



DNV GL - HEALTHCARE

HIP & KNEE REPLACEMENT CERTIFICATION (HKRC) REQUIREMENTS

Revision 16.0

Table of Contents

USE OF DNVGL- HEALTHCARE HIP AND KNEE REPLACEMENT PROGRAM CERTIFICATION REQUIREMENTS 3

INTRODUCTION 4

ABBREVIATIONS 6

QUALITY MANAGEMENT SYSTEM (QM) 7

 QM.1 QUALITY MANAGEMENT SYSTEM..... 7

 QM.2 QUALITY OUTLINE/PLAN 7

 QM.3 QUALITY OBJECTIVES 7

 QM.4 QUALITY REPRESENTATIVE..... 7

 QM.5 DOCUMENTATION AND PROGRAM REVIEW 8

 QM.6 SYSTEM REQUIREMENTS..... 8

 QM.7 MEASUREMENT, MONITORING, ANALYSIS..... 8

 QM.8 PATIENT SAFETY SYSTEM 9

PROGRAM MANAGEMENT (PM) 9

 PM.1 TOP MANAGEMENT..... 9

 PM.2 TOP MANAGEMENT COMMITMENT 10

 PM.3 PROGRAM LEADERSHIP 10

NURSING SERVICES (NS) 11

 NS.1 NURSING SERVICES..... 11

STAFFING MANAGEMENT (SM) 11

 SM.1 PERSONNEL (GENERAL) 11

 SM.2 COMPETENCE, TRAINING AND AWARENESS..... 11

 SM.3 DETERMINING AND MODIFYING STAFFING..... 12

 SM.4 JOB DESCRIPTION 12

 SM.5 ORIENTATION..... 12

 SM.6 STAFF EVALUATIONS 12

PATIENT RIGHTS (PR) 13

 PR.1 PATIENT RIGHTS 13

 PR.2 ADVANCE DIRECTIVE 13

 PR.3 LANGUAGE AND COMMUNICATION 13

 PR.4 INFORMED CONSENT 13

 PR.5 GRIEVANCE PROCEDURE 14

INFECTION PREVENTION AND CONTROL (IC) 14

 IC.1 INFECTION PREVENTION AND CONTROL SYSTEM 14

MEDICAL RECORDS SERVICE (MR) 14

 MR.1 COMPLETE MEDICAL RECORD 14

 MR.2 RECORD CONTENT..... 14

 MR.3 IDENTIFICATION OF AUTHORS 15

 MR.4 REQUIRED DOCUMENTATION..... 15

PHYSICAL ENVIRONMENT (PE) 15

 PE.1 INFRASTRUCTURE 16

 PE.2 WORK ENVIRONMENT 16

 PE.3 SAFETY MANAGEMENT SYSTEM 16

 PE.4 SECURITY MANAGEMENT SYSTEM 16

PE.5	MEDICAL EQUIPMENT MANAGEMENT SYSTEM	16
PE.6	UTILITY MANAGEMENT SYSTEM.....	17
HIP AND KNEE REPLACEMENT PROGRAM SERVICE DELIVERY (SD)		17
SD.1	PLANNING FOR SERVICE DELIVERY	17
SD.2	REVIEW OF REQUIREMENTS RELATED TO THE HIP AND KNEE SERVICES	17
SD.3	CONTROL OF SERVICE DELIVERY.....	18
SD.4	PROTOCOLS/PATHWAYS.....	18
SD.5	ADMISSION REQUIREMENTS (if admitted).....	18
SD.6	SURGICAL SERVICES	18
SD.7	CONSULTATION.....	19
SD.8	PLAN OF CARE.....	19
SD.9	MEDICATION MANAGEMENT	19
SD.10	CASE MANAGEMENT	20
SD.11	REHABILITATION SERVICES	20
SD.12	PATIENT/FAMILY/COMMUNITY EDUCATION	21

USE OF DNVGL- HEALTHCARE HIP AND KNEE REPLACEMENT PROGRAM CERTIFICATION REQUIREMENTS

Effective Date

DNV GL- Healthcare Hip and Knee Replacement Certification Requirements, HKRC - Version 16.0.
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Federal Laws, Rules and Regulations

The most current version of Federal law and the Code of Federal Regulations referenced in this Certification Program document are incorporated herein by reference and constitute Hip and Knee Replacement Program Certification requirements.

The Hip and Knee Replacement Certification (HKRC) requirements are based in whole or in part of the Centers for Medicare and Medicaid Services (CMS) Conditions of Participation (CoP) and in consideration of guidelines, recommendations and practices recognized by the American College of Orthopaedic Surgeons and the American Association of Hip and Knee Surgeons.

The Hip and Knee Replacement Program (HKRP), through its association with the host hospital participating in the Medicare and Medicaid program, is expected to comply with current CoP. When new or revised requirements are published, the HKRP is expected to demonstrate compliance in a time frame consistent with the effective date as published by CMS in the Federal Register and/or as required by DNV GL- Healthcare.

DNV GL- HEALTHCARE HIP AND KNEE REPLACEMENT PROGRAM CERTIFICATION

INTRODUCTION

The Hip and Knee Replacement Program Certification is offered by DNV GL- Healthcare and integrates requirements related to the CMS CoP for hospitals.

The Hip and Knee Replacement Program Certification is designed to recognize excellence in orthopedic surgery within the scope of Hip and Knee Replacement and related procedures, inclusive of initial diagnostic services, surgical services, and therapies related to Hip and Knee Replacement. The certification will mean that a hospital has demonstrated compliance with the DNV-GL Healthcare standard and adherence to guidelines of the American Academy of Orthopaedic Surgeons and the American Association of Hip and Knee Surgeons.

REGULATORY AND POLICY REFERENCE

- The CMS Conditions of Participation for hospitals are in 42 CFR Part 482.
- The DNV GL- Healthcare Hip and Knee Replacement Program Certification Requirements, and applicable CMS State Operations Manual (SOM) appendices provide the policies and procedures regarding certification activities.
- Pathways and Guidelines of the American Academy of Orthopaedic Surgeons.
- American Association of Hip and Knee Surgeons
- National Association of Orthopaedic Nurses
- Relevant recommendations of the Centers for Disease Control
- Relevant recommendations of the Association for Professionals in Infection Control and Epidemiology

Healthcare organizations seeking and maintaining certification must participate in the Medicare program and be in compliance with the CMS CoP. Compliance with the CMS CoP may be demonstrated by maintaining accreditation with DNV GL- Healthcare or another accreditation organization, approved by CMS to deem healthcare organizations in compliance with the CoP.

These Hip and Knee Replacement Program Certification Requirements address healthcare organizations that are either applying for DNV GL- Healthcare certification of their HKRP or are currently certified by DNV GL- Healthcare. When a healthcare organization has applied for but not received DNV GL- Healthcare certification, it is referred to as an "Applicant Organization." When a healthcare organization is currently certified by DNV GL- Healthcare, it is referred to as a "Certified Organization".

If the Certification Assessment is completed in conjunction with a DNV GL- Healthcare Accreditation Survey for the hospital, the assessment will not be announced to the HKRP. If the Certification Assessment is conducted separate and apart from a DNV-GL Accreditation Survey, the HKRP will be provided advance notice of the upcoming survey, not to exceed one month prior to the assessment of the HKRP.

SURVEYOR INFORMATION GATHERING AND ASSESSMENT

The objective of assessment activities is to determine the HKRP's compliance with the requirements through observations, interviews, and document review.

- The surveyors will focus attention on actual and potential patient outcomes, as well as required processes.
- The surveyors will assess the care and services provided, including the appropriateness of the care and services within the context of the certification requirements.
- The surveyors will visit the surgical services, imaging locations and other patient care settings as appropriate to the level of services provided by the HKRP.
- The surveyors will review clinical records, staff records, medical staff files and other documentation necessary to validate information gained from observations and interviews.

ABBREVIATIONS

AAHKS	American Association of Hip and Knee Surgeons
AANA	American Association of Nurse Anesthetists
AAOS	American Academy of Orthopaedic Surgeons
AAON	National Association of Orthopaedic Nurses
APIC	Association for Professionals in Infection Control and Epidemiology
AORN	Association of Perioperative Registered Nurses
ASA	American Society of Anesthesiologists
CDC	Centers for Disease Control
CMS	Centers for Medicare and Medicaid Services
CoP	Conditions of Participation
NAON	National Association of Orthopaedic Nurses
SOM	State Operations Manual

QUALITY MANAGEMENT SYSTEM (QM)

QM.1 QUALITY MANAGEMENT SYSTEM

The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the Hip and Knee Replacement Program (HKRP), medical staff, and administrative officials) is responsible and accountable for ensuring that the HKRP implements and is included in the host hospital quality management system. The host hospital will assure that adequate resources are allocated for measuring, assessing, improving, and sustaining the HKRP's performance and reducing risk to patients.

- CR.1 The HKRP must be involved in and implement the host hospitals method for maintaining an ongoing system for managing quality and patient safety.
- CR.2 The HKRP must implement quality assessment (QA) and performance improvement (PI) efforts to address priorities for improved quality of care and patient safety and ensure that corrective and preventive actions are implemented and evaluated for effectiveness.
- CR.3 The HKRP has established measurable quality objectives and the results are analyzed addressed; and
- CR.4 Appropriate information from the HKRP has been submitted to the host hospital oversight group for quality management.
- CR.5 The HKRP must have a formal documentation process for all policies, procedures, protocols, and forms.
 - CR.5a All policies, procedures, protocols and forms are reviewed at least annually with date of the review/revision documented.
 - CR.5b All previous policies, procedures, protocols, and forms are removed from any manuals, references or patient care areas to ensure that only the most current versions are available for use.
- CR.6 Control of Records: the HKRP ensures that suitable records are maintained.

QM.2 QUALITY OUTLINE/PLAN

The HKRP shall clearly outline its methodology, practice and related policies for addressing how quality and performance are measured, monitored, analyzed and continually improved to improve health outcomes and reduce risks for patients.

QM.3 QUALITY OBJECTIVES

The governing body shall ensure that HKRP quality objectives, including those needed to meet requirements for the Hip and Knee Replacement Program Certification, are established. The quality objectives shall be measurable and consistent with the requirements of the HKRP.

QM.4 QUALITY REPRESENTATIVE

A quality representative shall be designated and shall have the responsibility and authority for ensuring that the requirements of the HKRP are implemented and maintained.

QM.5 DOCUMENTATION AND PROGRAM REVIEW

CR.1 Any variation, deficiency or non-conformity identified by the HKRP shall be addressed by the appropriate committee (or, appropriate department or individual). Appropriate actions will be determined, applied, and documented.

CR.2 Program Review shall be performed at regular intervals, at a minimum of once a quarter, with an annual evaluation of the effectiveness of the HKRP components and metrics.

Note: Documentation of actions may take the form of a Failure, Mode and Effect Analysis, Root Cause Analysis, Performance Report, Non-Conformity Report, specific Improvement Project analysis, etc.

QM.6 SYSTEM REQUIREMENTS

The HKRP will participate in and follow the system requirements of the host hospital in establishing a quality system. The HKRP shall be required to have the following as a part of this system:

CR.1 Interdisciplinary group to oversee the HKRP specific quality data that includes the medical director of the HKRP, the nurse coordinator (or nurse practitioner or physician's assistant) and a quality facilitator. Other discipline representatives and practitioners members are at the discretion of the organization. The interdisciplinary group shall conduct quality and programmatic reviews;

CR.2 Written document defining the quality oversight process, to include components of the HKRP clinical and non-clinical services;

CR.3 Measurable quality objectives; and,

CR.4 Goal Measurement / Prioritization of activities to include:

CR.4a Focus on problem-prone areas, processes, or functions;

CR.4b Consideration of the incidence, prevalence and severity of problems in these areas, processes or functions; and,

CR.4c Consideration of efforts to affect health outcomes, improve patient safety and quality of care.

QM.7 MEASUREMENT, MONITORING, ANALYSIS

The HKRP shall strive to optimize overall effectiveness of processes and systems of the service. This goal shall be accomplished by identifying primary performance measures for each component and for the program function as a whole (both process and outcome measures) and by employing the methodologies for collaboration with key stakeholders.

Evaluations of the HKRP shall encompass overall patient outcomes, linkages among key components of the HKRP, and potential problems that could impede the care provided by the HKRP. Furthermore, the HKRP shall develop performance measures and strategies for measuring, refining and reassessing the following key system components for total hip and total knee replacement:

- CR.1 Patient Length of Stay;
- CR.2 Pre-Admission Education;
- CR.3 Discharge Disposition to Home: (Patients discharged directly home from the hospital without transfer or admission to an inpatient rehabilitation center);
- CR.4 Surgical Site Infection Rate: (This rate will include 90 days following a patient’s surgery, not just their hospitalization period);
- CR.5 Readmission Rates;
- CR.6 Venous thromboembolism (VTE) Prophylaxis;
- CR.7 Pain Management; and,
- CR.8 Mortality Rate.

QM.8 PATIENT SAFETY SYSTEM

- CR.1 The HKRP shall follow and participate in the host hospitals program for establishing clear expectations for identifying and detecting the prevalence and severity of incidents that impact or threaten patient safety.
- CR.2 The host hospital’s Patient Safety System shall be documented and shall address the following:
 - CR.2a Detection;
 - CR.2b Preventative and corrective action;
 - CR.2c Defined processes to reduce risk;
 - CR.2d Implementation of action plans
 - CR.2e On-going measurement to ensure action effectiveness;
 - CR.2f Management review of response and resource allocation to the results of the patient adverse event and other analyses; and,
 - CR.2g Policy and practice of informing patients and/or families about unexpected adverse events

PROGRAM MANAGEMENT (PM)

The HKRP shall establish, document, implement and maintain the HKRP and continually improve its effectiveness in accordance with the requirements of the DNV GL- Healthcare Hip and Knee Replacement Program Certification.

PM.1 TOP MANAGEMENT

- CR.1 The host hospital top management is responsible and accountable for ensuring the following:

- CR.1a The host hospital must be accredited by an organization approved by CMS or certified by the state agency acting on behalf of CMS;
- CR.1b The HKRP is in compliance with all applicable Federal and State laws regarding the health and safety of its patients;
- CR.1c The HKRP is licensed by the appropriate State or local authority responsible for licensing of HKRP's (if applicable);
- CR.1d The personnel working in the HKRP are properly licensed or otherwise meet all applicable Federal, State and local laws;
- CR.1e Responsibilities and authorities are defined and communicated to the HKRP;
- CR.1f Appointment and qualifications of the medical director for the HKRP:
 - CR.1f(i) The medical director for the HKRP must have sufficient knowledge of the diagnosis and treatment of diseases of the hip and knee joints as evidenced by:
Board certification in orthopedic surgery or completion of a recognized fellowship in total joint replacement with board eligibility with a defined plan to achieve board certification.

PM.2 TOP MANAGEMENT COMMITMENT

Top management shall provide evidence of its commitment to the development and implementation of the HKRP and continually improving its effectiveness by:

- CR.1 Communicating to the HKRP the importance of meeting customer as well as statutory and regulatory requirements;
- CR.2 Establishing and assisting in meeting the HKRP mission, goals and objectives; and,
- CR.3 Ensuring the availability of resources and information necessary to support the operation and monitoring of these processes.

PM.3 PROGRAM LEADERSHIP

The HKRP leadership shall:

- CR.1 Define in writing the programs mission and scope of service which describes the design, implementation and evaluation of the processes needed for the HKRP service delivery;
- CR.2 Determine criteria and methods needed to ensure consistent, effective care and treatment;
- CR.3 Conduct program reviews to determine achievement towards goals, objectives and outcomes
- CR.4 Monitor, measure, and analyze program processes; and,
- CR.5 Implement actions necessary to achieve planned results and continual improvement of these processes

NURSING SERVICES (NS)

NS.1 NURSING SERVICES

- CR.1 The HKRP must have a well-organized nursing service with a plan of administrative authority and delineation of responsibilities for the delivery of patient care under the HKRP.
- CR.2 There shall be 24-hour nursing services and a Registered Nurse must supervise and evaluate the nursing care for each HKRP patient.
- CR.2a Nursing staff not directly assigned to the HKRP shall receive education, training and direction for managing patients that have undergone hip and knee replacement as defined by the HKRP.
- CR.3 Nursing staff providing care to HKRP patients must have demonstrated competency in caring for the HKRP patient population documented annually.

STAFFING MANAGEMENT (SM)

SM.1 PERSONNEL (GENERAL)

Personnel performing work affecting conformity to the HKRP requirements shall be competent on the basis of appropriate education, training, skills and experience.

- CR.1 The host hospital shall have a policy and practice for outlining and verifying that each staff member possesses a valid and current license or certification as required by the HKRP and Federal and State laws. This written policy shall be strictly enforced and compliance data reported to top management.

SM.2 COMPETENCE, TRAINING AND AWARENESS

The HKRP shall:

- CR.1 Determine the necessary competence for personnel performing work affecting conformity to HKRP requirements;
- CR.2 Have evidence to demonstrate initial and ongoing training in the care of patients undergoing hip and knee replacement;
- CR.3 Where applicable, provide training or take other actions to achieve the necessary competence;
- CR.4 Evaluate the effectiveness of the actions taken;
- CR.5 Provide continuing education or other equivalent educational activity no less than annually to staff members assigned to the HKRP patients, as determined appropriate by the HKRP Director and as appropriate to the care practitioners' level of responsibility related specifically to HKRP services;
- CR.6 Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; and,

CR.7 Maintain appropriate records of education, training, skills and experience.

CR.7a The HKRP shall determine the appropriate number of hours of education to be provided initially and on-going to maintain the appropriate clinical competencies.

Note: This requirement may be met in a variety of ways, including online continuing medical credits, attendance at grand rounds, regional and national meetings and various educational courses.

SM.3 DETERMINING AND MODIFYING STAFFING

CR.1 The method for determining and modifying staffing shall be validated through periodic reporting of variance from core staffing, outlining justification and linking that justification with patient and process outcomes, including any untoward patient events or process failures.

CR.2 This validation shall be completed and reported to quality management oversight, when indicated.

SM.4 JOB DESCRIPTION

CR.1 All HKRP personnel, whether clinical or supportive, including contract staff, shall have available a current job description that contains the experience, educational and physical requirements, and performance expectations for that position.

SM.5 ORIENTATION

CR.1 All HKRP personnel, whether clinical or supportive, including contract staff, shall receive an orientation to specific job duties and responsibilities, and their work environment, as required by Federal and State law and regulation and the HKRP. The HKRP shall determine orientation content that must take place prior to the individual functioning independently in their job.

SM.6 STAFF EVALUATIONS

CR.1 The performance/competency evaluation shall contain indicators that will objectively measure the ability of HKRP staff to perform all job duties as outlined in the job description.

CR.2 The staff shall be evaluated initially and on an on-going basis against indicators that measure issues and opportunities for improvement that are identified through the following, as applicable:

CR.2a Variations and problem processes identified through the analysis of outcomes measurement as required by the HKRP Program;

CR.2b New technology/equipment/processes;

CR.2c Customer satisfaction feedback;

CR.2d Scheduled training session outcomes;

CR.2e Staff learning needs assessments that include variations identified through prior staff performance measurement;

CR.2f Staff feedback;

CR.2g Medical staff feedback; and,

CR.2h Requirements of Federal and State law (as applicable).

- CR.3 The HKRP shall follow the host hospitals definition for timeframe of the evaluation process, not to exceed one calendar year, and a policy and practice for sharing the indicators measurement of individual staff members with those staff members that allows for staff feedback.
- CR.4 The HKRP shall follow the host hospital requirement that each staff member, including contract staff, participate in continuing education as required by individual licensure/certification, professional association, law or regulation.

PATIENT RIGHTS (PR)

PR.1 PATIENT RIGHTS

The host hospital shall protect and promote each patient's rights. The host hospital shall inform, whenever possible, each patient and/or legal representative (as allowed under State law) of the patient's rights in advance of providing or discontinuing care and allow the patient to exercise his or her rights accordingly. The host hospital shall comply with 42 CFR 482.13.

PR.2 ADVANCE DIRECTIVE

The HKRP must allow the patient to formulate advance directives and to have HKRP staff and practitioners comply with the advance directives in accordance with the host hospital policies as well as Federal and State law, rules and regulations.

- CR.1 The HKRP shall document in the patient's medical record whether or not the patient has executed an advance directive.
- CR.2 The HKRP shall not condition the provision of care or otherwise discriminate based on the execution of the advance directive.
- CR.3 The HKRP shall ensure compliance with State law regarding the provision of an advance directive.
- CR.4 The HKRP shall provide education for staff regarding the advance directive.
- CR.5 When the advance directive exists and is not in the patient's medical record, a written policy for follow-up and compliance shall exist.

PR.3 LANGUAGE AND COMMUNICATION

The HKRP shall communicate with the patient and/or legal representative in language or format that the patient and/or legal representative understands.

- CR.1 HKRP policy and practice provides for competent individuals to interpret the patient's language for individuals who do not speak English or provide alternative communication aids for those who are deaf, blind, or otherwise impaired.

PR.4 INFORMED CONSENT

The HKRP shall obtain an informed consent from each patient or authorized representative for the provision of medical care under the HKRP. The consent shall include an explanation of risks, benefits,

and alternatives for procedures, diagnostic tests, and participation in activities related to the HKRP, as defined by the medical staff and State law.

PR.5 GRIEVANCE PROCEDURE

The HKRP shall participate and follow the host hospital formal grievance procedure for submission of a patient's written or verbal grievance to the HKRP that provides for the following:

- CR.1 A list of whom to contact to file a grievance;
- CR.2 The HKRP has the responsibility for effective operation of the grievance process, as indicated by and through the host hospital policy. The HKRP must follow the host hospital policies on:
 - CR.2a Review and resolution of grievances;
 - CR.2b Specification of reasonable timeframes for review and response to grievances;
 - CR.2c HKRP contact person;
 - CR.2d Steps taken to investigate;
 - CR.2e Results of the grievance process; and,
 - CR.2f Date of completion.

INFECTION PREVENTION AND CONTROL (IC)

IC.1 INFECTION PREVENTION AND CONTROL SYSTEM

- CR.1 The HKRP shall participate in the host hospital's infection control and prevention program to maintain a sanitary environment for HKRP patients, staff, and others.

MEDICAL RECORDS SERVICE (MR)

MR.1 COMPLETE MEDICAL RECORD

- CR.1 The host hospital shall maintain a medical record service in compliance with 42 CFR 482.24-Condition of participation: Medical Record Services.

MR.2 RECORD CONTENT

- CR.1 The medical record shall contain information to:
 - CR.1a Justify treatment and admission (if applicable);
 - CR.1b Support the diagnosis; and,
 - CR.1c Describe the patient's progress and response to medications and services
- CR.2 All entries shall be:
 - CR.2a Legible, complete, dated and timed; and,
 - CR.2b Authenticated by the person responsible for providing or evaluating the services provided consistent with host hospital and HKRP policy.

- CR.3 Authentication may include written signatures or initials. Electronic authentication is permissible.
- CR.4 All orders must be dated, timed and authenticated promptly by the prescribing practitioner.
- CR.5 Verbal orders must be in accordance with Federal and State law and authenticated within the time frame required by the host hospital and/or State law.
 - CR.5a Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.
 - CR.5b Verbal orders must be authenticated in accordance with Federal and State law by the ordering practitioner or a practitioner responsible for the care of the patient.

MR.3 IDENTIFICATION OF AUTHORS

- CR.1 The HKRP shall follow the host hospital system to identify the author of each entry into the medical record.

MR.4 REQUIRED DOCUMENTATION

All records must document the following, as appropriate:

- CR.1 Evidence of a physical examination, including a health history must be performed on all patients admitted for inpatient care and/or prior to surgery or procedure requiring anesthesia services;
- CR.2 Admitting diagnosis (if admitted);
- CR.3 Results of all consultative evaluations of the patient and appropriate finding by clinical and other staff involved in the care of the patient;
- CR.4 Documentation of complications, organization acquired infections, and unfavorable reactions to drugs and anesthesia;
- CR.5 Properly executed informed written consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, signed by the patient or his/her authorized representative;
- CR.6 All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition;
- CR.7 Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow up care; and,
- CR.9 Final diagnosis with completion of medical records within thirty, (30) days following discharge.

PHYSICAL ENVIRONMENT (PE)

The HKRP will abide by the management systems for maintaining the Physical Environment in place under the operation of the host hospital, including applicable Life Safety Code (LSC) and National Fire Protection Association (NFPA) standards, as well as applicable CMS CoP and accreditation organization requirements if the organization is currently accredited.

PE.1 INFRASTRUCTURE

The host hospital shall determine provide, and maintain the infrastructure needed to achieve conformity to the HKRC Requirements. Infrastructure includes, as applicable:

- CR.1 Buildings, workspace and associated utilities;
- CR.2 Process equipment (both hardware and software); and,
- CR.3 Supporting services (such as transport, communication, or information systems).

PE.2 WORK ENVIRONMENT

The host hospital shall determine and manage the work environment needed to facilitate patient care.

- CR.1 The facilities for the HKRP shall be maintained to ensure the safety of patients, visitors, and staff.
- CR.2 The HKRP must maintain adequate and safe facilities for its services.

PE.3 SAFETY MANAGEMENT SYSTEM

- CR.1 The host hospital shall provide and maintain safe and adequate diagnostic and therapeutic facilities.
- CR.2 The host hospital shall require that facilities, supplies, and equipment be properly maintained and ensure an acceptable level of safety and quality. The extent and complexity of facilities shall be determined by the services offered under the HKRP.
- CR.3 The host hospital shall require that the HKRP maintain an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries.
- CR.4 The host hospital shall address safety recalls and alerts involving the HKRP.

PE.4 SECURITY MANAGEMENT SYSTEM

- CR.1 The host hospital shall develop a system that provides for a secure environment.
- CR.2 The host hospital shall provide for identification of patients, employees, and others.
- CR.3 The host hospital shall require a process for reporting and investigating security related issues.

PE.5 MEDICAL EQUIPMENT MANAGEMENT SYSTEM

- CR.1 The host hospital shall ensure that effective processes are in place for the acquisition, safe use, and the appropriate selection of equipment used within the HKRP.
- CR.2 The host hospital shall address issues related to the HKRP's initial service inspection,

orientation, and the use of physician owned, rental, or demonstration equipment.

PE.6 UTILITY MANAGEMENT SYSTEM

- CR.1 The host hospital shall ensure maintenance, testing, and inspection processes for critical utilities used in the operation of the HKRP.
- CR.2 The host hospital shall ensure emergency processes for utility system failures or disruptions.
- CR.3 The host hospital will ensure that all relevant utility systems shall be maintained, inspected and tested.

HIP AND KNEE REPLACEMENT PROGRAM SERVICE DELIVERY (SD)

SD.1 PLANNING FOR SERVICE DELIVERY

The HKRP shall plan and develop the processes needed for service delivery. Planning of the HKRP service delivery shall be consistent with the requirements of the processes of the DNV GL- Healthcare Hip and Knee Certification Program Requirements. In planning for service delivery, the HKRP shall determine the following, as appropriate:

- CR.1 Quality objectives and requirements for the HKRP;
- CR.2 The need to establish processes and documents, and to provide resources specific to the HKRP;
- CR.3 Required verification, validation, monitoring, and measurement, specific to the HKRP;
- CR.4 Records needed to provide evidence that the processes meet requirements. The output of this planning shall be in a form suitable for the HKRP's method of operations.
- CR.5 Communication to the targeted patients the care, treatment and services provided by the program and the means for accessing care, treatment or services after hours (if applicable).

SD.2 REVIEW OF REQUIREMENTS RELATED TO THE HIP AND KNEE SERVICES

Prior to seeking HKRP Certification, the HKRP shall review the HKRC Requirements and shall ensure:

- CR.1 The HKRP requirements are clearly defined;
- CR.2 The HKRP has the ability to meet the defined HKRC Requirements;
- CR.3 Records of the results of the review and actions arising from the review shall be maintained;
- CR.4 If any HKRC Requirements are changed, the HKRP shall ensure that all relevant documents are amended; and,
- CR.5 Communication to all relevant personnel is made about any changes and the competence of all practitioners is reassessed when new techniques or responsibilities are introduced and periodically within the timeframes defined by the HKRP.

SD.3 CONTROL OF SERVICE DELIVERY

The HKRP shall plan and carry out services under controlled conditions. Controlled conditions shall include, as applicable,

- CR.1 The availability of information that describes the characteristics of the HKRP;
- CR.2 The availability of work instructions, as necessary;
- CR.3 The use of suitable equipment;
- CR.4 The availability and use of monitoring and measuring equipment; and,
- CR.5 The implementation of monitoring and measurement.

SD.4 PROTOCOLS/PATHWAYS

- CR.1 The HKRP is responsible for developing and maintaining pathways, protocols, order sets and processes to treat patients for hip and knee replacement.
 - CR.1a A pathway, clinical protocol, clinical practice guideline, or order set is based on the scientific data and recognized professional organizations. The organization must evaluate and update any pathway, clinical protocol, clinical practice guideline, or order set when more data and information on the guideline topic become available.
 - CR.1b Appropriate participating surgeons, practitioners, and other clinical staff are to be involved in the adoption of the pathway, clinical protocol, clinical practice guideline, or order set.

SD.5 ADMISSION REQUIREMENTS (if admitted)

- CR.1 The HKRP shall ensure that every patient is under the care of a:
 - CR.2a Doctor of medicine or osteopathy, with expertise in orthopedics and other related clinical privileges specific to hip and knee replacement must render care, order medications and manage emergency situations; and that;
 - CR.2b Orthopedic Surgeons shall be board certified or board eligible with a defined plan to achieve board certification.

SD.6 SURGICAL SERVICES

- CR.1 Surgical services provided under the HKRP shall be well organized, appropriate to the scope of the services offered for hip and knee replacement, and provided in accordance with acceptable standards of practice. National standards of practice include the recommendations of professional organizations such as AAHKS, NAON, AORN, CDC, APIC, ASA, AANA, AAOS and other professional organizations as applicable to surgical services. Surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care, and must be consistent with needs and resources.

- CR.1a When outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.
- CR.2 The organization of the surgical services shall be supervised by either a registered nurse or by a doctor of medicine or osteopathy. The surgical team involved with those patients with hip and knee replacement shall have the appropriate experience, training and other criteria to be met as defined by the HKRP. This will include Practitioners, Registered Nurses, Licensed Practical Nurses, and Surgical Technologists (Operating Room Technicians).
- CR.2a Qualified registered nurses shall perform circulating duties in the operating room. If a qualified registered nurse is present who is immediately available to respond to emergencies, licensed practical nurses and surgical technologists may assist in circulatory duties under the supervision of that registered nurse, if State Law and medical staff policies and procedures permit.
- CR.3 For the effective delivery of surgical services provided by the HKRP, the following will be established and maintained:
- CR.3a Times will be allocated accordingly for the Operating Rooms specifically for hip and knee replacement procedures. The HKRP will document case time and any downtime of the surgical suites;
- CR.3b The HKRP will coordinate with the Central Sterile/Sterile Supply Team to prepare and maintain standardized orthopedic surgical trays;
- CR.4 The HKRP shall maintain a current and complete call schedule with contact information of the physicians on staff and/or available for the HKRP.

SD.7 CONSULTATION

- CR.1 Medical professionals providing remote consultations have training and expertise to meet the host hospital requirements for telemedicine consultations.
- CR.2 The medical staff shall define in its bylaws the circumstances and criteria under which consultation or management by a physician or other qualified licensed independent practitioner is required to address any co-morbidities of the patients under the care of the HKRP as required.

SD.8 PLAN OF CARE

- CR.1 HKRP staff shall develop and maintain a plan of care prepared by qualified individuals for each patient within 24 hours of admission that reflects the input of other disciplines, as appropriate. Documentation of these interdisciplinary findings, including relevant co-morbidities and interventions, shall be included in the plan of care as appropriate.
- CR.2 The plan of care will include initial discharge planning for continuing care and treatment based on needs, condition, and prognosis of the patient.

SD.9 MEDICATION MANAGEMENT

- CR.1 The host hospital shall provide pharmacy services that meet the needs of the patients. Medications will be administered in accordance with accepted professional principles. The

pharmacy service will be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service must have an adequate number of qualified personnel to ensure medication management services, including emergency services.

- CR.2 All medications shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws. All drugs and biologicals shall be administered only upon the orders of the practitioner responsible for the care of the patient in accordance with approved medical staff policies and procedures, and accepted standards of practice.
- CR.3 All compounding, packaging, and dispensing of medication shall be under the supervision of a pharmacist.

SD.10 CASE MANAGEMENT

- CR.1 A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise, the management of the patient through discharge.
 - CR.1a The responsible personnel should have experience in case management, discharge planning, knowledge of social and physical factors that affect functional status at discharge, and knowledge of community resources to meet post-discharge needs.
- CR.2 The discharge planning evaluation shall include:
 - CR.2a An evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services; and,
 - CR.2b An evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the organization.
 - CR.2c A means to inform the patient or the patient's family of their freedom to choose among participating Medicare providers of post-hospital care services, and must, when possible, respect patient and family preferences when they are expressed.
- CR.3 The discharge planning evaluation shall be completed on a timely basis so that appropriate arrangements are made before discharge, and unnecessary delays in discharge are avoided.
- CR.4 The discharge planning evaluation shall be a part of the patient's medical record and be used when forming the discharge plan with the patient or individual acting on his or her behalf.
- CR.5 If the results of the discharge evaluation so indicate, or at the request of the patient's physician, a registered nurse, social worker, or other appropriately qualified personnel shall develop, or supervise the development of, a discharge plan and associated educational materials.
 - SR.5a The results of the discharge planning evaluations must be discussed with the patient or individual acting on their behalf.

SD.11 REHABILITATION SERVICES

- CR.1 The HKRP provides rehabilitation, occupational or physical therapy services as appropriate. The service(s) shall be provided in a manner that ensures the patient's health and safety.
- CR.2 Staff (including physical therapists, physical therapy assistants, occupational therapists, or occupational therapy assistants) shall meet the qualifications as defined by the medical staff and the HKRP and consistent with State law. Staff will have experience in the treatment of hip and knee replacement patients or sports medicine injuries.
- CR.3 The HKRP shall require physical and occupational therapists to be readily available by consultation for patient assessment and therapy during the patient hospitalization. Consults and assessments will be completed within 24 hours of admission or within 24 hours once the patient is medically stable.
 - CR.3a If the HKRP does not have inpatient rehabilitation services on site, there shall be a documented referral protocol in place and knowledge of nearby facilities offering this service.
- CR.4 The HKRP shall have a written treatment plan that is in accordance with the practitioner's orders or other qualified individuals as authorized by the medical staff to order the services. The orders, treatment plan and results, notes and other related documentation shall be maintained in the patient's medical record.
- CR.5 The treatment plan and the personnel qualifications must be in accordance with national acceptable standards of practice.

SD.12 PATIENT/FAMILY/COMMUNITY EDUCATION

- CR.1 The HKRP will ensure that it provides for the involvement of patients and/or family members in:
 - CR.1a Making decisions about the plan of care goals during hospitalization.
 - CR.1b Discussing and planning for lifestyle changes for preventive practices and to manage their recovery post-surgery.
 - CR.1c Discussing and planning for post hospital needs, including possible placement to a rehabilitation or skilled nursing facility.
- CR.2 The education programs and other material provided by the HKRP will reflect involvement from the appropriate disciplines involved in the care and treatment of patients having hip and knee replacement.
- CR.3 Community education shall be offered at least once per year and should stress knowledge in the community about the treatment protocols as well as emerging strategies for hip and knee replacement.

HIP & KNEE REPLACEMENT CERTIFICATION (HKRC) REQUIREMENTS

The Hip & Knee Replacement Certification (HKRC) Program is offered by DNV GL Healthcare Inc. (DNVGL HC) and integrates requirements related to the CMS Conditions of Participation for hospitals (CoPs).

HKRCs are designed to recognize excellence in orthopedic surgery within the scope of Hip and Knee Replacement and related procedures. The certification will mean that a hospital has demonstrated compliance with the DNV GL Healthcare standard and adherence to guidelines of the American Academy of Orthopedic Surgeons.

The intent of the HKRC is to provide initial diagnostic services, surgical services and therapies related to Hip and Knee Replacement.

Since 2008, DNV GL Healthcare has accredited more than 400 hospitals across the United States.

In addition to Accreditation, DNV GL Healthcare provides Center of Excellence Certification for Acute Stroke Ready Centers, Primary Stroke Centers, Comprehensive Stroke Centers and Managing Infection Risk.

DNV GL - Healthcare is now proud to announce our latest Center of Excellence offering, Hip & Knee Replacement Certification.

To learn more, visit us online at www.dnvglhealthcare.com; talk with us using our Live Chat feature located on our homepage, or email us at healthcaresales@dnvgl.com.

DNV GL is a world-leading certification body. We help businesses assure the performance of their organizations, products, people, facilities and supply chains through certification, verification, assessment, and training services.

Within healthcare, we help our customers achieve excellence by improving quality and patient safety through hospital accreditation, managing infection risk, management system certification and training.

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