new to NKC or promoted from within, and whether the person does or does not have dialysis experience, there is training for all new managers and supervisors. This includes education on a host of administrative, clinical, quality and safety topics. Specific to quality and safety, new managers and supervisors receive training in such topics as:

- The role of Patient Safety and Quality Officer
- CMS 5 STAR quality rating and Quality Incentive Program (QIP)
- Quality improvement reports on intranet
- Infection control
- Quality Assessment and performance improvement processes (QA/PI)
- Safety Alert System
- TB testing, notification and guidelines
- Needle stick and blood/body fluid exposure

In addition, new managers/supervisors meet one-on-one with leaders throughout the organization to learn about their roles, services they provide and quality/safety in their areas.

f. <u>Personnel and credentialing file maintenance</u>

Each employee has a personnel file maintained in the Human Resources department. These files contain information collected during the hiring process, including information gathered on clinical employees during credentialing. Information includes performance evaluations, re-credentialing, and corrective actions and other relevant activities, are kept in these files.

Medical Staff members and AHPs each have a credentialing file maintained in the MD Staff System. Information about performance evaluations, credentialing, corrective actions and other relevant activities, are kept in MD Staff. Clinical managers have personnel files that contain annual skill competency reviews

assure knowledge and skill competencies. An employee health record is maintained on every staff member to assure compliance with vaccinations, color blindness and testing requirements for any exposures.

g. Monitoring and reporting quality and safety metrics

Key to NKC's quality and safety program is the ability to identify, track, and report on performance and outcome metrics. There are systems and processes in place to monitor those data points that directly or indirectly indicate the organization's level of success in managing quality and safety.

i. Key quality & safety metrics

Many of NKC's metrics were determined by the Centers for Medicare & Medicaid Services (CMS) to measure and report the quality of renal dialysis services provided under the Medicare ESRD program. Since 2012, ESRD programs have operated within a value based payment program, with a penalty for all payments if quality thresholds are not met; this is called the CMS Quality Incentive Program (QIP). For each payment year under the QIP, CMS sets updated rules related to the measures selected and thresholds to be met.

For payment year 2018, these were the measures:

> Adequacy of Dialysis, Hypercalcemia, Vascular Access, Infections, Readmissions, Transfusions, Patient Engagement Survey Results, Depression and Pain Assessment, Healthcare Worker Immunization, and reporting mineral metabolism and anemia measures.

CMS has also identified for QA/PIs specific quality indicators or performance measures associated with health outcomes and prevention/reduction of medical errors. Each clinic or program must measure, analyze, and track quality indicators or other aspects of performance that are adopted or developed to reflect processes of care. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. The metrics must include, but not be limited to, the following:

- Adequacy of dialysis
- Nutritional status
- Mineral metabolism and renal bone disease

- Anemia management
- Vascular access
- Medical injuries and medical errors identification
- Patient satisfaction and grievances
- Infection control
- Water and dialysate quality and safety
- Safe machine maintenance
- Regulatory citations

In addition, NKC develops quality metrics that are important to the organization. Examples include infections, blood pressure, bone/mineral, transplants, and mental health competency training.

ii. Monitoring and Reporting

Quality and safety data are captured from multiple sources. The electronic medical record (EMR) and the online Safety Alert System (SAS) are 2 primary sources of data. In addition, NKC is surveyed by CMS on a routine basis. The hospital services program is also reviewed by The Joint Commission and WA State DOH as part of a hospital survey.

Outcome and performance data are regularly reviewed by clinic employees in the QA/PI process and reported to the Operations, Quality and Safety Committee. Safety data is reviewed by the Safety Committee, which also provides information to the Operations, Quality and Safety Committee. As appropriate, the OQSC provides summary level information, as well as specific information on sentinel events, to the Board Quality & Safety Committee and as appropriate to the entire Board of Trustees.

Processes are also in place to meet the reporting requirements of governmental and regulatory agencies. This includes ongoing reporting to CMS as required by the Conditions of Coverage through a system called CROWNweb. In addition, there are policies related to reporting events to specific agencies as needed. Some examples include:

- Infection control surveillance and reporting of communicable diseases to Public Health - Seattle & King County (i.e., the health department)

- The medical device incident reporting to the FDA of an unexpected death while using dialysis equipment
- Tracking and reporting of clinic operations and patient access to treatment during emergency events as required by CMS (reported through the NW Regional Network).

h. Data security and patient confidentiality

NKC is committed to the highest level of patient confidentiality and strives to ensure the organization meets all HIPAA requirements.

Systems used to secure patient information are all HIPAA compliant. They include:

- Clarity by Visonex – the electronic medical record (EMR)
- SAS – The safety alert system used to capture safety incidences
- Encrypted secure email option when Personal Health Information (PHI) is sent within the organization
- The hospital medical record, accessed by the hospital services employees in each respective hospital

When there is a specific quality or safety incident, communications are protected using the SAS and secure email. For reports, data is aggregated and personal information de-identified. There are also policies related to password protection of Word documents and Excel files containing sensitive information.

Employees are trained in privacy and HIPAA law (see Attachment K). All employees also sign a Confidentiality Policy, (see Attachment L), which states "As an individual having access to confidential information, you are required to conduct yourself in strict conformance with applicable laws and NKC policies governing confidential information."

It is also policy to appropriately and legally acquire, store, manage, access, use and disclose Protected Health Information (PHI) in a manner that at all times maximizes the security of the information and preserves the privacy of our patients.

PHI may only be accessed by, or disclosed to:

- Other healthcare providers / caregivers who require specific information to safely and effectively perform their tasks;

- Other healthcare providers or insurance companies involved in securing payment for healthcare services;

- Other employees who must use PHI to measure or monitor overall quality and outcomes in a care environment

- Others as legally required

i. Quality assessment/performance improvement activities

The QA/PI teams at each clinic and within the home and hospital programs are a major component of the organization's quality and safety program. There are currently 22 of these local interdisciplinary teams: 20 outpatient clinics, 1 home dialysis and 1 hospital services team. Their major objectives are to work towards measurable improvements in health outcomes and prevention/reduction of medical errors. (See Attachment M)

The Medical Director of each clinic's program leads the monthly QA/PI meeting at which performance metrics are reviewed to assess problem areas, conduct root cause analyses, prioritize improvement opportunities and make/execute action plans to bring about improvement. They do this through a review of standard performance metrics used throughout the organization, as well as through metrics they decided as a team warrant review. In their analyses of the data they can compare themselves to other NKC locations to help identify problem areas.

Each QA/PI team has the authority to make changes needed to improve quality and safety of their program. Changes of significance are presented to the Operations, Quality and Safety Committee to ensure overall organizational standards and processes are maintained and to identify when a change should be considered for implementation organization-wide.

j. Addressing and taking action on quality and safety concerns

Through the process of continuously monitoring and reporting on quality and safety metrics, employees at all levels may identify concerns and initiate a process of addressing them. This can be done through a variety of different paths. Some of the predominant paths to taking action on quality and safety concerns are as follows:

i. The quality assessment and performance improvement (QA/PI) activities at each location are used to identify and address issues at the clinic/program level. Each location can make improvements as deemed appropriate. Information on findings and successful improvements is reported to the Operations, Quality and Safety Committee and senior management to determine whether such improvements should be made throughout all locations.

ii. The Safety Alert System (SAS) can be accessed throughout the entire organization and is used to report safety issues and concerns. When an issues/concern is entered, the system automatically notifies key leaders within minutes who then determine the appropriate course of action based on the severity and topic

iii. Employees at all levels are encouraged to report quality and safety concerns to their managers, who then determine how best to address them.

iv. For quality issues that require significant research to define, or innovative approaches to address, Leadership may convene a Quality Task Force that works under the direction of the Patient Safety and Quality Officer in collaboration with the CNO and CMO

v. Quality and Safety concerns that are raised to the Operations, Quality and Safety Committee are addressed by the Committee, which determines a course of action and assigns appropriate resources to make improvements.

vi. Patients are encouraged to report quality and safety concerns. They have multiple options: discussion with clinical employees, clinic manager, medical director, clinical director, social worker and ombudsperson (Director of Quality of Life Services). Grievances may also be reported to the Northwest Renal Network or Department of Health.

k. Infection control

Infection control is the highest priority quality concern at NKC. Efforts to manage infection rates are continuous and ongoing, rather than viewed as one time projects. Infection control is included in employee training, a required topic in each clinic and program's monthly QA/PI session, and captured in numerous policies and procedures. There are over 25 infection control policies that touch on topics such as handwashing, droplet precautions, working with Hepatitis B and labeling of contaminated equipment.

Infection control is a high priority in both internal and external performance audits. Problems, when identified, are quickly addressed through development and implementation of action plans. Progress on these action plans are often monitored by the Operations, Quality and Safety Committee, depending on the severity of the issue.

The infection prevention program outlines a full scope approach to preventing infections and addressing them appropriately when they occur. The Infection Prevention Officer is the primary resource for employees and medical staff. In addition, an Infectious Disease Advisor is available for consultation.

l. Practice guidelines

Practicing with widely tested guidelines and procedures is believed to enhance the overall quality and safety of patient care.

Registered nurses employed by Northwest Kidney Centers Hospital Services must follow the Washington State Nurse Practice Act, which is found in the Revised Code of Washington (RCW) Chapter 18.79. Dialysis Technicians employed by Northwest Kidney Centers Hospital Services provide dialysis treatments under the supervision of a Hospital services RN and must follow the RCW 18.360.050. All Hospital Services policies and procedures are written and /or revised in accordance to the appropriate RCW.

NKC has numerous policies that provide guidelines on how specific procedures should be completed. Examples include procedures for:

- Needle insertion
- Catheter uncoupling
- Catheter dressing change
- Completing the diabetic foot examination
- Administration of specific medications

NKC's Education Department is responsible for preparing, adapting and modifying procedures to meet best practices, and for educating all clinical employees about relevant practices.

m. Disaster/emergency management

The Safety Officer works to prepare all employees and medical staff for potential emergencies and disasters. This includes the following activities:

- Development of protocols that informs on what actions to take, how to behave and who to contact for specific situations (e.g., earthquake, fire, etc.). This is made accessible to all employees and medical staff in each clinic in the "orange emergency disaster book."
- Ongoing clinic risk assessments to identify potential issues that could create, or inhibit response to, an emergency.
- Implementation of mock emergency drills in every location and participation in regional drills (i.e., Cascadia rising).
- Emergency preparedness training, which begins during new employee orientation and is ongoing
- Annual review of CMS required Emergency Preparedness Plan and unit specific Hazard Vulnerability Assessments.
- Regular audits of environmental risks at every NKC clinic and building

In addition, patients in the clinics are taught how to disconnect themselves from dialysis machines should it need to be done quickly in an emergency. Patients are informed about seasonal risks of storms and how to use the emergency diet if they cannot reach their dialysis clinic for their regular treatment.

As a member of Northwest Healthcare Response Network, NKC participates

in forums, planning sessions and drills with hospitals and others to prepare for emergencies.

o. Quality & safety in research studies

All research using NKC resources, patients, their families and caregivers, and information are coordinated through the Kidney Research Institute (KRI), a collaboration between NKC and the University of Washington. NKC research policies comply with national regulations regarding human subjects.

The NKC policy on research (see Attachment N) provides specific guidance on factors related to the quality and safety of patients and patient information involved in research studies:

- Institutional oversight and coordination
- Research approvals
- Compliance with national regulations regarding human subjects
- An Operations coordinating group
- Communications about research
- Research collaboration and data use
- Participation of an NKC nephrologist who is a credentialed member of the Medical Staff
- Appropriate investigators and research staff
- Study recruitment and consent
- Documentation
- Finance

The Kidney Research Institute (KRI) maintains a registry of patients who have consented to having their medical records reviewed and used. Patients who decline to participate will not have their medical records used for this purpose. There is no discrimination in treatment or service based on participation or non-participation. Patients have the right to withdraw consent at any time without repercussion.

5. QUALITY AND SAFETY IMPROVEMENT

Throughout NKC's quality and safety program, there is a strong emphasis is on improvement. Information is not only monitored, but also acted upon as appropriate to make care better. This includes taking action on

improvement opportunities identified through tracking of performance metrics, negative events such as safety events and injuries, patient feedback, root cause analyses, and audits. Improvement is also sought by making this CQSIP plan available to all management and employees (on the intranet) and by assessing performance
against the plan's goals, strategies and tactics on an annual basis.

a. Complaints and grievances

NKC has a complaint/grievance policy and process (see Attachment O) that applies to patients, family members, visitors and others. This policy is provided to each patient, documented in the medical record, and reviewed with patients on an annual basis. This policy includes information on how to file a complaint either internally or to external regulatory agencies, and that patient confidentially with be maintained.

When complaints are received, the unit or department manager is responsible for investigation, documentation resolution and follow-up. If that manager is a party to the complaint, these activities are reassigned to that person's immediate supervisor. This process is to be completed, with a written response to the person who filed the complaint, within 15 business days and fully documented in the quality improvement reporting system. There is an escalation process should the complainant be dissatisfied with the outcome.

Complaints/grievances are assessed based on a severity index. They are reviewed at the clinic level in the QA/PI meetings. Those that are most severe are reviewed by the Operations, Quality and Safety Committee. If the response to a complaint requires legal input (e.g., may result in a malpractice claim), the Risk Officer contacts external legal counsel. NKC has an ombudsman to coordinate patient complaints and grievances on behalf of the patients. Depending on the nature of the complaint and if it is related to a specific employee or provider, information about the complaint may be held in that employee's personnel file or a physician's credentialing file.

b. Sentinel events

If there is an unexpected occurrence that involves death or serious physical or psychological injury, or risk thereof, NKC initiates a sentinel event analysis (see Attachment P) that is led by the Patient Safety and Quality Officer. This involves an investigation and categorization of the root causes of events

that impact patient or employee safety, health, quality care or environment. A sentinel event root cause analysis template is used to ensure a structure to the analysis approach and that it is thorough and complete. The goal of the process is to ensure that a preventable adverse event or risky chronic problem does not reoccur. The sentinel event root cause analysis process focuses on systems and processes, not individual performance. This can lead to quality and safety strategies implemented across the entire organization. Sentinel events are used in case reviews with Medical Directors for education and improvement.

Sentinel event root cause analyses and action plans are reviewed in depth by the Operations, Quality and Safety Committee and the Board Quality and Safety Committee. The event is "open" until the Board Quality and Safety Committee deems that the action plan is complete and gains sustained; then it is "closed". The Board of Trustees receives a summary report of each sentinel event at their regular meeting.

c. Safety events and injuries

NKC has procedures in place for safety events and injuries to both patients and employees. These include actions that should be taken, as well as how an incident is reported and investigated. The safety alert system (SAS) is used to record safety events and injuries so they can be appropriately investigated, reported and resolved (see Attachment Q). It is also used to identify needed safety event and injury prevention improvements. The SAS system automatically notifies key administrators of an incident and management is required to note assessment and actions in response. The Patent Safety and Quality Officer reviews SAS reports daily as part of their standard work. Weekly SAS trends reports are sent to the CNO and CMO and shared with the executive leadership and OSQC for oversight and response. The Administrator on Call (AOC) is available to respond 24/7 to any employee who requires assistance with safety events and injuries as well as other unexpected organizational events.

The most common patient safety events relates to falls. For these, NKC has a guideline for employees to respond (see Attachment R) as well as a specific protocol for employees to evaluate the "pathway" of interventions that occurred; this is for the specific purpose of quality improvement.

d. Audits

NKC conducts regular internal audits of facilities and programs, and are subject to unannounced external regulatory audits. The most common audit is the CMS survey conducted for CMS by the Department of Health; or a deemed status organization these are unannounced and are routinely conducted every three years or when a patient compliant has been lodged with DOH. When issues are identified through these audits, action plans are quickly developed and implemented. The corrective action plan is prepared by the Clinical Director of the clinic. The Operations, Quality and Safety Committee is responsible for compliance with all laws and regulations and ensures follow up to audits.

e. Professional liability, costs and awards

The Risk Management Officer is responsible for striving to ensure the organization limits and manages avoidable risks, educates employees about risk management, has appropriate liability protection, and tracks any settlements and awards.

i. Liability protection

Employees acting within the scope of their duties at Northwest Kidney Centers are covered by a liability policy that protects them against suits for malpractice, personal injury or property damage on or away from the premises. This includes coverage for the management activities of contracted clinic Medical Directors.

NKC also provides an umbrella directors' and officers' liability policy for Board members and members of Board Committees.

NKC provides medical professional liability (i.e., malpractice insurance) coverage for employed physicians through the Physicians Insurance Company. The contracted medical directors are covered under their own malpractice insurance. All contracted and appointed physicians on the Medical staff are required to be covered by a malpractice policy of at least $1M; this is validated during the credentialing process.

ii. Costs for injury prevention and safety improvement activities

NKC has a strong focus on quality and safety that is accompanied by a structure of distributed accountabilities and responsibilities. As a result, direct and indirect costs of injury prevention and safety improvement activities are not tracked in aggregate as a budget line item. A great deal of what is done in program administration, clinic management and delivery of clinical services relates to injury prevention and safety improvement; it is not of value to quantify it on an organizational level.

Instead, NKC has the ability to track costs associated with specific prevention and improvement activities. Through the Safety Alert System (SAS), the organization is notified of injury and safety concerns. Once an issue is logged in SAS, the system requires follow-up actions to be monitored and will not allow an issue to be "closed" until the actions and resolutions are recorded. With this information, the direct costs of a specific prevention or improvement activity can be monitored
though a review of accounts payable records and capital/operational budgets. Monitoring indirect costs would be a significant challenge.

iii. Settlements and awards

The risk management officer, who sets guidelines to mitigate risks and investigates liability risks to the organization, holds the risk management files and tracks all settlements and awards.

f. CQSIP plan evaluation, update and availability

It is intended that the CQSIP plan be a "living" document used not only to educate new and existing stakeholders on quality and safety activities, but also to serve as a guide for those activities.

The Operations, Quality and Safety Committee will review the Plan on an annual basis in late spring and update as needed as part of preparations for the next fiscal year. This evaluation is to include consideration of, at minimum, the following:

- Effectiveness at supporting and enhancing the Quality and Safety Improvement Program

- Progress towards attainment of the program's missions, goals, strategies and tactics

- Accuracy in representing the current state of the program, as well as an aspirational view of where the program should go

- Alignment of both the organization's and program's missions, goals, strategies and tactics

- Alignment with WAC 246-50-020 the Washington Department of Health's guidelines for a Coordinated Quality Improvement Program Plan

- Updates to the annual strategies and tactics

This Plan is posted on the NKC intranet (K-net) where all employees and medical staff have access to read it and provide feedback.

Attachments

A. NKC Strategic Plan
B. CQSIP Plan FY18 Strategies and Tactics
C. NKC bylaws
D. Operations, Quality and Safety Committee (facility governing body) policy
E. Medical Staff bylaws sections related to quality, safety, hiring & credentialing
F. Employee application and hiring process policy
G. Medical Staff credentialing application
H. Employee credentialing policy
I. Performance evaluation policy
J. Progressive discipline policy
K. Privacy - Staff Training
L. Confidentiality Policy and Agreement
M. QA/PI Policy
N. Research Policies
O. Complaint/Grievance policy
P. Sentinel event and root cause analysis policy
Q. Safety Alert (SAS) and process improvement policy
R. Patient found down policy