



DNV GL - SPINE SURGERY PROGRAM CERTIFICATION (SSPC) REQUIREMENTS

Version 18.0

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USE OF DNVGL- HEALTHCARE SPINE SURGERY PROGRAM CERTIFICATION REQUIREMENTS

Effective Date

DNV GL- Healthcare Spine Surgery Program Certification Requirements, SSPC – Version 18.0

Effective Date: June 18, 2018

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 Spine Surgery Program Certification requirements.

The Spine Surgery Program Certification (SSPC) requirements are based in whole or in part of the Centers for Medicare and Medicaid Services (CMS) Conditions of Participation (CoP).

The Spine Surgery Program (SSP), 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 SSP 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 SPINE SURGERY PROGRAM CERTIFICATION

INTRODUCTION

The Spine Surgery Program Certification is offered by DNV GL- Healthcare and integrates requirements related to the CMS Conditions of Participation (CoP) for hospitals.

The Spine Surgery Program Certification is designed to recognize excellence in orthopaedic surgery within the scope of Spine Surgery and related procedures, inclusive of initial diagnostic services, surgical services, and therapies related to Spine Surgery.

Certification will mean that a hospital has demonstrated compliance with the DNV-GL Healthcare SSPC requirements.

REGULATORY, POLICY AND GUIDELINE REFERENCES

The CMS Conditions of Participation for hospitals are in 42 CFR Part 482

The DNV GL- Healthcare Spine Surgery Program Certification Requirements, and applicable CMS State Operations Manual (SOM) appendices provide the policies and procedures regarding certification activities.

North American Spine Society (NASS) clinical guidelines offer evidence-based recommendations addressing key clinical questions for specific diagnoses.

National Association of Orthopaedic Nurses (NAON) Clinical Practice Library resources

Relevant recommendations of the Centers for Disease Control

Relevant recommendations of the Association for Professionals in Infection Control and Epidemiology

CERTIFICATION STATUS

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 Spine Surgery Program Certification Requirements address healthcare organizations that are either applying for DNV GL- Healthcare certification of their SSP 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 SSP. If the Certification Assessment is conducted separate and apart from a DNV-GL Accreditation Survey, the SSP will be provided advance notice of the upcoming survey, not to exceed one month prior to the assessment of the SSP.

SURVEYOR INFORMATION GATHERING AND ASSESSMENT

The objective of assessment activities is to determine the SSP'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, rehabilitation locations and other patient care settings as appropriate to the level of services provided by the SSP.

The surveyors will review clinical records, personnel records, medical staff files, and other documentation necessary to validate information gained from observations and interviews.

Glossary

AASP	American Academy of Spine Physicians
AANA	American Association of Nurse Anesthetists
AAOS	American Academy of Orthopaedic Surgeons
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
NASS	North American Spine Society
SIS	Spine Intervention Society
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 Spine Surgery Program (SSP), medical staff, and administrative officials) is responsible and accountable for ensuring that the SSP 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 SSP's performance and reducing risk to patients.

- CR.1 The SSP must be involved in and implement the host hospitals method for maintaining an ongoing system for managing quality and patient safety.
- CR.2 The SSP 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 SSP has established measurable quality objectives and the results are analyzed addressed; and
- CR.4 Appropriate information from the SSP has been submitted to the host hospital oversight group for quality management.
- CR.5 The SSP 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 SSP ensures that suitable records are maintained.

QM.2 QUALITY OUTLINE/PLAN

The SSP 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 SSP quality objectives, including those needed to meet requirements for the Spine Surgery Program Certification, are established. The quality objectives shall be measurable and consistent with the requirements of the SSP.

QM.4 SPINE SURGERY PROGRAM MANAGEMENT REPRESENTATIVE

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

QM.5 DOCUMENTATION AND PROGRAM REVIEW

- CR.1 Any variation, deficiency or non-conformity identified by the SSP 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 SSP 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 SSP will participate in and follow the system requirements of the host hospital in establishing a quality system. The SSP shall be required to have the following as a part of this system:

- CR.1 Interdisciplinary group to oversee the SSP specific quality data that includes the medical director of the SSP, the nurse navigator (or nurse practitioner or physician's assistant) and a quality facilitator. Other discipline representatives and practitioners are at the discretion of the organization. The interdisciplinary group shall conduct quality and Program reviews;
- CR.2 Written document defining the quality oversight process, to include components of the SSP 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 SSP shall strive to optimize overall effectiveness of Program processes and systems. This goal shall be accomplished by identifying primary performance measures for each component and for the Program function (both process and outcome measures).

Evaluations of the SSP shall encompass overall patient outcomes, linkages among key components of the SSP, and potential problems that could affect the care provided by the SSP, including contract services.

Documentation of quality improvement initiatives, performance measures and/or clinical indicators are presented and discussed at least quarterly.

The SSP shall develop performance measures and strategies for measuring, refining and reassessing the following key system components:

- 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 Antibiotic Prophylaxis;
- CR.7 Venous thromboembolism (VTE) Prophylaxis;
- CR.8 Pain Management; and,
- CR.9 Mortality Rate.

QM.8 PATIENT SAFETY SYSTEM

- CR.1 The SSP shall follow and participate in the host hospitals' Patient Safety System (incident report system), 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 SSP shall establish, document, implement and maintain the SSP and continually improve its effectiveness in accordance with the requirements of the DNV GL- Healthcare Spine Surgery 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 SSP is in compliance with all applicable Federal and State laws regarding the health and safety of its patients;
 - CR.1c Criteria that include aspects of individual character, competence, training, experience and judgment is established for the selection of individuals working for the Spine Surgery Program, directly or under contract.
 - CR.1d The personnel working in the SSP are properly licensed or otherwise meet all applicable Federal, State and local laws;
 - CR.1e Responsibilities and authorities are defined and communicated within the Spine Surgery Program; and
 - CR.1f Appointment and qualifications of the Medical Director for the SSP:
 - CR.1f(i) The Medical Director for the SSP will be an Orthopaedic/Neuro Surgeon or other MD/DO with qualifications as defined for the diagnosis and treatment of the Spine.

PM.2 MANAGEMENT COMMITMENT

Host hospital top management shall provide evidence of its commitment to the development and implementation of the SSP and continually improving its effectiveness by:

- CR.1 Communicating to the SSP the importance of meeting customer as well as statutory and regulatory requirements;
- CR.2 Establishing and assisting in meeting the SSP 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 Spine Surgery Program 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 SSP 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.

MEDICAL STAFF (MS)

MS.1 MEDICAL STAFF

- CR.1 The SSP shall include criteria for determining the privileges to be granted to Spine Surgery Program practitioners and a procedure for applying the criteria to those individuals that request privileges.
- CR.2 The host hospital shall comply with 42. CFR 482.22 – Condition of participation: Medical Staff.

NURSING SERVICES (NS)

NS.1 NURSING SERVICES

- CR.1 The host hospital 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 SSP.
- CR.2 There shall be 24-hour nursing services and a Spine Program Coordinator must coordinate with nurse managers, the supervision and evaluation of the nursing care for each patient of the SSP.

CASE MANAGEMENT (CM)

CM.1 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 the availability of the services;
 - CR.2b An evaluation of the likelihood of a patient's capacity for self-care or the possibility of the patient being cared for in the environment from which he or she entered the organization: and,
 - 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.

STAFFING MANAGEMENT (SM)

SM.1 PERSONNEL (GENERAL)

Personnel performing work affecting conformity to the SSP 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 SSP 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 Spine Surgery Program shall:

- CR.1 Determine the necessary competence for personnel performing work affecting conformity to SSP requirements;
- CR.2 Have evidence to demonstrate initial and ongoing training in the care of patients undergoing Spine Surgery;
- 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 SSP patients, as determined appropriate by the SSP Director and as appropriate to the care practitioners' level of responsibility related specifically to SSP 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 SSP shall determine the appropriate number of hours of education to be provided initially and on-going to maintain the appropriate clinical competencies.
 - CR.7b Nursing staff not directly assigned to the SSP shall receive education, training and direction for managing patients that have undergone Spine Surgery with hours and content defined by the SSP.

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.

SM.4 JOB DESCRIPTION

- CR.1 All SSP 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 SSP 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 SSP. The SSP 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 SSP 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 SSP;
 - 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 SSP 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 SSP 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.
- CR.5 Indicator measurement for contract staff may be modified based on spine surgery outcomes. Modification of this measurement must take place no less than annually and shall be justified by data analysis.
- CR.6 The SSP shall aggregate the objective performance data for the individual staff and within each job classification to identify variations for further training, coaching and mentoring:

CR.6a Re-measurement shall follow any intervention: and,

CR.6b The outcomes of this measurement shall be reported in the aggregate to top management.

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.

- CR.1 The host hospital shall comply with 42 CFR 482.13 – Condition of Participation: Patient Rights.

PR.2 ADVANCE DIRECTIVE

The SSP must allow the patient to formulate advance directives and to have SSP 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 SSP shall document in the patient's medical record whether or not the patient has executed an advance directive.
- CR.2 The SSP shall not condition the provision of care or otherwise discriminate based on the execution of the advance directive.
- CR.3 The SSP shall ensure compliance with State law regarding the provision of an advance directive.
- CR.4 The SSP 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 SSP shall communicate with the patient and/or legal representative in language or format that the patient and/or legal representative understands.

- CR.1 SSP 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 SSP shall obtain an informed consent from each patient or authorized representative for the provision of medical care under the SSP. The consent shall include an explanation of risks, benefits, and alternatives for procedures, diagnostic tests, and participation in activities related to the SSP, as defined by the medical staff and State law.

PR.5 GRIEVANCE PROCEDURE

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

- CR.1 A list of whom to contact to file a grievance;
- CR.2 The SSP has the responsibility for effective operation of the grievance process, as indicated by and through the host hospital policy. The SSP 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 SSP 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 SSP shall participate in the host hospital's infection control and prevention Program to maintain a sanitary environment for SSP 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 SSP 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 SSP 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.8 Final diagnosis with completion of medical records within thirty (30) days following discharge.

PHYSICAL ENVIRONMENT (PE)

The SSP will abide by the management systems for maintaining the Physical Environment in place under the operation of the host hospital and applicable CMS CoP and accreditation organization requirements.

PE.1 INFRASTRUCTURE

The host hospital shall determine provide, and maintain the infrastructure needed to achieve conformity to the Spine Surgery Program 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 SSP shall be maintained to ensure the safety of patients, visitors, and staff.
- CR.2 The SSP 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 SSP.
- CR.3 The host hospital shall require that the SSP 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 SSP.

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 SSP.
- CR.2 The host hospital shall address issues related to the SSP'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 SSP.
- 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.

SPINE SURGERY PROGRAM SERVICE DELIVERY (SD)

SD.1 PLANNING FOR SERVICE DELIVERY

The SSP shall plan and develop the processes needed for SS service delivery. The SSP processes shall be consistent with the DNV GL Spine Surgery Program Certification Requirements.

In planning SS services delivery, the SSP shall determine:

- CR.1 Quality objectives and requirements for the SSP;
- CR.2 Required processes and documents, and necessary resources specific to the SSP;
- CR.3 Required verification, validation, monitoring, and measurement, specific to the SSP;
- 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 SSP's method of operations; and,
- 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 SPINE SURGERY SERVICES

The SSP shall review requirements related to the SSP. This review shall be conducted prior to the SSP's commitment to provide services to patients and shall ensure:

- CR.1 The SSP requirements are clearly defined;
- CR.2 The SSP has the ability to meet the defined SSPC Requirements;
- CR.3 Results of the review and actions arising from the review shall be maintained;
- CR.4 If any SSPC Requirements are changed, the SSP 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 SSP.

SD.3 CONTROL OF SERVICE DELIVERY

The SSP 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 SSP;
- 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 PERFORMANCE EVALUATION

The SSP shall evaluate the performance and effectiveness of the Program as a part of its QMS (see QM.7).

The SSP must collect and analyze data on at least the following performance measures:

- 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 Antibiotic Prophylaxis;
- CR.7 Venous thromboembolism (VTE) Prophylaxis;
- CR.8 Pain Management; and,
- CR.9 Mortality Rate.

SD.5 SPINE SURGERY PROGRAM PROTOCOLS/PATHWAYS

- CR.1 The SSP is responsible for developing and maintaining pathways, protocols, order sets and processes to treat patients for Spine Surgery.
 - 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.6 ADMISSION REQUIREMENTS (if admitted)

- CR.1 The SSP shall ensure that every patient is under the care of a:
 - CR.1a Doctor of medicine or osteopathy, with expertise in orthopaedics and/or neurology with clinical privileges specific to Spine Surgery must render care, order medications and manage emergency situations; and that;
 - CR.1b Orthopaedic/Neuro Surgeons shall be board certified or board eligible.

SD.7 SURGICAL SERVICES

- CR.1 Surgical services provided under the SSP shall be well organized, appropriate to the scope of the services offered for Spine Surgery and provided in accordance with acceptable standards of practice and clinical guidelines as appropriate. Standards of practice might include resources such as the recommendations or guidelines of professional organizations such as NASS, 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 Spine Surgery shall have the appropriate experience, training and other criteria to be met as defined by the SSP. 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 SSP, the following will be established and maintained:
 - CR.3a Times will be allocated accordingly for the Operating Rooms specifically for Spine Surgery procedures. The SSP will document case time and any downtime of the surgical suites; and,
 - CR.3b The SSP will coordinate with the Central Sterile/Sterile Supply Team to prepare and maintain standardized orthopedic surgical trays.
- CR.4 The SSP shall maintain a current and complete call schedule with contact information of the physicians on staff and/or available for the SSP.

SD.8 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 SSP as required.

SD.9 PLAN OF CARE

- CR.1 SSP 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 inpatient plan of care will include initial discharge planning for continuing care and treatment based on needs, condition, and prognosis of the patient.

SD.10 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.11 REHABILITATION SERVICES

- CR.1 The SSP 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 SSP and consistent with State law. Staff will have experience in the treatment of Spine Surgery patients or sports medicine injuries.
- CR.3 The SSP 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 SSP 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 SSP 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 SPINE SURGERY INTERDISCIPLINARY TEAM

- CR.1 Spine Surgery patients must be managed by an interdisciplinary team of medical professionals with the appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care.

The SSP Team must include, at a minimum, all the following individuals:

- CR.1a The SSP Medical Director;
- CR.1b Spine Program navigator/coordinator (nurse, nurse practitioner, physician assistant);
- CR.1c Case Manager; and,

- CR.1d Rehabilitation Representative.
- CR.2 The SSP shall maintain an interdisciplinary approach to proper medical care of the SS patient, including the participation of nurses, occupational therapists, physical therapists, and pharmacists, as appropriate.

SD.13 PATIENT AND FAMILY EDUCATION

- CR.1 The SSP 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; and,
 - 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 SSP will reflect involvement from the appropriate disciplines involved in the care and treatment of patients having Spine Surgery.

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