





المعايير الوطنية لخدمات الرعاية الصحية المنزلية

CBAH

NATIONAL STANDARDS FOR HOME HEALTHCARE SERVICES

FIRST EDITION 2022

National Standards for Home Healthcare Services

Saudi Central Board for Accreditation of Healthcare Institutions

First Edition 2022

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is a not-for-profit governmental organization, that has been required by its formation order to support all healthcare organizations in Saudi Arabia through different mechanisms, including the production of scientific peer-reviewed standards, materials, and publications.

The mission of CBAHI is to continuously improve the safety and quality of healthcare services in the Kingdom of Saudi Arabia, by supporting healthcare facilities to continuously comply with the accreditation standards. CBAHI does this through the provision of preparation, on-site assessment, monitoring, education, publications, and consultation services.

CBAHI is making every possible effort to separate its consultative and educational programs as well as all publications it produces from its accreditation activities. This manual is produced for the sole use of individual healthcare facilities and healthcare professionals in Saudi Arabia. CBAHI provides supplementary educational sessions to explain the intent of this manual and its contents and therefore, attendance at these activities helps achieve compliance with the quality and safety standards followed by accreditation. Attendees at CBAHI training, orientation, and educational programs and purchasers of its publications will not have distinctive treatment by any CBAHI associates including CBAHI surveyors, nor receive any privilege regarding assessment scoring results or outcome.

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المركـز السـعودي لاعتمـاد المنشـآت الصحيـة ، ١٤٤٣هـ فهرسة مكتبة الملك فهد الوطنية أثناء النشر

المركز السعودي لاعتماد المنشآت الصحية المعايير الوطنية لخدمات الرعاية الصحية المنزلية . المركز السعودي لاعتماد المنشآت الصحية – الرياض، ١٤٤٣هـ

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المركز السعودي لاعتماد المنشآت الصحية (سباهي) هو الجهة الرسمية المخولة منح شهادات اعتماد الجودة لكافة المرافق الصحية الحكومية والخاصة التي تعمل في المملكة العربية السعودية. ينبثق المركز أساساً عن المجلس الصحي السعودي، ويعتبر جهة غير هادفة للربح، يتولى بشكل أساسي تقييم المنشآت الصحية بغرض تحديد مدى التزامها بتطبيق معايير الجودة وسلامة المرضى التي صممها المركز لهذا الغرض. بدأ المركز عمله تحت مسمى المجلس المركزي لاعتماد المنشآت الصحية بقرار معالي وزير الصحة رئيس مجلس الخدمات الصحية رقم (١٤٤١٨) وتاريخ ١-٩-٤٣١هـ، واستمر في تأدية المهام المناطة به حتى صدور قرار مجلس الوزراء الموقر رقم (١٧١) وتاريخ ١-١٤-١٤٣٤هـ، القاضي بتحويله إلى المركز السعودي لاعتماد المنشآت الصحية، واستمراره في وضع وتطبيق المعايير الوطنية للجودة وسلامة المرضى في كافة المرافق الصحية ومنح شهادات الاعتماد المتعلقة بذلك. يعتبر الحصول على الاعتماد الوطني من قبل المركز السعودي إلزامياً على كافة المرافق الصحية الحكومية والخاصة بموجب القرار سالف الذكر و بموجب قرار المجلس الصحي السعودي رقم (٨/٨) و تاريخ والحاصة بموجب القرار سالف الذكر و بموجب قرار المجلس الصحي السعودي رقم (١٨/٨) و تاريخ المركز وإثبات ذلك بالحصول على شهادة الاعتماد كمتطلب مستقبلي من متطلبات الاستمرار في المركز وأثبات ذلك بالحصول على شهادة الاعتماد كمتطلب مستقبلي من متطلبات الاستمرار في المرخبص للمنشآت الصحبة الخاصة.

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is the official agency authorized to grant accreditation certificates to all governmental and private healthcare facilities operating today in Saudi Arabia. CBAHI has emerged from the Saudi Health Council as a non-profit organization. The principal mission of CBAHI is to set the healthcare quality and patient safety standards against which all healthcare facilities are evaluated for evidence of compliance. The Central Board for Accreditation of Healthcare Institutions (CBAHI) was founded in October 2005 by the Ministerial Order Number (144187). Since its formation, CBAHI continued to pursue its mission until 30-9-2013 at which time the Cabinet of Ministers Decree Number (371) called for changing of the name to become the Saudi Central Board for Accreditation of Healthcare Institutions, and also mandated national accreditation by CBAHI on all healthcare facilities. To encourage more participation in this ambitious national initiative, the Ministry of Health plans to mandate CBAHI accreditation as a future prerequisite for the renewal of operating licenses for all private Organizations.

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Foreword

The healthcare sector in Saudi Arabia is witnessing an ambitious transformation at all levels, particularly in terms of service quality. This transformation is intended to bridge the gap between the current and desired healthcare system. The Kingdom's leadership has been eager to undertake such transformational actions to assure the availability, sufficiency, efficiency, and safety of the healthcare services offered to more than 35 million citizens and residents. The main goal focuses on improving the health of communities whilst increasing the capacity of healthcare services to meet the demands of one of the fastest growing population rates.

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) plays a vital role in the Saudi health system. It is the independent entity responsible for setting the healthcare provision standards and assessing the compliance of healthcare organizations against these standards. CBAHI has strived to establish evidence-based standards that encompass a wide range of healthcare organizations with various scopes, in order to enhance the quality and safety of healthcare services.

This manual is designed to serve many home healthcare services across the country, hence ensuring that the home healthcare service they provide is effective and meet the desired standards which is of prime importance in terms of quality of care and patient satisfaction. We hope that this manual serves as a road map for administrators and health practitioners providing home healthcare services in building a patient-centric care system.

CBAHI is a reputable entity that is recognized in the region and internationally for promoting quality in the Saudi health system through its accreditation process. The International Society for Quality in Health Care (ISQua) accreditation further adds to CBAHI's standing and its credibility in the healthcare community.

On behalf of all staff members working in the Saudi healthcare system, I extend our appreciation and gratitude for the limitless support coming from our top leadership to ensure the health and lasting prosperity of the people of Saudi Arabia.

Fahad AlJalajel
Minister of Health & Chairman of Saudi Health Council

Standards Development Committee/Advisory Committees and Experts Panel

Experts representing all health sectors in Saudi Arabia, including physicians, nurses, pharmacists, laboratory specialists, infection control practitioners, biomedical engineers, administrators, and public policymakers, have actively guided the development of the National Home Healthcare Services. In addition, several professional bodies have assisted as well with the development and refinement of the standards. CBAHI would like to thank all health authorities, organizations, and individuals who participated in or provided external commentaries on this important national initiative. The following is a list of participants in alphabetical order.

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Preface

In the healthcare industry, evaluation is an essential part of every executive activity. Globally, appealing approaches have been employed to regulate and evaluate healthcare quality internally and externally. Accreditation has been cited as the most commonly used strategic external quality evaluation tool in healthcare. It is a systematic evaluation based on predefined standards that focus on sustainable quality improvement, patient-centeredness, and patient safety. In Saudi Arabia, since its inception in 2005, the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) has strived to support healthcare facilities by ensuring continuous compliance with quality and patient safety standards.

Over the last decade or so, the Saudi health system has witnessed significant progress at all levels. One remarkable area was the great expansion in the number and complexity of home healthcare services. This is in alignment with worldwide advancement in the medical field, with a greater emphasis on continuous performance improvement and measurement. In that, CBAHI is pleased to introduce the first edition of the National Standards for home healthcare services. These evidence-based standards are intended to support home healthcare services in Saudi Arabia improving the quality and safety of patient care. Being comprehensive, detailed, and occasionally prescriptive in design and nature, this edition of the standards was built to be relevant and applicable to the licensed home healthcare services operating in the Kingdom of Saudi Arabia.

During the development of this manual, the development team considered the variety in the quality levels across the continuum of care in home healthcare services and strived to create a set of standards that would apply to all home healthcare services. This manual contains important information on accreditation eligibility, scheduling of surveys, survey preparation, survey visit, and accreditation decision rules. In the remaining part, accreditation standards are distributed among relevant chapters.

We sincerely thank the committees, teams, and task forces that contributed to the development, compilation, designing, reviewing, and producing this manual. We would like also to convey our appreciation to the healthcare professionals who have been obliging and generous with their professional feedback, time, constructive comments, and suggestions.

CBAHI welcomes all stakeholders' perspectives, suggestions, and comments. Only by this constructive collaboration, we can improve the quality and safety of our patients.

Dr. Salem Al Wahabi Director General – CBAHI

PARTI

INTRODUCTION & EXPLANATORY NOTES

CBAHI at a Glance

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is the official agency authorized to grant healthcare accreditation to all governmental and private healthcare facilities operating today in the Kingdom of Saudi Arabia.

Having originally emerged from the Saudi Health Council as a non-profit organization, CBAHI is primarily responsible for setting quality and safety standards to ensure a better and safer healthcare system. Its first official inauguration occurred after the Ministerial Decree number 144187/11 in October 2005, which called for the formation of the Central Board for Accreditation of Healthcare Institutions, tasked with the initiation of a national voluntary healthcare accreditation program. In 1434/2013, the Council of Ministers mandated accreditation by CBAHI and gave the board its current name.

The Saudi Central Board's mission is to set standards and assess performance for better healthcare. The vision of the Saudi Central Board is to lead healthcare accreditation in the Middle East.

In addition to the Home Healthcare Services Certification Program, CBAHI now provides many accreditation programs, including Primary Healthcare, Hospital Healthcare, Ambulatory Healthcare, and Clinical Laboratories and Blood Banks.

CBAHI's goal is to achieve two conjoined initiatives, in congruence with (the 2030) vision. The first initiative is to expand the range of efficient and effective accreditation programs to cover healthcare services. The second initiative is to work with a variety of partners to support the health system in Saudi Arabia and the region by increasing the depth of quality improvement and patient safety, as well as by disseminating knowledge through training and education. Driven by its core values, and a dedicated team of surveyors and staff, CBAHI is determined to be a major driving force and a recognized standard for the provision of safe and high-quality healthcare.

CBAHI is proud to be one of the few healthcare accreditation agencies globally, accredited by the International Society for Quality in Healthcare (ISQua).

Healthcare Accreditation: Definition and Importance

Healthcare accreditation/certification is an assessment process that involves a rigorous, transparent, and comprehensive evaluation by an external independent accreditation body. The healthcare facility (HCF/service) undergoes an appraisal of its systems, processes, and performance by peer reviewers or surveyors to ensure that all tasks are conducted in a manner that meets applicable, predetermined and published national standards. Before the external evaluation, i.e., the survey visit, the HCF/service is expected to conduct a comprehensive self-assessment to determine its level of preparedness and how close it is to achieving full compliance with the standards. Therefore, accreditation/certification represents the healthcare accreditation body's public recognition of the achievement of accreditation/certification standards by the HCF/service. Standards set out a common framework to support the HCF/service to provide effective, timely, and quality services. They are designed to facilitate the delivery of improved care and treatment to the citizens and residents of Saudi Arabia.

Evidence from scientific research shows that engagement in a robust healthcare accreditation/certification program improves the structure, process, and outcome of care that healthcare facilities/services provided. Accreditation/certification is more than just a certificate to be obtained and hung on the wall. Accreditation/certification, when used correctly, can provide the following advantages:

- Accreditation/certification provides a framework for organizational structure and management. Accreditation/certification standards focus on the governance and leadership structures and functions within a HCF/service and the appropriate management of its business and day-to-day activities.
- Accreditation/certification helps improve patient safety and minimizes the risk of near misses, adverse outcomes, and medical errors. Ensuring patient safety through risk management and reduction is at the center of all accreditation/certification standards and is the ultimate goal of the self-assessment and survey activities.
- Accreditation/certification enhances community confidence in the quality and safety
 of care provided. When the HCF/service achieves accreditation/certification, the
 message is clear its leaders are committed to providing a nationally accepted
 standard of care in health services delivery.
- Surveyed HCF/services have found that seeing their operation through the eyes of experienced surveyors gave them a practical, more objective assessment of their internal administrative and clinical processes, as well as practical proposals for improving their processes and services delivered to the community.
- in the long term, accreditation/certification increases efficiency. It enhances lean practices, which leads to decreasing waste and achieving optimal results with less consumption of resources.
- Accreditation/certification helps improve a healthcare facility's competitiveness.
- Increasing public trust in an accredited/certified facility/service will encourage more
 patients to seek care and treatment there. This will increase its market share and
 improve its competitiveness in the healthcare sector.
- Achieving accreditation/certification will fulfill the regulations required by the Ministry
 of Health, which is now considering linking national accreditation/certification by
 CBAHI to the licensing of healthcare facilities/services.
- At this stage, registration with CBAHI and enrollment in its national accreditation/ certification programs is accepted by the Ministry of Health as satisfactory evidence for license renewal. However, eventually, all HCF/services operating in Saudi Arabia will be required to achieve CBAHI accreditation.
- Accreditation/certification has a link to reimbursement from insurers and other third parties. There is a growing tendency, nationally and internationally, to link accreditation with eligibility for insurance reimbursement.
- Accreditation/certification provides a robust tool for continuous quality improvement efforts in the HCF/service. It helps the facility/service leadership to ensure the sustainability of quality improvement projects and initiatives.
- Accreditation/certification provides excellent learning and educational opportunities.
 This is accomplished by educating staff on best practices and emphasizing the importance of patient education and patient rights.

Scope of Accreditation Surveys

The scope of the CBAHI survey includes all standard related functions of the surveyed HCF/ service. Each assessment survey is tailored to the type, size, and range of facility/service offered. Applicable standards from this manual are determined by CBAHI based on the scope of the services provided by the HCF/service undergoing the survey. Additionally, the survey team will consider the specific applicability of individual standards.

Any special medical procedures/services performed in the home healthcare services which are covered in any other CBAHI set of standards must also be followed. This might include services like pharmacy services and medication use/prescription, and so on.

Standards Development Process

A standard is a statement of excellence or an explicit predetermined expectation that defines the essential functions, activities, processes, and structures required from HCF/services to ensure the provision of safe, quality care and services.

Peer experts in their specific fields develop standards. It is against these standards that conformity of the healthcare facility is evaluated. Stated succinctly, a standard describes a HCF's/service's acceptable performance level. Within this context, there should be no confusion between accreditation/certification standards and licensure standards. When applied to the licensure of an individual practitioner or facility, the licensure standard is usually set at a minimal level designed to protect public health and safety. Accreditation/certification standards, on the other hand, are designed as optimal and achievable. When met, standards establish a high-quality level in a system.

CBAHI standards and those of all other relevant accrediting agencies focus on three significant aspects depending on which area they are addressing: structure, process and outcome.

Structure: Standards related to structure address the system's inputs, such as workforce, design of the HCF/service building, the availability of personal protective equipment for health workers, such as gloves and masks, and the availability of equipment and supplies, such as microscopes and laboratory reagents.

Process: Standards related to process address the clinical and administrative activities or interventions carried out within the HCF/service in the care of patients or the management of the facility/service or its staff. Examples include patient assessment, patient education, and medication administration.

Outcome: Standards related to outcome involve assessing an intervention's benefits and whether the activity's expected purpose was achieved. They provide information regarding predicted outcomes that are being realized. Examples include data regarding patient satisfaction, healthcare-associated infections, medication errors, sentinel events, and adverse falls and injuries.

CBAHI standards set expectations for HCF/service performance which are relevant, understandable, measurable, beneficial and attainable. Standards were built to serve as the basis of an objective evaluation process that can help HCFs/services measure, assess, and improve performance. CBAHI strives to be a nationally recognized symbol of excellence, respected throughout the industry and by other relevant authorities, as an assurance that accredited HCFs/services meet rigorous standards of quality and operational integrity that emphasize consumer protection and patient engagement. Therefore, the standards development process at CBAHI follows a long and robust methodology to ensure our standards are correct, evidence-based, relevant, and straightforward.

There are a variety of methodologies or approaches that have been used globally for healthcare accreditation standards development such as department-oriented standards, scope of services-oriented standards, or quality System essentials. The National Standards for home healthcare service contains standards of quality and patient safety that are descriptive in nature. Standards are included in five chapters: Leadership of the service (LD), Provision of Care (PC), Management of Information (MOI), Infection Prevention and Control (IPC), and Facility Management and Safety (FMS). The aim of these standards and the surveyor programs is to provide answers to the following four questions:

- Is the healthcare facility well-led?
- · Is the care delivered safe, effective and patient-centered?
- Is the environment, in which the care provided, good?
- Are the internal and external customers satisfied?

CBAHI used a 'hybrid methodology' to help answer these four questions positively. Some of the standards are departmental based, whereas others are based on quality metrics to ensure standards implementation, environmental safety, and internal and external customer satisfaction.

Specialized task forces develop the first draft of CBAHI standards, including focus groups and standards development committees that utilize input from a variety of sources, including:

- The standards set by professional scientific societies, both locally and internationally.
- Scientific literature review and research studies.
- Relevant laws, rules, and regulations.
- National (or international) emerging issues related to healthcare quality and patient safety.
- Input from healthcare professionals, providers, and patients.
- Panels of experts and consensus on best practices, given the current state of knowledge and technology.
- Environmental inspection.
- Evaluation results from previous surveys, if available.

The process of standard development can last several months before an initial draft is produced. The draft standards are then distributed nationally for review and made available for comment on the standards through a field review process. Based on the feedback received during the field review, the draft standards may be revised and again reviewed by the relevant experts and technical committees. The draft standards are finally reviewed and approved by the Standards Development Steering Committee and provided to the CBAHI Board for comments and remarks before submission to the Saudi Health Council for approval. Thereafter, the standards are made available to the target HCFs/services and an e-version is made available too on the CBAHI website.

To comply with the guidelines of the International Society for Quality in Healthcare (ISQua), a period of six months is allowed for publishing of the standards before they are effective. Through this, HCFs/services are given adequate time to familiarize themselves with and implement the standards.

Also, CBAHI surveyors are taught how to assess compliance with these standards.

No matter how robust the methodologies used in developing the standards, room for improvement will always exist. Therefore, once the standards are in effect, ongoing feedback is sought for continuous improvement purposes. This is one of several CBAHI initiatives for improving the efficiency and effectiveness of internal processes, including standards development to better meet the needs and expectations of our partners.

Structure of the National Standards for Home Healthcare Services.

The National Standards for Home Healthcare Services (HHS) are assembled into five chapters consisting of critical services and functions that HHS provides in Saudi Arabia. The standards within these chapters are arranged according to the workflow within the services.

The chapters are:

- Leadership of the Service (LD)
- Provision of Care (PC)
- Management of Information (MOI)
- Infection Prevention and Control (IPC)
- Facility Management and Safety (FMS)

Each chapter includes a brief introduction that explains the chapter's relevance and contribution to safe and quality patient care. Each standard consists of a stem standard represented by a concise statement, followed by one or more sub-standards to further illustrate the standard's requirements. Each sub-standard is constructed to independently serve as the evidence of compliance that is going to be measured and scored during the onsite survey. Each standard is accompanied by an explanation to help the HCFs understand the intent behind it.

No matter how robust the methodologies used in developing the standards, room for improvement will always exist. Therefore, all comments and remarks on standards can be made and viewed on the CBAHI website, which includes an electronic form that allows HCFs, experts and other interested parties to comment on current standards. The form allows for continual stakeholder feedback on the standards. This is one of several CBAHI initiatives for improving the efficiency and effectiveness of internal processes, including standards development, to better meet the needs and expectations of our partners.

Accreditation/Certification Survey

CBAHI surveyors typically employ a variety of evaluation techniques and strategies to objectively decide whether the facility/service meets standards related to critical systems and functions, such as governance and leadership, patient care processes, medication management, infection control, management, and safety of the facility environment and quality assurance. For example, the survey team may review written documents (e.g., strategic and operational plans and budgets and clinical policies and procedures). In addition to reviewing documents, surveyors will interview facility/service leaders, physicians, nurses, employees, and patients to determine the facility's/service's performance and compliance with standards. For example, the surveyor might interview a staff member to check on the process he or she would complete to report a medical error that caused harm to one of the patients receiving care in that facility. Similarly, a surveyor might interview a patient about his or her level of satisfaction with the care the HCF/service provides.

HCF/service leaders, including members of the governing body, may be interviewed regarding facility/service processes and how they are designed to meet planning, budgeting, quality assurance activities, and human resources management standards. When applicable, surveyors tour the facility's/service's buildings and patient care areas to evaluate standards related to overall cleanliness, building safety, fire safety, waste management, equipment and supply management, infection control, and emergency preparedness. Other diagnostic and support services such as the laboratory, radiology, pharmacy, central sterile services, and the day procedure unit are also assessed for safety, effectiveness, quality control, and equipment management.

In summary, during an onsite survey, when applicable, surveyors use various evaluation approaches to determine the facility's/service's compliance or performance regarding applicable structure, process, and outcome standards. These methods might include any combination of the following:

- Interviews with facility/service leadership, clinical and support staff, patients, and families.
- · Observation of patient care and services.
- Facility/service tour and observation of patient care areas, building facilities, equipment management, and diagnostic testing services.
- Review of written documents such as policies and procedures, orientation and training plans, budgets, and quality improvement plans.
- · Review of personnel files.
- Review of patients' medical records.
- Evaluation of the facility's/service's achievement of specific outcome measures (e.g., acquired infection rates, patient satisfaction) through review and discussion of monitoring and improvement activities.

This Manual Contains 54 Standards distributed throughout five chapters. The standards are:

	List of Standards
Number	Standard
LD.1.	The governing body defines its structure and operational responsibilities in a written document.
LD.2.	The governing body approves and evaluates the home healthcare service's quality and patient safety, and risk management initiatives.
LD.3.	The home healthcare service has a defined, current, and clear organizational chart.
LD.4.	The home healthcare service is effectively managed by a qualified director.
LD.5.	The home healthcare service has a clear scope of services based on community needs.
LD.6.	The leaders work collaboratively to develop the home healthcare service's strategic plan.
LD.7.	The leaders transform the approved strategic plan into an operational plan.
LD.8.	the home healthcare service's leaders work collaboratively to develop and maintain a staffing plan.
LD.9.	All categories of staff have clearly written job descriptions.
LD.10.	There is a process in place for credentialing and re-credentialing all healthcare providers.
LD.11.	All medical staff members have current delineated clinical privileges.
LD.12.	All new staff attend a mandatory orientation program.
LD.13.	There is a policy that ensures healthcare staff are competent in specific procedures and operating equipment.
LD.14.	There is a program for continuing education and training of all categories of staff.
LD.15.	The leaders develop an effective process to evaluate staff performanc, e at least annually.
LD.16.	The home healthcare service implements a comprehensive program to protect the health and safety of staff.
LD.17.	The leaders develop ethical standards to guide patient care and staff code of conduct.
LD.18.	The leaders support and protect the patient and family's rights.
LD.19.	The leaders develop and implement a policy and procedure to ensure and facilitate the patients' right to voice their complaints, concerns, and suggestions.
LD.20.	The home healthcare service has an implemented policy for controlling the development and maintenance of key documents.
LD.21.	The home healthcare service develops a comprehensive quality improvement and patient safety program.
LD.22.	The leaders prioritize and select a set of indicators that focus on the structure, processes, and outcomes of the services provided.
LD.23.	The leaders develop and implement a comprehensive risk management program.
LD.24.	The home healthcare service implements an incident reporting policy.

List of Standards		
Number	Standard	
LD.25.	The home healthcare service has a program to select and monitor clinical and operational contracts.	
LD.26.	The leaders implement policies and procedures to guide efficient procurement of equipment purchased or donated, medications, and essential medical consumables following national laws and regulations.	
PC.1.	Patients have access to home healthcare services based on their health needs and available services, and they are registered to receive the required services.	
PC.2.	The home healthcare service has a process to ensure the correct identification of patients.	
PC.3.	Patients are clinically assessed and reassessed through an established assessment and reassessment policy and procedure.	
PC.4.	The most responsible physician (MRP) develops a care plan to meet patient needs, considering cultural and spiritual matters.	
PC.5.	Healthcare providers are vigilant in detecting early warning signs warranting the patients' referral to a hospital.	
PC.6.	The home healthcare service develops and monitors the implementation of evidence-based guidelines for home healthcare.	
PC.7.	Diagnostic laboratory services are available or outsourced to meet the needs of the patient population served.	
PC.8.	The home healthcare service develops a policy and procedure for reporting critical test results.	
PC.9.	The home healthcare service develops a policy and procedure on safe medication management following local rules and regulations.	
PC.10.	Nursing Home Visit bags are properly prepared and regularly checked through an established procedure.	
PC.11.	The home healthcare service's staff assist patients and, when appropriate their families, in fully participating in making informed decisions about their care, treatment, and procedures.	
PC.12.	The home healthcare service has a process for discharge/termination services provided for the patient.	
MOI.1.	The home healthcare service defines, in a policy, the information that needs to be shared internally and with other external entities, and its format.	
MOI.2.	All patients seen in the home healthcare service have unique medical records.	
MOI.3.	The home healthcare service has a policy for making entries in the patient medical records.	
MOI.4.	The home healthcare service has a process for completing and storing patient medical records.	
MOI.5.	The home healthcare service develops a policy and procedure for the use of information technology.	
MOI.6.	The leaders ensure the integrity and security of telemedicine, teleradiology, and other diagnostic remote contracted services.	

List of Standards		
Number	Standard	
IPC.1.	The home healthcare service implements a coordinated program to reduce the risk of healthcare-associated infections.	
IPC.2.	The leaders develop and ensure the implementation of infection control policies and procedures targeting the most important infection risk processes during home visits.	
IPC.3.	Personal protective equipment is readily accessible and available and is used correctly by staff in all patient care areas.	
IPC.4.	The home healthcare service supports its patients and, when appropriate their families, in the safe disposal of medical waste.	
IPC.5.	The home healthcare service develops policies and procedures that address employees' screening, immunization, and post-exposure management.	
FMS.1.	The leaders establish and support a facility management and safety program.	
FMS.2.	The leaders ensure that the home healthcare service environment is safe for patients and staff.	
FMS.3.	The leaders develop and monitor the implementation of a fire prevention program.	
FMS.4.	The leaders develop a hazardous material (HAZMAT) plan.	
FMS.5.	The leaders develop a plan for the inspection, testing, and maintenance of medical equipment.	

PARTH

ACCREDITATION/ CERTIFICATION POLICIES

Eligibility for Accreditation

All HCF/services licensed to practice in Saudi Arabia are eligible for CBAHI accreditation/certification. However, eligibility for a survey visit is contingent upon the following requirements:

- The HCF/service meets all licensing requirements to operate as indicated by the statutes and regulations of the Ministry of Health.
- The HCF/service meets any additional licensing requirements as per other relevant authorities such as Civil Defense, Saudi Commission for Health Specialties, or Saudi Food and Drug Authority.
- The HCF/service meets the legal definition of home healthcare service:
 - Licensed as a home healthcare service under the laws governing healthcare institutions in Saudi Arabia.
 - o Maintain an organized healthcare staff and nursing services.
 - o Provides diagnostic and therapeutic services for home healthcare patients.
- The HCF/service provides home health care services covered by CBAHI National Standards.
- The HCF/service has been in operation for at least 12 months before the on-site survey.
- The HCF/service completes and returns an application form.
- In case the HHS is a part of healthcare facility services and not a stand-alone service; the healthcare facility has to be accredited by CBAHI.
- CBAHI healthcare facility (hospital or ambulatory) accreditation remains valid for at least 6 months at the time of the certification survey.

Registration with CBAHI

Registration with CBAHI for accreditation/certification is required for all eligible HCF/services. This is the first step towards accreditation/certification. The HCF/service is required to register by completing the registration form located on CBAHI's website. Registration is a quick yet essential step that provides the Healthcare Accreditation Department at CBAHI with the necessary information about the registering facility. A system-generated autoreply with a code number will be provided to the registering facility/service upon successful registration. This code number will subsequently be used for all future communications with CBAHI.

Accreditation/Certification Pathway

To obtain CBAHI accreditation/certification, a healthcare facility/service must complete several activities. Upon successful registration, the following resources will be provided to the HCF/service seeking CBAHI accreditation/certification:

- National Standards
- · Healthcare Accreditation Guide

The Accreditation Guide provides all required information to help the HCF/service prepare for the survey visits. It contains an abstract of each survey activity, including logistical needs, session objectives and suggested participants in the survey activities. Each year CBAHI decides on which HCFs/services to be visited in its specific accreditation/certification program/ service, based on the operational plan and the HCF/ service accreditation/certification cycle, for that particular year. CBAHI will notify those HCFs/services included in its yearly accreditation/s plan by the manner of a letter of enrolment.

CBAHI provides ongoing HCF/services Orientation Programs in different locations throughout the year. HCFs/services are encouraged to attend at least one of these orientation programs. Although any HCF/service can attend, preference is given to facilities selected for the current year's accreditation/certification plan. During these orientation sessions, accreditation/

certification policies and survey processes are explained in detail. In which, HCF/service representatives are given the opportunity to enquire about the intent of standards and how they should be implemented. The dates and venues of the orientation programs will be communicated to the HCFs/services promptly.

All HCFs/services enrolled in The accreditation/certification are encouraged to conduct a comprehensive self-assessment using the Self-Assessment Tool (SAT) that CBAHI provides upon registering for accreditation/certification. This tool is intended to help the facility assess how close it is to satisfactory compliance with the standards and requirements. It also provides an idea of how much preparation and time the HCF/service needs prior to the real survey visit. If objectively and effectively conducted, self-assessment provides better insight into the baseline situation of each facility and provides a common communication tool between the facility seeking accreditation and the accrediting body. As a rule, the SAT is for the HCF's internal use, but CBAHI might require it before conducting the survey to help determine the level of facility preparedness.

Some HCFs/services may choose to have a mock Survey visit. This visit is offered by CBAHI mainly as an educational tool by experienced peer surveyors to clarify accreditation/certification policies, standards, and their explanations. In addition to determining the applicability of the accreditation/certification chapters and verifying the self-assessment's findings. It should be noted, however, that mock surveys are subject to the available resources at CBAHI and the level of commitment demonstrated by the HCF/service towards achieving compliance with the standards.

The HCF/service may choose to participate directly in an on-site real survey visit. The time interval between registration and the achievement of accreditation/certification is 6 to 18 months, on average. HCFs/services are allowed to have a maximum of Two on-site accreditation/certification survey attempts within Two years time frame. Therefore, the facilities/services that will eventually prove incapable of achieving accreditation/certification, as reasonably persuaded by CBAHI, will be suspended temporarily from participation in the national accreditation/certification program and referred to the relevant authorities for further action.

Once a HCF/service has applied for an on-site real accreditation/certification survey visit and completed the pre-survey requirements as mentioned above, the tentative year of the visit will be determined based on CBAHI operational plan and communicated to the HCF/service by the registration department. As CBAHI real accreditation/certification visits are unannounced, HCF/service will be notified about the date of the survey and the survey team, seven days before the date of the real survey, can time frame have extended in the same specific cession. In all cases, the service agreement must be acknowledged and duly signed by the facility/ service and a copy returned to CBAH, and the HCF/service must provide evidence of payment of the required accreditation fee.

Survey Team

To earn and maintain accreditation/service certification, the HHS must undergo a survey conducted by the CBAHI survey team. CBAHI handles all scheduling arrangements for surveys in coordination with the HCF/service. The date of the survey visit will be determined in accordance with CBAHI's yearly operational plan.

Generally, the survey team is composed of two healthcare professionals. The size and specialties of the survey team members are usually fixed, but this might change according to the size of the HCF/service and its scope of services.

The survey is conducted under the leadership of a Visit Team Leader (VTL) that has been designated by CBAHI. The visit team leader is responsible for assuring that all survey activities

are completed within the specified timeframe and according to CBAHI's policies and survey guide. The HCF/service under survey is required to facilitate the work of the survey team members and to allow the visit team leader to practice his/her role and responsibilities, which include:

- Preparing and communicating the survey plan to the HCF/service;
- Chairing the opening and closing meetings;
- Communicating with facility/ service leadership regarding survey progress and initial findings;
- Evaluating team progress and adjusting survey plans as needed; when required;
- Coordinating and preparing the survey report and submitting it to CBAHI.

Rescheduling of Surveys

HHS scheduled for survey is strongly encouraged to adhere to the survey date set by CBAHI. However, rescheduling may be considered for review at CBAHI's discretion on a case- by-case basis, and in accordance with the postponement of the accreditation/certification survey policy.

CBAHI makes every possible effort to carry out survey visits as per schedule. Under limited circumstances, postponement may be considered if the two conditions of accepting postponement exist. The two conditions are; a justifiable cause, and an official letter reaching CBAHI at least 60 calendar days prior to the survey date. Justifiable causes may include;

- Significant natural or internal disasters (e.g. food, thunder, earthquake, major fire).
- Major renovation work that hinders the daily operation of the facility.
- Change of ownership or affiliation (e.g. merge and/or acquisition) within Six months prior to the date of the survey.
- A mandate to stop operation by a governmental authority.
- Relocation of the healthcare facility to another building/campus within Six months prior to the date of the survey.
- State of war when the healthcare facility might be affected or involved.

In all cases, postponement must not exceed Six months. For an extended period, in case the postponement cause still exists, approval from the CBAHI director general is required.

Accreditation/Certification Decision Rules

The HHS must meet all applicable standards at an acceptable level to be accredited/certified. CBAHI utilizes a multilevel process for making accreditation/certification and reaccreditation/recertification decisions. This is to ensure fairness, consistency, objectivity, and accuracy. As such, CBAHI benefits from any relevant report and/or significant finding or issue related to the surveyed facility that was brought to CBAHI's attention by relevant health authorities or previous accreditation surveys.

Accreditation/certification decisions are released and communicated to the HCF/service within 30 days after the conclusion of the survey visit. The accreditation/certification decision-making process is based on:

- The findings of the survey team members as recorded in the survey report.
- The factual accuracy review of the draft report by the participating HCF/service of any issue of fact found in the report before the accreditation/certification decision is made.
- Review/discussion during the meeting of the accreditation decision committee (ADC) for a significant finding that makes the survey outcome undetermined. This committee may request additional evidence before making a final recommendation for an accreditation decision. All accreditation/certification decisions are then ratified by the CBAHI Director General.

It is important to note that the decision to grant accreditation/certification is based primarily on the findings of the on-site survey as recorded by the surveyors in the survey report. However, the overall numerical score the HCF/service obtains is one important factor, among others, upon which the ADC members rely when making their recommendations. Other factors Include of the non-compliant standard(s); for example the degree of severity and immediacy of risk to patients, families, or staff safety.

Criticality has several levels. The most serious is when the surveyor notices an immediate threat to safety or quality of care. Examples include, Expired material is being used, a bare electrical wire is hanging down without any protection, and A patient is not properly identified. When a CBAHI surveyor notices an immediate threat, whether or not it is directly linked to the standards, the survey team leader will notify the HCF/service director and include the findings in the survey report.

Each standard is composed of a stem statement and sub-standard/s. The sub-standard is the measurable element to be scored by the surveyor during the on-site survey. Each sub-standard has equal weight and is scored on a three-point scale as follows:

- 0 = Insufficient Compliance (less than 50% compliance with the standard).
- = Partial Compliance (from 50% to less than 85% compliance with the standard).
- 2 = Satisfactory Compliance (85% and more compliance with the standard).
- N/A = Not Applicable.

The score of each standard is calculated using the sum of the scores of the sub-standards. The overall score of the HCF/service is calculated using the sum of the scores of all the applicable sub-standards divided by the maximum score. When one or more standards of this manual do not apply to a particular HCF/service, they are indicated by "NA." Non-applicable standards are not scored and are not included in either the numerator or denominator of the overall score.

The ADC shall recommend one of the following accreditation decisions:

Accredited/Certified

Accreditation/certification will be awarded when the surveyed HHS demonstrates overall acceptable compliance with all applicable standards at the time of the initial survey (or reaccreditation/certification), and when there are no issues of concern related to the safety of patients or staff. Accreditation/certification will also be recommended when the HHS has successfully addressed all post-survey requirements and does not meet any rules for denial. Scoring Guidelines:

- Overall score 75% or above.
- No other significant concern related to the safety of patients or staff.

Denial of Accreditation/Certification

Denial of accreditation/certification results when an HHS shows significant non-compliance with the accreditation/certification standards at the time of the survey. It also results if one or more of the other reasons leading to the denial of accreditation/certification have not been resolved. When the HHS is denied accreditation/certification, it is prohibited from participating in the accreditation/certification program for six months unless the Director-General of CBAHI, for a good reason, waives all or a portion of the waiting period.

- Overall score less than 75%.
- Presence of an immediate threat to the safety of patients or staff, that CBAHI surveyors observed during the survey.

- Significant non-compliance with the accreditation/certification standards at the time of the survey.
- Failure to submit the post-survey requirements promptly.
- The HHS was subjected to a focused survey but still could not meet the requirements for accreditation/certification.
- Reasonable evidence exists of fraud, plagiarism, or falsified information related to the
 accreditation/certification process. Falsification is defined as the fabrication of any
 information (given by verbal communication or paper/electronic document) provided
 to CBAHI by an applicant or certified HHS through redrafting, additions, or deletions
 of a document's content without proper attribution. CBAHI perceives plagiarism as
 the deliberate use of other HHS original (not common knowledge) material without
 acknowledging its source.
- Refusal by the HHS to conduct a survey.

Appeal Against an Accreditation/Certification Decision

A surveyed HCF can appeal against the following accreditation/certification outcomes:

- Denial of accreditation/certification, provided this is not due to a failure to submit the
 post-survey requirements in a timely manner after granting accreditation/certification
 or a failure to meet requirements after a follow-up focused survey.
- Suspension/Revocation of accreditation/certification.

All appeals shall be made within a maximum of fifteen calendar days from receipt of the official survey report by submitting a cover letter to be sent from the center's director to the CBAHI's Director General. This should include documentation to support the argument for the appeal and a completed Appeal Request Form (ARF) located on CBAHI's portal. Letters sent via electronic mail or facsimile will not be considered.

Grounds for Appeal

The HHS is entitled to an appeal if the appeal is based on one or more of the following grounds:

Relevant and significant information which was available to the survey team was not considered in the making of the accreditation decision.

- Relevant and vital information available to the survey team was not considered in making the accreditation/certification decision.
- The surveyors' report was inconsistent with the information presented to the survey team
- The existence of perceived bias among the surveyor(s).
- Information provided by the survey team was not duly considered in the survey report.
- The outcome of the appeal, if in favor of the appealer, will change the accreditation/ certification status. CBAHI will not consider appeals that will not result in a change of accreditation/certification status.

Initial acceptance of the appeal request can occur only when clear and convincing evidence indicates that the facility/service meets at least one of the grounds for appeal. The appeal request shall set forth the specific grounds for the request, and shall include a statement of the reasons for each ground, along with any other relevant statements or documents the HCF/ service desires to include. Centers applying for an appeal must identify the specific alleged procedural failures or the specific manner in which the decision was arbitrary or unreasonable and not based on, or consistent with, CBAHI standards and policies. Accepted appeals, including all relevant reports and evidence, are thoroughly studied by the appeal committee. One of the following decisions shall be made and communicated to the appealing HCF/service in a timely manner:

- The adverse decision is upheld.
- The healthcare facility's appeal is upheld, and the denial of accreditation is modified or reversed. In this circumstance, a full or focused re-survey may be conducted.

Accreditation/Certification Maintenance (Post-Survey Requirements)

CBAHI has redesigned its accreditation/certification to represent a continuous process versus a once-every-three-year evaluation. Accreditated/certified HHSs must maintain their accreditation/certification status by showing their continued compliance with the standards and requirements of CBAHI throughout the accreditation/certification cycle and following the specified time frames. This translates into standing and ad hoc requirements.

Standing Requirements for Accreditation/Certification Maintenance

Corrective Action Plan (CAP)

When accreditation/certification is awarded to a HHS, a Corrective Action Plan (CAP) addressing all standards that were not in satisfactory compliance during the survey may be requested by CBAHI for review and acceptance within 120 days from the date of the accreditation/certification decision. The CAP ideally focuses on demonstrating what has been done rather than what will be done. The CAP should identify all non-compliant standards, the requirements for improvement, the corrective actions that have been or will be taken (with dates and responsible individuals), and, as applicable, the monitoring measures to ensure the sustainability of the actions taken. A delay in submitting the CAP that exceeds 30 days beyond the due date without justification might result in a temporary suspension of the accreditation/certification certificate.

Midterm Self-Assessment

An accredited HHS must participate in a mid-cycle self-evaluation of standards compliance (Midterm Self-Assessment). Fifteen months from accreditation/certification, the HHS should start utilizing the self-assessment tool to assist in the periodic review of its performance against the standards. The HHS then has three months to complete the assessment.

Completing the midterm assessment will allow the HHS to identify areas of non-compliance with the standards and create a plan for correction of deficient areas to ensure the HCF/service comes into compliance before the following survey. For those areas self-identified as non-compliant with CBAHI standards, the HHS may be requested to submit a CAP to CBAHI that includes evidence to substantiate that the standard has been brought into compliance. The relevant department at CBAHI will review each facility's/service's plan of action via a telephone interview. It will indicate whether the action plan and timetables are acceptable for bringing the standard into compliance.

A delay in submitting the midterm assessment by more than 60 days from the due date without an acceptable justification to CBAHI may result in a temporary suspension of accreditation/certification, followed by revocation of accreditation/certification if the total delay exceeds 90 days.

During the next on-site visit following the submission of the midterm assessment, the surveyor will look for evidence of compliance/correction that the HCF/service provided as part of the plan of action. When there is a legitimate concern about the safety and quality of services provided by an accredited/certified center at the time of the mid-term assessment, CBAHI may require the center to undergo a mid-cycle survey, (a fee will be charged to cover costs) and to submit a plan of action for areas of non-compliance.

Ad Hoc Requirements for Accreditation Maintenance

Reporting of a sentinel event

When a sentinel event occurs, as defined by CBAH, in an accredited/certified facility, it must be reported immediately. A subsequent root cause analysis (RCA), and the risk reduction action must be submitted within the time frame defined by CBAHI.

A sentinel event is defined as any event leading to serious patient harm or death and that is caused by healthcare rather than the patient's underlying illness. By investigating sentinel events, one can identify deficiencies in healthcare systems and processes and put actions in place to prevent recurrence. CBAHI calls for the following with regard to sentinel events:

- Open disclosure/open communication. Patients and their families are entitled at all times to truthful and transparent communication and explanation of any sentinel events happening to them.
- When a reportable sentinel event occurs in a HCF/service accredited/certified by CBAHI, the HCF/service must provide evidence of reporting to CBAHI, HCF/service that are not accredited/certified by CBAHI are not required to report. In addition to reporting, CBAHI may become aware of the occurrence of a sentinel event through communication from one of CBAHI's surveyors, the media, a patient or relative, the HCF's/service's employees, or through other means of communication.
- CBAHI is interested in knowing about reportable sentinel events when they occur
 in HCF/service for learning and disseminating lessons learned to the medical
 community, thereby avoiding the recurrence of such events in the future. Medical
 errors and adverse events are opportunities for education and quality improvements.
- Reporting must be safe. Patients, families, and staff are encouraged and should be empowered by the HCF/service leadership to report any sentinel event without fear of retribution. CBAHI has zero tolerance for accredited HCFs/services taking disciplinary actions against a staff member who reports a sentinel event. If the disciplinary action proves to be related to reporting, this can negatively impact the HCF's/service's accreditation/certification status.
- The outcome of a reported sentinel event is dependent on the level of commitment the HCF/service demonstrates towards studying the root cause(s) of the incident and re-designing its processes and systems to prevent a recurrence. When CBAHI is persuaded of this constructive approach by the concerned HCF/service in dealing with sentinel events, accreditation/certification is usually maintained. When this is not the case, CBAHI will pursue this further to decide on the HCF's/service's eligibility to maintain its accreditation/certification until the required corrections are made. In situations where the accreditation/certification certificate is valid for less than six months and CBAHI is not persuaded that the corrections have been made, an early full re-accreditation/re-certification survey may be warranted.

Notification of significant changes

Accredited/certified HCF/service must notify CBAHI in writing about any significant structural/ functional/ regulatory changes that took place after the accreditation/certification survey was conducted. Written notification should be submitted no more than 30 days after the initiation/ occurrence of such changes through the CBAHI portal. These changes include, but are not limited to the following:

- A national regulatory body has mandated closure for all or part of the HCF/service.
- HCF/service is not in compliance anymore with other relevant rules and regulations (e.g. civil defense license).
- HCF/service accreditation/certification by other international accrediting organizations has been suspended or revoked.
- A new service is initiated for which CBAHI has standards, and that was not included in the last survey.
- Any of the services are being offered in a new location or branch.
- Major construction/destruction/renovation work has been undertaken in any of the HCF/service buildings, floors or units.
- A significant increase (30% or above) or decrease in the volume of services/bed capacity has been experienced.
- The HCF/service has merged with or acquired an unaccredited facility.
- A significant change has occurred in the governance or ownership.

CBAHI will evaluate the impact of these changes and a decision for conducting a focused survey may be warranted accordingly.

Accreditation/Certification Suspension and Revocation

CBAHI expects nothing but the truth, honesty and sincere intentions in all dealings and propositions from HCF/services engaged in its accreditation/certification program. This "good faith" engagement applies continuously throughout the accreditation/certification cycle. The HCF/service must ensure that it is not violated. In addition, accredited HCF/services must maintain the same momentum both before and after accreditation/certification. Some might argue that it is a natural tendency to ease back after a survey visit. However, compliance with the standards must not drop simply because the survey is completed, and accreditation/certification has been awarded. Should CBAHI become aware, by any means of an accredited HCF/service that is not in compliance with the standards, CBAHI will verify the situation and take appropriate action.

CBAHI may receive information regarding possible violations by accredited HCF/services through several channels; most importantly reports of related government agencies, written or verbal complaints, and the media. Types of violations include, but are not limited to, the following:

- CBAHI becomes aware of an immediate threat to the safety of patients or staff in an accredited HCF/service.
- The HCF/service is not committed to the specified time frames for accreditation/ certification, for example, maintenance of timely submission of a corrective action plan after accreditation/certification or timely submission of a midterm self-assessment.
- The HCF/service failed to report a sentinel event as per the relevant policy without an acceptable justification.
- The HCF/service is committing an act of misuse (see the policy on accreditation certificate and seal), deception, or any deliberate misrepresentation of the truth (see the policy on truthfulness and the ethics clause).
- The HCF/service is discouraging communication or taking disciplinary action/reprisal

- against patients or staff members trying to communicate directly with CBAHI about safety or quality of care concerns.
- The HCF/service intentionally lacks commitment to continuous compliance with CBAHI standards. This complacent behavior is incompatible with the CBAHI accreditation/certification process.
- The HCF/service is deliberately violating any of the other accreditation/certification
 policies mentioned in this manual or other supporting documents and manuals
 provided by CBAHI for accreditation/certification.

Once CBAHI is convinced that one or more of the above-mentioned violations exists in an accredited HCF/service, it responds by taking one of the following actions, in any order:

- Issuing a letter of "At Risk of Suspension of accreditation/certification."
- · Suspension of accreditation/certification.
- Revocation of accreditation/certification.

CBAHI determines the level of response to a specific violation based on several factors, including the severity of the violation, its frequency, previous accreditation/certification history, the source of information regarding the violation, and the findings and conclusion of CBAHI's inquiry. When necessary, a focused or complete survey might be conducted for validation before a response can be given or an action taken. This kind of survey is always for one or more of the above causes (e.g., when concerns have been raised about an accredited/certified facility's/service's continued compliance with CBAHI standards). An accredited/certified HCF/ service may undergo a survey at any time, at the discretion of CBAHI, and the survey is usually unscheduled (the HCF/service receives 48 hours' notice before the survey) or unannounced (without advance notice), depending on the seriousness and type of violation. Surveys can include either all the healthcare services or only those areas in which a severe concern may exist. HCF/services are usually charged for these surveys, regardless of the outcome. Results can affect the HCF's/service's accreditation/certification status. If the HCF/service does not allow CBAHI surveyors to conduct the survey, CBAHI may change the facility's/service's status to Revocation of Accreditation/Certification.

It should be noted that if a facility's accreditation/certification is suspended, the HCF/services can regain accreditation/certification once the causative violation has been rectified. However, the suspension will not be lifted before the specified prohibition period of 12 months from the date of suspension as per CBAHI policy.

Revocation of accreditation/certification is a serious consequence that prohibits participation in the CBAHI accreditation/certification program for a minimum of 18 months from the date of revocation as per CBAHI policy.

For both suspension and revocation of accreditation/certification, CBAHI will communicate the new accreditation/certification decision to the relevant authorities and display it publicly. The Director General of CBAHI, with appropriate reason, can waive all or a portion of the prohibition period of the suspension or revocation decisions.

Random Surveys

To support CBAHI's ongoing quality assurance initiatives, an accredited/certified facility/ service may be selected for a random survey from nine to 30 months after an accreditation/ certification survey. Random surveys are unannounced. A five percent sample of all certified HHS is randomly selected each year for this activity. These random, unannounced surveys are a means by which CBAHI evaluates the consistency and quality of its program while also demonstrating to the public and regulators that accredited HHSs remain committed to CBAHI standards throughout the accreditation/certification cycle. Random surveys also provide CBAHI and its surveyors with opportunities to further consult with accredited HHSs in the interval between regular surveys. No fee shall be charged to the HHS when a random survey is conducted.

The HCF/service may be selected for a validation survey visit as part of an inter-rater reliability program for CBAHI surveyors within one month after receiving the accreditation/certification decision report. This visit outcome does not impact the accreditation/certification status granted in the actual accreditation/certification survey visit. The HHS will not bear any financial cost.

Accreditation/Certification Certificate and Seal

Once accreditation/service certification is granted, HCF/services are encouraged to display the CBAHI logo, accreditation/certification certificate and seal on the facility's/service's bulletin boards, banners, website, newsletters, brochures, and headed stationery.

CBAHI requires all accredited/certified healthcare facilities/services to follow the guidelines and conditions for the appropriate use of the CBAHI logo, accreditation/certification certificate, and seal. Specifically, CBAHI works to ensure that no accreditation/certification material is used in a way that may mislead the public or others or provide false information related to a healthcare facility's/service's accreditation/certification status.

Upon receiving the certificate package, accredited HCFs/services must sign and return a disclaimer/guidelines form related to the conditions of display and publication of the CBAHI logo, accreditation/certification certificate, and seal. These include:

- The printing of the accreditation/certification seal is accurate and legible, with no degradation or distortion.
- The size of the CBAHI logo and its accreditation/certification seal should remain in the same permitted proportion as that provided.
- The CBAHI logo, certificate, and seal should be used in the same format, with no extra graphics or words.
- The HCF/service employs the same colors used in the CBAHI logo or black and white when the logo is used for certain printed materials such as newspaper advertisements, newsletters, brochures, flyers, and posters.
- The HCF/service is prohibited from using the CBAHI logo or accreditation/certification seal on business cards.

Upon expiry of the certificate validity period or suspension/revocation of the accreditation/certification, the HCF/service shall immediately take action to refrain from using the CBAHI logo, accreditation certificate, and seal.

Release of Accreditation/certification -Related Confidential Information

CBAHI asserts that a HCF/service undergoing its accreditation/certification survey is expected to provide access to information related to the evaluation of their compliance with CBAHI standards.

As a guiding policy to a HCF/service engaged in its different accreditation/certification programs, CBAHI commits to keeping confidential all information obtained or received during the accreditation/certification process, including all survey data and information that surveyors come across during the survey process.

For an HCF/service participating in the CBAHI accreditation/certification program, some information is subject to public release. This includes:

- The healthcare facility/service accreditation/certification status being posted on the CBAHI website.
- The areas of the HCF/service that were included in the accreditation/certification survey.
- The standards under which the accreditation/certification survey was conducted.

Other accreditation/certification-related information is not subject to public release except the HCF/service in question. The exception to this rule is when CBAHI receives an official request for clarification from relevant health authorities or public health agencies. This information includes:

- Accreditation/Certification Committee minutes and agenda materials.
- The accreditation/certification certificate.
- The post-survey requirements, including any CAPs.
- The results of investigations related to a sentinel event, including the root cause analysis prepared in response to that event.
- The results of investigations involving any falsified information the healthcare facility/ service provided to CBAHI.
- Any other information related to compliance with CBAHI standards obtained from the HCF/service before, during, or after the accreditation/certification survey.

Complaints against an Accredited/Certified Healthcare Facility/Service

CBAHI is interested in collecting information from various sources to improve the quality and safety of all accredited HCFs/services. These sources may include complaints from patients, their families, HCF/service staff, government agencies, the media, and the public.

Staff members at any given HCF/service accredited by CBAHI must be informed that they may make complaints directly to CBAHI without fear of retaliatory actions from their HCF/service.

CBAHI addresses all complaints that would help identify possible non-compliance with its accreditation/certification standards, thereby posing a possible threat to the safety of patients, staff, or the public. More precisely, CBAHI can evaluate complaint information only in terms of its relevance to compliance with CBAHI's standards. Issues of a personal nature or individual disputes should be dealt with by the concerned facility/service or the regional health authority. CBAHI cannot follow up on complaints about HCF/services which are not accredited/certified.

When CBAHI receives a complaint against an accredited/certified HCF/service, CBAHI will conduct an initial screening to determine its relationship to standards and impact on patient safety. If the complaint does not relate to compliance with CBAHI standards, a response of "non-relevance" will be forwarded to the complainant, who will be advised to forward the complaint to the HCF/service leadership or the regional health authority. A response shall be made accordingly if the complaint relates to compliance with one or more CBAHI standards.

The response will depend on a risk assessment matrix that determines the probability and severity of the complaint. CBAHI will check for any other complaints regarding the same HCF/ service. CBAHI will give one or both of the following responses.

- CBAHI may write to the HCF/service about the complaint. When requested, the HCF/service must make available its records of complaints and subsequent actions taken.
- CBAHI may decide to visit the healthcare facility/service to verify whether a problem
 exists in meeting the standards involved in the complaint. Such visits are usually
 unannounced, and the outcome may change the accreditation/certification decision.

It is CBAHI policy not to disclose any information related to patients or complainants unless authorized to do so. In addition to information about the complaint's relevance to CBAHI standards, the complainant will receive the following information:

- The course of action CBAHI took regarding the complaint.
- Whether CBAHI has decided to act regarding an HCF/service accreditation/ certification decision following completion of the complaint's investigation.

To file a complaint against a CBAHI-accredited/certified healthcare facility/service, an individual can send his/her concern via the contact form on the CBAHI website. The individual can also file the complaint directly by calling the Universal Access Number 920012512. CBAHI requires that the complainer reveal his or her identity. Therefore, CBAHI will not consider anonymous complaints.

Conflict of Interest

CBAHI works to ensure the integrity and fairness of all businesses conducted by employees working in the central office and the surveyors.

In addition, all healthcare facilities/services engaged in the CBAHI accreditation/service certification process are required to refrain from any actual or potential act or behavior that might create a conflict of interest, including:

- Proposing any fee, remuneration, gift, or gratuity of any value to CBAHI employees or surveyors for the performance of their duties or survey-related activities.
- Employing, contracting, or having any financial relationship with CBAHI employees
 or surveyors to provide consulting or related services in any capacity, either directly or
 through another party. This includes services provided in preparation for the survey,
 assisting in preparing the self-assessment, conducting mock surveys, helping with
 the interpretation of the standards, and the like. All requests for consulting services
 utilizing CBAHI employees or surveyors shall be directed to CBAHI.
- Not declaring to CBAHI any business (including consulting) or recruiting relationship with one or more CBAHI surveyors either directly or through another party with whom he or she is affiliated at any time during the preceding three years.

Truthfulness and Ethics Clause

CBAHI strives to maintain the highest ethical and legal standards in the conduct of its business. This includes honesty, transparency, and truthfulness in all its dealings, and avoidance of all situations that might appear unethical or illegal. The same is expected from the HCFs/services seeking CBAHI accreditation/certification. CBAHI employees are committed to politely declining any gifts or gratuities offered to them or to members of their families, including spouses, children, and parents, when the donor expects something in return. Such gifts or gratuities may be attempts to gain an unfair advantage or influence the manner in which the employee or surveyor performs his/her job duties. Gifts of nominal value may be accepted as tokens of appreciation or goodwill provided they are given as gestures of a professional relationship and do not involve or create the appearance of any commitment in terms of survey results or accreditation/certification decisions. When to other transportation means is available.

Business lunches, tea, coffee, and snacks during the survey are permitted. Other social gatherings are prohibited, and the HCF/service is encouraged not to offer such activities to the survey team. Using the HCF/service vehicle to transport the survey team to and from the survey site is acceptable.

CBAHI's confidential and proprietary business information is safeguarded and is utilized only in keeping with the best interests of CBAHI, its obligations to third parties, and the highest ethical and legal standards. Such information must not be disclosed to a third party without prior approval of a duly authorized member of CBAHI management for an acceptable reason. In line with CBAHI's core values and relevant policies, CBAHI maintains the confidentiality of all data and information about CBAHI and the HCF/service.

CBAHI is also committed to resolving complaints and ethical issues raised by CBAHI employees or client HCF's/services to ensure justice, confidentiality, impartiality, timeliness, and feedback to the complainants.

PART I I I

ACCREDITATION STANDARDS

Leadership of the Service (LD)

Introduction

For any home healthcare service (HHS), quality and patient safety depend on effective leadership. The owner of the HHS may be a single private owner, a group of private owners, or a governmental entity. In all cases, the owner (private or governmental) constitutes the governing body or the governance for the HHS. The governance or governing body is ultimately responsible for the provision of safe and quality patient care. The HHS's director, selected by the governing body, ensures the safety and quality of patient care. The HHS may be directed by the single owner, who then carries the role of governance and leadership at the same time. All home healthcare services need to have a clearly stated mission.

It is the responsibility of the leadership of the HHS to develop the mission and provide adequate resources to fulfill this mission. To ensure the quality and safety of healthcare services, the leadership group members must work collaboratively, communicate effectively through clear lines of authority, and coordinate and integrate the services provided.

This chapter addresses the roles and responsibilities of the Governance and Leadership group for the following processes:

- · Organizational structure
- Structure and function of the governing body
- Roles and responsibilities of the home healthcare service leaders
- · Mission, vision, scope of services, and strategic planning
- Effective human resource management
 - o Staffing plan and recruitment
 - Job descriptions for all types of employees
 - o Credentialing and privileging
 - Staff orientation and education
 - o Staff performance evaluation
 - Staff health and safety program
- Patient and family rights
- Quality improvement and patient safety
 - o Developing and maintaining the program's policies
 - o Developing and supporting a quality improvement and patient safety program
 - o Developing and supporting a risk management program
 - o Contract oversight

LD.1. The governing body defines its structure and operational responsibilities in a written document.

- **LD.1.1.** The governing body approves and periodically reviews the home healthcare service's mission, vision, and values and makes it public.
- **LD.1.2.** The governing body approves the home healthcare scope of services, plans, programs, and key policies and procedures.
- **LD.1.3.** The governing body approves the home healthcare service's operating and capital budgets and other resources required to execute the operational plan efficiently.
- **LD.1.4.** The governing body defines any approval authority delegation.
- **LD.1.5.** The governing body appoints a qualified director responsible for managing the home healthcare service.

Explanation

The governing body (owner(s), board of directors) should define its structure, role, and responsibilities in a written document. Roles and responsibilities of the governing body include approval of strategic and operational plans and budget, mission and vision, the scope of services, the risk management program, and policies and procedures. The home healthcare service mission, vision, and values are aligned with KSA Vision 2030 and should be made public. The roles and responsibilities of the governing body also include appointing the home healthcare service's director and defining any leadership delegation authority that highlights the person responsible for managing the home healthcare service in the absence of the home healthcare service's director. The home healthcare service has established and implemented written policies and procedures regarding conflict of interest and the procedure for disclosure.

LD.2. The governing body approves and evaluates the home healthcare service's quality and patient safety, and risk management initiatives.

- **LD.2.1.** The governing body annually approves the quality and patient safety, and risk management initiatives.
- **LD.2.2.** The governing body receives and evaluates the quality and patient safety reports, corrective actions, and outcomes from the home healthcare service, including risk management, at least quarterly.
- **LD.2.3.** Recommended corrective actions by the governance are documented and received by the home healthcare service director for implementation.

Explanation

The governing body ensures patient and staff safety by approving the quality and patient safety and risk management programs and periodically evaluating their effectiveness. At least every three months, the governance should receive reports on selected indicators, all safety concerns that staff reported, all medical complications, and all financial and other administrative risk issues. Governance, together with leadership, should work to formulate an action plan to prevent errors and mitigate risk. Governance observes and documents the implementation and outcomes of corrective actions.

LD.3. The home healthcare service has a defined, current, and clear organizational chart.

- **LD.3.1**. An approved and updated organizational chart identifies the relationship between the home healthcare service's governance, leadership, and other staff, with titles.
- **LD.3.2.** The staff are aware of the organizational chart and its intent and can demonstrate their relationship to it.

Explanation

Efficient and effective healthcare facility/service management requires effective staff communication and clear reporting lines. The organizational chart is developed to present the relationship between the governance (the owner or board of directors) and the home healthcare service's managing director(s) and between the managing director(s) and the front-line staff. Managerial positions in the chart are reported by title and name. All program staff should know their position concerning the organizational chart, their line of command, and required reporting.

LD.4. The home healthcare service is effectively managed by a qualified director.

- **LD.4.1.** The director, with other leaders, develops the mission, vision, and values statements and communicates them to all staff.
- **LD.4.2.** The director ensures service compliance with all relevant laws, regulations, and policies.
- **LD.4.3.** The director ensures the availability of adequate and proper resources for the planned services in accordance with the approved operating budget.
- **LD.4.4.** The director ensures a safe and functional HHS facility environment for staff.

Explanation

The home healthcare service needs to be managed daily by a director. The job description of the home healthcare service's director highlights his/her roles and responsibilities and the required job qualifications and experience. The director is responsible for the home healthcare service's compliance with all applicable governmental laws and regulations, including, but not limited to, patient care regulations, medication management, licensure, staffing licensure and certification, civil defense requirements, municipality requirements, and other applicable regulations. The director is responsible for responding to all governmental inspections, including clear action plans for compliance. Accreditation/certification of the home healthcare service by CBAHI is the ultimate responsibility of the home healthcare service's director. The director ensures the adequate number and the right mix of staff required for the day-to-day activities. He/she also ensures the continuous availability of the required supplies, medications, and resources to run the home healthcare service safely. The director recommends all required policies, procedures, protocols, and clinical practice guidelines that are required for the clinical, managerial, and financial integrity of the home healthcare service. The director ensures the facility is designed to deliver the intended services safely and securely for patients and staff.

LD.5. The home healthcare service has a clear scope of services based on community needs.

- **LD.5.1.** The scope of services includes the specialty services available, the number of staff in each specialty, the level of professional coverage for the age group served, and working hours.
- **LD.5.2.** The scope of services is available to the public.

The home healthcare service functions according to a predefined scope of services document developed collaboratively between governance and the home healthcare service's leaders (the home healthcare service's director, medical director, nursing director, human resources director, finance director, and administration director, as applicable). The scope of services includes the range of clinical services in each provided specialty based on the home healthcare service's location and the community needs (i.e., preventive, health promotion, curative, and rehabilitative). The scope of services includes the number of clinics for each specialty, age group, and working hours. The average number of patients anticipated to be seen, and the maximum number who can be seen should also be highlighted. The scope of services also includes the level of professional coverage, for example, consultants versus specialists.

LD.6. The leaders work collaboratively to develop the home healthcare service's strategic plan.

- **LD.6.1.** The strategic plan is guided by the mission and vision as well as inputs from patients/service users, their families, staff, and, where possible, the wider community.
- **LD.6.2**. The strategic plan is based on a comprehensive evaluation of internal and external environmental factors.
- **LD.6.3.** The strategic plan addresses all clinical and non-clinical services and programs.
- **LD.6.4.** The strategic plan spans a period of three to five years and is reviewed regularly.
- **LD.6.5.** The strategic plan includes the goals and objectives required to fulfill the home healthcare service's mission.

Explanation

Home healthcare services require planning to continue their mission and achieve their vision. This planning may include mastering current services (programs of excellence) or introducing new services. The strategic planning is based on a comprehensive evaluation and analysis of the internal and external operational and environmental factors that may affect the home healthcare service's mission and vision, such as SWOT analysis and PEST analysis. The plan specifies clear goals and objectives to achieve in a specified time frame.

LD.7. The leaders transform the approved strategic plan into an operational plan.

- **LD.7.1.** Leaders translate the center's goals and objectives into operational plans with defined projects, clearly delineated responsibilities, required resources, and time frames.
- LD.7.2. Leaders communicate the plans to all staff.
- **LD.7.3.** Departmental directors develop annual departmental plans in alignment with the service strategic plan.
- **LD.7.4.** The leaders ensure the use of evidence-based and best practice information to develop and improve the services.
- **LD.7.5.** The leaders plan and budget for the upgrade or maintenance of vehicles, equipment, and other resources.
- **LD.7.6.** The leaders meet regularly to review the key performance indicators of services, surveys, audits, and feedback, and use the collected data to improve the service's operations.

The strategic plan should be converted into an operational plan that contains steps to follow and staff assigned to lead and execute. Plans and resources are all approved by governance and tabulated for further timely implementation. Staff involved in and/or affected by the plan should be informed accordingly. The services should be evidence-based, and all policies and practice guidelines that the leaders develop should be based on referenced and updated practices. Regular leadership meetings shall take place to ensure that all plans are carried out effectively and that policies and practice guidelines are followed. The leaders should develop an annual budget, taking into consideration any additional cost for replacing or upgrading equipment, upgrading services, and periodic maintenance and repair. The budget should be distributed between the different patient care areas to ensure seamless and safe patient care.

LD.8. The home healthcare service's leaders work collaboratively to develop and maintain a staffing plan.

- **LD.8.1.** The staffing plan ensures that services meet the needs of safe patient care.
- **LD.8.2.** The staffing plan defines the number, type, and credentials required of staff and defines their roles.
- **LD.8.3.** The home healthcare service recruits and assigns appropriately qualified staff as outlined in the staffing plan.
- **LD.8.4.** The home healthcare service updates the staffing plan annually, monitors deficiencies, and takes improvement actions accordingly.

Explanation

The home healthcare service's leaders (when applicable, the home healthcare service director, HR director, medical director, nursing director, and administrative director) work together to formulate a staffing plan based on workload and considering the scope of services of the different programs. The plan should include the number, type, and qualifications of staff required in all the home healthcare service areas (medical and non-medical) to ensure safe patient care, according to the national/ international rules and regulations. The plan should be updated annually, monitored to identify deficiencies, and appropriate improvement actions are taken to ensure adequate staff coverage.

LD.9. All categories of staff have clearly written job descriptions.

- **LD.9.1.** The job description outlines the knowledge, skills, and attitude necessary to perform the job responsibilities.
- **LD.9.2.** The job description clearly defines the roles and responsibilities for the position.
- **LD.9.3.** Job responsibilities and clinical work assignments are based on the evaluation of staff credentials.
- **LD.9.4.** The job description is discussed with and signed by the staff upon hiring and is kept in the personnel file.

Explanation

For smooth operational performance and accountability, each staff member will have his/her job description that outlines daily responsibilities, necessary qualifications, skills, and experience. Job descriptions assist in recruiting the right staff for vacant positions and constitute the basis for the staff evaluation, whether it is probationary or carried out at the end of the year. This job description is discussed with each staff personally. At the time of hiring, the job description is signed to acknowledge that the staff is fully aware of the job, its requirements, and its responsibilities.

LD.10. There is a process in place for credentialing and re-credentialing all healthcare providers.

- **LD.10.1.** The credentialing process applies to all clinical staff members licensed to provide patient care on a full-time, part-time basis or visiting basis.
- **LD.10.2.** The credentialing process includes gathering, verifying, and evaluating credentials, including licensing, education, training, and experience.
- **LD.10.3.** The credentials are verified from the source directly or through a third party with documented evidence kept in the personnel file.
- **LD.10.4.** The home healthcare service ensures the registration of healthcare professionals with the Saudi Commission for Health Specialties and licensing by the Ministry of Health following the laws and regulations of Saudi Arabia.

Explanation

The home healthcare service must make all efforts to ensure the placement of new staff in the correct position initially and every two years after that. This credentialing process applies to all clinical staff licensed to provide patient care (physicians, nurses, physiotherapists, technicians).

The credentialing process involves:

- Collecting all the information related to the staff (education, training, experience, competencies, and licensure).
- Verifying credentials from the primary source.
- Evaluating staff credentials to ensure the staff fits in his/her assigned position.

According to rules and regulations, the home healthcare service ensures that all healthcare professionals are registered with the Saudi Commission for Health Specialties and licensed by the MOH. All staff who are credentialed and approved to work in the home healthcare service should ensure their credentials are kept safely with the administration.

LD.11. All medical staff members have current delineated clinical privileges.

- **LD.11.1.** The home healthcare service has a policy and procedure for granting privileges to medical staff.
- **LD.11.2.** Clinical privileges are determined based on the staff's current competence, privileging policy, and available services.
- **LD.11.3.** The medical staff's clinical privileges are recommended by the medical director and approved by the governing body, either directly or by appropriate delegation.
- **LD.11.4.** The clinical privileges are reviewed and updated every two years and earlier if needed.

Explanation

The privileging of physicians is the most beneficial proactive risk management approach concerning patients' safety. It allows physicians to perform procedures and surgeries for which they have been made qualified by education, training, and certification. This prevents patients' exposure to the risk of morbidities. Each physician should list the invasive procedures that he/she is allowed or privileged to perform. The home healthcare service must have a policy and procedure for granting individual privileges. Clinical privileges are distributed in the areas where the physician is practicing. The privileging process is reviewed and updated every two years and earlier if a physician receives new training on a specific procedure or is found to be potentially dangerous in performing other procedures.

LD.12. All new staff attend a mandatory orientation program.

- **LD.12.1.** The general orientation program for newly hired staff includes information about the home healthcare service's mission, vision, values, organizational structure; patient and family rights; safety and security; infection control; and quality, patient safety, and risk management programs.
- **LD.12.2.** Each new staff attends a job-specific orientation program that helps in executing the job responsibilities outlined in the staff's job description.

Explanation

All new staff (full-time, part-time, visiting, and volunteers) are oriented to the home healthcare service. A general orientation should include information about the home healthcare service such as:

- · Mission, vision, and values.
- · Current organizational structure.
- Code of conduct and ethical framework.
- Patient and family rights.
- Safety and security.
- Infection control.
- Quality and patient safety and risk management programs.

The orientation also includes a specific job orientation, which teaches the staff the requirements for patient assessment and documentation, and how to deal with patient transfers, among other essential processes in the staff's area of practice. Policies related to vacations, penalties, grievances, and separation may be compiled into a manual provided or accessible to staff.

LD.13. There is a policy that ensures healthcare staff are competent in specific procedures and operating equipment.

- **LD.13.1.** The policy contains a list of procedures requiring competency assessment for each category of staff.
- **LD.13.2.** All staff are assessed upon hiring and annually for the required competencies.
- **LD.13.3.** The policy addresses the required training and competency testing of staff operating specialized equipment to ensure safe operation.
- **LD.13.4.** Only properly trained and competent staff are allowed to use specialized equipment and medical devices.

Explanation

To ensure patients' safety, nurses, physical therapists, and other allied healthcare staff must be tested annually on their competency in specific procedures, according to their scope of work, such as:

- Taking blood samples.
- Inserting intravenous lines.
- Inserting an indwelling urinary catheter or simple urinary catheterization.
- Inserting nasogastric tubes.
- Infection control practices and precautions (isolation procedures, hand hygiene, the use of personal protective equipment, preventing needlestick injuries).

Competency assessment results are documented in staff personnel files for evidence and monitoring of compliance with the policy. Corrective action is required if staff is not competent, and a re-assessment is needed. To reduce risk to patients and staff and increase operational efficiency, staff receive appropriate training regarding the safe operation of medical equipment. Periodic competency testing is required, and newly introduced equipment is not used until the staff is trained and tested competent in its use.

LD.14. There is a program for continuing education and training of all categories of staff.

- **LD.14.1.** The home healthcare service has a scheduled education and training program based on staff needs.
- **LD.14.2.** The home healthcare service leaders encourage and compensate staff to attend educational and training activities relevant to the home healthcare scope of services and in line with the labor law.
- **LD.14.3.** All staff members who provide direct patient care maintain a valid certificate on basic life support (BLS).
- **LD.14.4.** The home healthcare service identifies other staff members to be trained in advanced life support as appropriate to the scope of service.

Explanation

Staff professional development is essential for improving home healthcare services. The home healthcare service should drive continuous medical and nursing education as well as appropriate education for other categories of staff. The simplest way to accomplish staff education is to provide a scheduled educational program fulfilling person-program care and the home healthcare scope of services and needs, including quality, patient safety, risk management, medication safety, infection control practices, patient/service user rights, complaint management, shared decision-making, communication skills, informed consent, the cultural beliefs, needs and activities of different patient/service user groups and how to deal with end-of-life patients. Also, the home healthcare service can grant either financial support or time off so that staff can attend conferences, symposia, training courses, and other educational activities. Although the scope of services of most home healthcare services does not include high-risk patients, a sudden cardiopulmonary arrest may occur and potentially be lethal. Therefore, all staff members providing direct patient care must have basic life support skills and certification. Advanced life support certifications like ACLS/PALS and others are also considered based on the scope of service. Staff personnel files should show documentation of training and education.

LD.15. The leaders develop an effective process to evaluate staff performance, at least annually.

- **LD.15.1.** The performance evaluation is based on objective criteria targeting staff knowledge, skills, and attitude.
- **LD.15.2.** The performance evaluation is conducted at the end of the initial probationary period and at least annually thereafter.
- **LD.15.3.** Evaluations include personal goals that the staff will aim to achieve over the next year.
- **LD.15.4**. The home healthcare service staff are involved in the evaluation of their performance by receiving feedback, commenting on, and signing the evaluation.
- **LD.15.5**. Information about staff credentials, privileges, competencies, orientation, training, education, and evaluation are kept securely in an updated personnel file.

Explanation

To ensure satisfactory staff performance according to the job descriptions and privileges, a standardized objective process for gathering and assessing the staff's performance, scope of practice, professional development, and attitude is developed for each staff category. The performance evaluation's objective criteria are shared with

the staff. The evaluation is carried out at the end of the initial probationary period and at least yearly after that. Staff also acknowledge their performance and comment on any required actions for improving their performance as set forth by their supervisors. The performance evaluation always includes the goals for the next year (part of the evaluation for the next year). Both the staff and the supervisor sign the performance evaluation, which is kept in the employee's personnel file.

LD.16. The home healthcare service implements a comprehensive program to protect the health and safety of staff.

- **LD.16.1.** The program covers all staff and is consistent with the relevant laws and regulations.
- **LD.16.2.** The program provides rules and regulations for the protection of staff from occupational health, safety hazards, and workplace violence.
- **LD.16.3.** The staff health and safety program incorporates the home healthcare service's quality, safety, risk management, and infection control programs, including health screening, immunization, and post-exposure management.
- **LD.16.4.** The staff has confidential and secure medical records that reflect their health status.

Explanation

The health and safety of staff are vital for the provision of high-quality care. A staff health and safety program should be available in all healthcare facilities. The home healthcare service ensures working areas are designed to reduce occupational risks. There is a vaccination program to protect staff liable to infection from common viral illnesses (e.g., varicella-zoster and hepatitis B).

Staff working in offices receive random checks of their posture behavior and their furniture to ensure its safety for their extended office hours. Manual workers receive information about the safe handling of goods and about avoiding strains and sprains and are monitored to ensure they implement this information. The home healthcare service has a policy to prevent needlestick injuries, ergonomics and other occupational hazards, such as radiation and chemical exposures. The home healthcare service also focuses on using personal protective clothing and equipment when dealing with infectious disease patients. The home healthcare service should focus on security issues to manage violence and aggression against staff. The home healthcare service should be well-coordinated with quality and patient safety and risk management programs. Reports about staff health and safety need to reach the governance as per the quality and patient safety program requirements. Staff files containing information about staff members' vaccinations and illnesses should be available and kept safe and secure.

LD.17. The leaders develop ethical standards to guide patient care and staff code of conduct.

- **LD.17.1.** Marketing for staff and services, if performed, is carried out ethically as per the applicable laws and regulations.
- **LD.17.2.** The leaders develop a set of values and a professional code of conduct for all staff
- **LD.17.3.** The leaders ensure that patients and their families are fully informed and protected when involved in clinical research projects, having a formal institutional review board approval for the research project before starting.
- **LD.17.4.** The leaders develop a process to receive and resolve ethical dilemmas, patient and non-patient related, in a reasonable time frame as determined by the home healthcare service.
- **LD.17.5.** The leaders develop policies and procedures for dealing with ethical issues including code status and end-of-life policies.

The leaders are responsible for developing the framework that governs how patient care is conducted ethically across home healthcare service activities. The values and professional code of conduct describe the home healthcare service expectations of staff regarding their behavior and communication with each other and with their patients. This includes the ethical portraying of services, proper and accurate billing; assuring that staff is engaging in ethical behavior with patients and staff; and assuring that staff is wearing appropriate attire. Patient-related dilemmas related to ethics may include decisions not to treat, to withdraw treatment, or discontinue treatment.

LD.18. The leaders support and protect the patient and family's rights.

- **LD.18.1.** The leaders develop and maintain a patient rights and responsibilities statement and develop processes that support their implementation.
- **LD.18.2**. The leaders ensure that information regarding patient rights and responsibilities is available to patients and families and that they are informed about their rights and responsibilities in a manner they can understand.
- **LD.18.3.** The health team provides care and services that are respectful of the patient's values and beliefs.
- **LD.18.4.** A patient's privacy is respected during all clinical interviews, examinations, procedures, and treatments.
- **LD.18.5.** The health team is responsible to ensure patient protection from neglect, exploitation, and abuse.
- **LD.18.6.** The leaders ensure that patients/families have the right to accurate billing for provided services.
- **LD.18.7.** Patients/families have the right to refuse or discontinue treatment or ask for a second opinion.

Explanation

Patient and family rights and responsibilities are paramount for ethical and safe patient care. The leaders are responsible to develop policies and procedures regarding patient and family rights, including the bill of rights. These policies and procedures should be available to patients and their families in written documents that are close at hand or displayed in the home healthcare service. The leaders ensure that staff is fully aware of the patient and family's rights and responsibilities and trained on executing them. The leaders exert efforts to ensure that patients are treated with dignity and that their privacy is continually respected. Leaders should also ensure the safety and security of patients' personal belongings. Patient and family rights ensure respect for patients' preferences and choices to the extent possible within the rules and regulations. The home healthcare service's price list should be accessible to patients and families. A receipt should be given for services rendered, including for insurance patients. It is the right of the patient and family to receive an initial estimated cost for their treatment if requested. The request for an itemized bill should be honored if requested by patients and families unless the service given is under the price list of a "package deal."

LD.19. The leaders develop and implement a policy and procedure to ensure and facilitate the patients' right to voice their complaints, concerns, and suggestions.

- **LD.19.1.** Patients' complaints are received by a specified channel(s) and resolved in a time frame described in the policy.
- **LD.19.2.** The home healthcare service assigns a staff member to be responsible for managing complaints.

- **LD.19.3.** Patient satisfaction surveys are conducted regularly.
- **LD.19.4.** Data collected from surveys and complaints are analyzed, used for improvement, and integrated into the quality and safety program.

Patients' satisfaction is a measure of their appreciation of the services that the home healthcare service provides. Patients' complaints identify areas that require the immediate attention of leaders. The leaders support the patients in their right to complain in a manner they prefer. The complaint system is the responsibility of the patient relations officer or similar staff, who should follow a policy and procedure. Every effort is made to finalize patients' complaints within the time frame defined in the policy. All complaints are analyzed and trended, and information presented to leaders for corrective actions is to be developed and implemented. Patients' satisfaction surveys should be conducted at least quarterly. Information and action plans from complaints and surveys are included in the quality and safety program and reported to governance.

D.20. The home healthcare service has an implemented policy for controlling the development and maintenance of key documents.

- LD.20.1. The home healthcare service has a unique identifier for each key document, with title, number, date of issue, and revision date.
- LD.20.2. Key documents are developed, approved, revised, and terminated by an authorized individual or committee.
- LD.20.3. Key documents are communicated to relevant staff and are always accessible.
- **LD.20.4.** A process is in place to ensure that key documents are consistently implemented.

Explanation

For the proper execution of crucial function documents, policies, procedures, and processes, they must be identical in their written format and have tags that identify the originating department, date of issue, date of revision, date of implementation, and date of expiry. Only authorized individuals can change policies. Key function documents, policies, procedures, and processes carry the name(s) of the author(s) and approving authority. A system must be in place to ensure that only approved, and non-expired policies are circulating and available to staff. All staff should be familiar with the available key function documents, policies, procedures, and processes relevant to their practice.

D.21. The home healthcare service develops a comprehensive quality improvement and patient safety program.

- LD.21.1. The program utilizes key performance indicators and patient and staff surveys to measure performance and improve both clinical and managerial areas.
- LD.21.2. The information generated from key performance indicators and surveys is readily accessible on a timely basis to those responsible for and involved in the delivery of the services and is utilized for making improvements and supporting the leaders' decision-making.
- LD.21.3. The home healthcare service implements at least one improvement project per year utilizing an evidence-based quality improvement method such as "FOCUS PDCA".

The home healthcare service should ensure its services' quality and continuous improvement by developing a quality management and patient safety program. Key performance indicators are utilized to measure the performance of the services provided. Staff is notified of the performance findings. The information provided is utilized to improve the clinical and managerial areas (structure, process, and outcome). Improvements in quality utilize an evidence-based approach such as FOCUS-PDCA.

LD.22. The leaders prioritize and select a set of indicators that focus on the structure, processes, and outcomes of the services provided.

- **LD.22.1.** The selection process of key performance indicators is based on the home healthcare service's essential processes and priorities.
- **LD.22.2.** Each indicator has an operational definition, defined numerator and denominator, data collection method and frequency, a mathematical expression such as ratio or percentage, and a desirable target.
- **LD.22.3.** The home healthcare service collects, validates, and analyzes performance indicators data by staff with appropriate knowledge and skills.
- **LD.22.4.** The performance monitoring results are discussed with staff, utilized in their evaluation, and reported quarterly to the governance, together with action plans taken for improvement.
- **LD.22.5.** The indicators are compared internally by historical trends and externally by benchmarking to other similar programs when available.

Explanation

The collection of key performance indicators follows an evidence-based approach. The indicators should cover a variety of issues based on structure, process, and outcome. The indicators are regularly presented to staff to enhance their performance and to be utilized in their evaluation. Benchmarking one's performance should be carried out internally (comparing historical data) and externally, either locally or internationally, to define the home healthcare service's position in terms of performance. A quarterly report should be presented to the governance with improvement action plans if required.

LD.23. The leaders develop and implement a comprehensive risk management program.

- **LD.23.1.** The home healthcare service addresses clinical, managerial, and financial risks.
- **LD.23.2.** The reporting of incidents, variances, and claims constitutes the program's essential reactive arm.
- **LD.23.3.** The home healthcare service develops and implements at least one proactive risk reduction approach per year.
- **LD.23.4.** The home healthcare service develops and periodically updates a risk register for all potential clinical, managerial, and financial processes in the home healthcare service.
- **LD.23.5.** The home healthcare service utilizes an evidence-based process for grading risks based on severity, frequency, and the likelihood of occurrence.
- **LD.23.6.** Information from the risk management program, including incidents, analysis, and improvement projects, is communicated to the staff and the governing body quarterly.

In general, the healthcare sector carries moderate to high risks. The home healthcare service should develop and implement a risk management program that covers all aspects of its activities: clinical, managerial, and financial. The home healthcare service risk management program should be based on incident reporting, analysis, and a proactive approach such as failure mode and effects analysis (FMEA) or any similar proactive risk management approach, to prevent future recurrences. The proactive approach should target improving high-risk, problem-prone, or high-volume practices that have a substantial financial impact, such as insurance rejections, or that can markedly improve patients or staff satisfaction. Risks should be graded according to an evidence-based unified score system. The home healthcare service should maintain a list registering all its risky practices and procedures. Written policies and procedures are established and implemented that outline the process for meeting patient needs in a disaster or crisis. Information collected from the risk management program is used to improve the system, and staff should be informed of the findings and improvement projects at least quarterly.

D.24. The home healthcare service implements an incident reporting policy.

- **LD.24.1.** The policy outlines the types of incidents to be reported, both internally and to relevant regulatory authorities, and the time frame and mechanism for reporting.
- **LD.24.2.** Sentinel events and major incidents are reported, investigated, and the findings are utilized to prevent their recurrence.
- **LD.24.3.** Incidences involving patients are documented in the medical record, and the physician informs the patient and family of any investigation results.
- **LD.24.4.** The home healthcare service compiles a report on incidences according to type and severity. An action plan to prevent its recurrence is distributed to staff and governance on a regular basis.

Explanation

The home healthcare service needs to develop an incident reporting policy with a unified reporting mechanism for all occurrences, variances, or accidents. Reporting includes near misses (accidents that were prevented or discovered before reaching the patient). The home healthcare service encourages staff to report without fear of retribution. Adverse events, particularly sentinel events, are reported to the relevant authorities as per local rules and regulations. All incidents are categorized by type and severity. The home healthcare service prepares a report on all incidences (including near misses) by their type and severity. Leaders develop an action plan to prevent the recurrence of incidents and accidents. The report on adverse events and actions taken is distributed to the staff and the governing body at least quarterly. Sentinel events are situations that lead to the death or severe incapacitation of a patient and may include the following:

- 1. Unexpected death.
- 2. An unexpected loss of a limb or function.
- 3. Retained instruments or sponges.
- 4. Serious medication error leading to death or significant morbidity.
- 5. Wrong site, wrong patient, or wrong procedure or surgery.

LD.25. The home healthcare service has a program to select and monitor clinical and operational contracts.

LD.25.1. Contracted entities are selected based on evidence-based criteria developed by the relevant department.

- **LD.25.2.** The home healthcare service director ensures relevant leaders' recommendations and approval on contracts.
- **LD.25.3.** The leaders ensure that the contracting entity and services provided meet applicable laws and regulations.
- **LD.25.4.** The leaders ensure that the services provided are integrated into the overall quality and patient safety program.
- **LD.25.5.** The leaders regularly monitor and document the compliance of contracted services with the appropriate standards and take documented corrective actions for improvement when standards are not met.

To ensure the best cost-effective outcomes from contracted services, the process owners will closely monitor the implementation of contracts related to outsourced services, such as housekeeping or laboratory services. To ensure that the monitoring process is translated into an agreed-upon process and outcome indicators, the process owners approve contracts before the leaders' final approval. Contract renewal is based on the findings from indicators monitoring.

- LD.26. The leaders implement policies and procedures to guide efficient procurement of equipment purchased or donated, medications, and essential medical consumables following national laws and regulations.
 - **LD.26.1.** Leaders ensure that contractors and suppliers of medical devices and supplies have a Medical Device Establishment License (MDEL).
 - **LD.26.2.** Leaders ensure that all newly purchased medical devices have a Medical Device Marketing Authorization (MDMA) certificate.
 - **LD.26.3.** Leaders approve newly introduced consumables based on a formal testing and feedback process from end-users.

Explanation

Non-approved medical equipment and supplies may not provide accurate investigation results, accurate monitoring parameters, or safe patient care. Therefore, leaders should develop a procurement policy to ensure only nationally approved medical equipment, medications, and essential supplies are procured. The Saudi Food and Drug Administration (SFDA) provides such information and performs visits to institutions to ensure that only approved equipment, medications, and supplies are in use. Newly introduced consumables require formal testing and approval by the enduser before purchase.

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Provision of Care (PC)

Introduction

Home healthcare services provide preventive, curative, and rehabilitative services. The home healthcare service accepts patients for services based on its capability to provide services that meet the identified patient's needs.

Providing optimum care requires careful planning, coordination, and communication. The home healthcare service provides an appropriate and thorough assessment for each patient. Patient care is planned and implemented to ensure the best possible outcome. To support continuity of care, patient assessment and care are documented in a complete medical record. The healthcare team must receive test results at the appropriate time. The patient and family's participation in the care plan is essential for its success, therefore their proper education is of utmost importance. Informed consent for procedures is one of the patients' and families' rights. As the care process may need to occur between multiple providers, a collaborative process should be in place to promote continuity and coordination of care when the patient is referred, transferred, or discharged. Staff training and the home healthcare service's readiness for cardio-pulmonary resuscitation is an integral part of managing unexpected complications that may arise.

Fundamental processes and activities addressed in this chapter include the following:

- Access to care, referrals, and the provision of emergency medical services.
- · Patient identification.
- Scope and content of the patient assessment and reassessment.
- · Care planning.
- · Evidence-based guidelines.
- Patients' and families' education and participation in the care plan.
- Medication management.
- Discharge/termination of home healthcare service.

PC.1.

Patients have access to home healthcare services based on their health needs and available services, and they are registered to receive the required services.

- **PC.1.1.** A standardized process for accepting and registering patients for services is based on their needs and available services.
- **PC.1.2.** A visit schedule is in place to organize patient visits, and staff is aware of the services provided.
- **PC.1.3.** An on-call coverage list is in place to enable patient access to care for non-emergency circumstances, after availability hours.
- **PC.1.4.** Patients are registered under the care of a specific home healthcare physician referred to as the Most Responsible Physician.
- **PC.1.5.** Patients/families are provided with the contact information of their healthcare providers.

Explanation

A uniform process for registering patients ensures a strong link between the patient and the unique medical record number generated. The use of a patient's full name and medical record number in identifying patients avoids miscorrelation with investigation results or performing a procedure on the wrong patient. Appointments reduce congestion and ensure the availability of services. Appointment staff are informed to be fully aware of the services provided and trained to direct patients to the appropriate services. Patients are accepted and registered under physician supervision. The home healthcare service provides patients, families, and the broader community with information about accessing its services using an appropriate format and language (e.g., displayed posters, brochures, handouts, and websites).

PC.2.

The home healthcare service has a process to ensure the correct identification of patients.

- **PC.2.1.** Patients are identified by at least two identifiers including their full name, as in a valid identification document, and a unique medical record number.
- **PC.2.2.** Patients are identified before starting any treatment, procedure, blood withdrawal, or administration of medications.
- **PC.2.3.** Patients/families are actively involved in the process of patient identification.

Explanation

Ensuring that the right patient receives the correct care is an essential aspect of safe care. Patient identification errors can occur in all types of clinical activities, whether diagnostic or therapeutic. The intent is to precisely identify the individual for whom the service or treatment is intended and, additionally, to match the service or treatment to that individual. Acceptable identifiers may be the patient's name (at least three names) and the medical record number, date of birth, and so on. At least two identifiers are used, and the patient's name should be one of them. The home healthcare service documents the identified patients' medical record number, number and time of visits, and desired staff qualifications.

Patient identification is reconfirmed during the:

Collecting blood samples and other specimens for clinical testing.

- Administration of medications.
- Performing a procedure.

PC.3.

Patients are clinically assessed and reassessed through an established assessment and reassessment policy and procedure.

- **PC.3.1.** Assessed and reassessed policies and procedures are developed collaboratively and highlight the minimum assessment requirements prior to providing care.
- **PC.3.2.** A multidisciplinary team does the initial assessment to identify the patient's home healthcare needs.
- **PC.3.3.** The physician documents the assessment of pain, medications, allergy, code status, and the psychosocial aspect at the initial assessment.
- **PC.3.4.** The health team recognizes patients' physical and mental limitations and assists the patient and family in incorporating the patient's remaining abilities into daily activities.
- **PC.3.5.** Patients with physical limitations who are at risk of falls or pressure ulcers are provided with adequate measures and precautions to reduce associated risks.
- **PC.3.6.** Assessment includes screening patients for malnutrition and referring patients who are malnourished or at risk for malnutrition for a nutritional assessment and management.
- **PC.3.7.** Subsequent reassessments are done by the provider of the home healthcare services to ensure the effectiveness of the care planning.

Explanation

Patient assessments are of paramount importance to reach the correct diagnoses and establish the appropriate plan of care. The home healthcare service should have an assessment policy and procedure that the various entities have developed collaboratively. The policy should identify the scope and content of the history and physical examination of the different specialties. During their first visit, all patients undergo a comprehensive history and physical examination, regardless of the nature of the disease. Patients are screened for nutritional needs, functional needs, the presence or absence of pain, fall risk, social needs, and environmental assessment. A home environmental assessment is done with recommendations for modification and alerts for patient and staff safety. A multidisciplinary team is involved in the initial assessment and may include a physician and nurse, social worker, and other specialties based on the need. Those patients who screen positive are thoroughly assessed and managed according to the findings. Hand washing and hand disinfection procedures are used correctly, as well as gloves and masks or eye protection as needed. The home healthcare service addresses the need for patient end-of-life care.

PC.4.

The most responsible physician (MRP) develops a care plan to meet patient needs, considering cultural and spiritual matters.

- **PC.4.1.** The most responsible physician develops and documents the care plan based on the patient's home healthcare needs.
- **PC.4.2.** The care plan is designed to achieve desired outcomes specified as measurable goals.
- **PC.4.3.** The care plan is updated only by the most responsible physician based on the outcome measures assessed by the visiting staff.
- **PC.4.4.** The care plan is comprehensive, covering all health aspects prevention, treatment, rehabilitation, and care at the end of life.
- **PC.4.5.** The home healthcare service establishes and implements telephone order and escalation policies.
- **PC.4.6.** The home healthcare service implements a standardized process to improve the effectiveness of communication between the most responsible physician and the visiting staff.

A documented care plan is vital to managing a patient's condition. The care plan is developed according to the assessment information that the healthcare team obtains. The plan is tailored to accommodate the patient and family's spiritual and cultural needs as well as the patient's medical condition. A collaborative care plan is developed involving nurses, dieticians, physiotherapists, social workers, occupational therapists, speech therapists, and clinical pharmacists. The care plan includes measurable goals, such as maintaining a pain score below 4. The most responsible physician reviews the care plan during every visit and changes it, if necessary, according to the patient's response. Telephone order and escalation protocols need to be established to guide any telephone order during the visit.

PC.5.

Healthcare providers are vigilant in detecting early warning signs warranting the patients' referral to a hospital.

- **PC.5.1.** The home healthcare service has an established policy and procedure to detect any early warning signs that warrant referring the patient to a higher healthcare setting.
- **PC.5.2.** In case of emergency, the healthcare providers aligned with the family, arrange with the Red Crescent to safely transfer the patient to the proper service/facility.
- **PC.5.3.** The healthcare providers endorse the patient to the response team and document this in the patient's medical record.

Explanation

The home healthcare service should have an assessment policy and procedure to detect any early warning signs that indicate deterioration of the patient's condition. During the visit, the healthcare providers should be vigilant and aware of any warning signs (clinical, psychological, social) that warrant referring the patient to a higher healthcare setting, and these findings are then documented in the patient's medical record. The healthcare providers, in cooperation with the family, arrange with the Red Crescent to transfer the patient to a higher healthcare setting based on national rules and regulations. The healthcare providers endorse the patient to the emergency response team and document the handover of the patient in the patient's medical record. The family should be educated about how to respond in an emergency and when to call the Red Crescent for an emergency.

PC.6.

The home healthcare service develops and monitors the implementation of evidence-based guidelines for home healthcare.

- **PC.6.1.** The guidelines cover wellness care, preventative care, chronic illness management, and end-of-life care.
- **PC.6.2.** The guidelines are updated at least every two years and their implementation is monitored.

Explanation

Certain chronic medical diseases and conditions can pose a great risk to the performance of home healthcare services. The home healthcare service is required to adopt and implement updated evidence-based guidelines for the management of certain conditions relevant to home healthcare services. Staff should comply with these guidelines and leaders should monitor the implementation to ensure the safety of the patient population.



Diagnostic laboratory services are available or outsourced to meet the needs of the patient population served.

- **PC.7.1.** The home healthcare service develops a policy and procedure for the ordering and processing of laboratory tests, including point-of-care tests.
- **PC.7.2.** A trained healthcare provider performs quality control for all point of care tests per the manufacturer's recommendation.
- **PC.7.3.** The most responsible physician acknowledges reviewing the expected test results within 24 hours from issuing the report.
- PC.7.4. The home healthcare service develops a test results turnaround document.

Explanation

Developing and maintaining a current scope of services that meets the needs of the patient population, clients, and customers is a sign of commitment to quality and professional practice. The scope of the diagnostic services (laboratory, radiology, and others) should be clearly defined and easily accessible to all lab staff, radiology staff, and other diagnostic services as indicated by internal and external customers. For example, the laboratory department needs to have a comprehensive specimen collection manual to guide the clinical staff in the lab in identifying the patient, test requisition, specimen collection, labeling, transporting, and handling of laboratory waste. Similarly, the radiology department also has a comprehensive guide that includes the procedures for patient identification, selection of imaging modality, informed consent, and sharing the results.

PC.8.

The home healthcare service develops a policy and procedure for reporting critical test results.

- **PC.8.1.** The policy defines which staff is responsible to receive critical test results.
- **PC.8.2.** The process involves the receiver writing down the result and reading back the findings to the result provider.
- **PC.8.3.** The read-back process and the physician's intervention are documented in the patient's medical record.

Explanation

Critical test results are reported following a process developed cooperatively. The process clearly defines the persons to be notified, the means of communication, the read-back sequence, and elements required for documenting the event (date, time, patient identification, critical test result, read-back documentation, and identification of both the notifying and notified persons).

PC.9.

The home healthcare service develops a policy and procedure on safe medication management following local rules and regulations.

- **PC.9.1.** The home healthcare service develops a process for medication reconciliation by the most responsible physician.
- **PC.9.2.** The home healthcare service develops a process for the safe prescribing of medications by the most responsible physician.
- **PC.9.3.** The home healthcare service develops a process for the safe administration of medications by healthcare professionals.
- **PC.9.4.** Adverse drug reactions and events are documented in the patient's medical record and are reported to the relevant local authorities as per the applicable laws and regulations.

Incorrect prescriptions cause 30% of medication errors; some of which can be serious. The home healthcare service should have a policy and procedure on the safe prescribing of medications to ensure that all prescriptions are identified by accurate patient demographics (name, age, file number), allergy status (identified on the prescription), and weight for pediatric prescriptions. Abbreviations are not used in prescriptions and a copy of the prescription is kept in the patient's medical record. All prescriptions should state and highlight the allergy status of the patient. In programs with pharmaceutical services, and as part of the prescription review process, pharmacy staff should discuss allergy status with the prescriber, and if necessary the prescriber can stop or change prescribed medication. Monitoring medication effects include observing and documenting any adverse effects. The home healthcare service ensures an established mechanism for reporting adverse events and defines the time frame within which the adverse event must be reported. The home healthcare service is responsible for ensuring that patients are treated as safely as possible. Aseptic measures are utilized during the dispensing and administering of medications.

Nursing Home Visit bags are properly prepared and regularly checked through an established procedure.

- **PC.10.1.** The contents of the home visit bag are suitable for the patient's needs.
- **PC.10.2.** Home visit bags are properly prepared according to the list of their contents with the expiry date of these contents clearly indicated.
- **PC.10.3.** There is a process for cleaning and disinfecting the home visit bags.

Explanation

The home visit bag, also known as a healthcare bag or nursing bag, is a very important part of at-home patient care. The home visit bag is properly prepared to appropriately address the patient's needs and the patients' and care teams' numbers. The home visit bag is safely stored in a designated area.

PC.11. The home healthcare service's staff assist patients and, when appropriate their families, in fully participating in making informed decisions about their care, treatment, and procedures.

- PC.11.1. Staff members provide patients/families with truthful and accurate information in a manner they can understand, regarding their illness, options for treatment, proposed treatment, potential benefits, potential complications, and the likelihood of success of treatment.
- **PC.11.2.** Patients'/families education is based on their healthcare needs.
- PC.11.3. Patients and families receive education to help them participate in the care process and understand any financial implications of their care choices.
- PC.11.4. Patients/families are provided with the identity and the professional status of the treating physician or other practitioners responsible and the contact details of the home healthcare providers.
- PC.11.5. Patient/family education is evaluated for effectiveness through demonstrating learning or verbalizes understanding.

Explanation

To assist patients and families in making informed decisions regarding accepting treatment or procedure, policies and procedures are established for patients/ caregivers including those patients with communication or language barriers, or special needs. The families should be provided the identity of the treating physician,

his professional status, and the team involved. Contact details of the home healthcare providers, physician, nurse, social worker, or call center are provided to the patient's family for more accessible communication.

Patient and family education is a cornerstone of the success of any treatment plan. The home healthcare service should develop policies and procedures for healthcare education during home visits. A patient and his/her family must be educated on their healthcare needs. Staff should make every effort to ensure the patient/family clearly understand the education provided. The education should include medication name(s), type, reason for use, how to safely administer medications, time, frequency, route, dose, anticipated actions, and potential side effects. Healthcare givers ensure the patient/family member demonstrates learning or verbalizes understanding. This education is documented in the patient's medical record.

PC.12. The home healthcare service has a process for discharge/termination services provided for the patient.

- **PC.12.1.** The most responsible physician specifies the estimated date of discharge/ terminating the service for each patient.
- **PC.12.2.** The most responsible physician decides the identifiable clinical criteria for discharge and ensures the patient's suitability and stability for discharge.
- **PC.12.3.** All medications and support services necessary for a safe discharge should be organized and documented in the discharge summary.
- **PC.12.4.** The patient is informed about how to communicate and obtain assistance if needed, post-discharge.

Explanation

The discharge/termination service policies and procedures outline the conditions when a patient will be discharged from the home healthcare service. Reasons for patient discharge from the home healthcare service may include improvement of the patient's condition to the degree that the patient no longer needs the home healthcare service, a decline in the patient's condition, death of the patient, or a request by the patient to discontinue the services. Discharge from the home healthcare service is documented in the patient medical record.

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Management of Information (MOI)

Introduction

Information management is a cornerstone for patient care and the decision support process by home healthcare service leaders. The home healthcare service leaders are required to design and implement an information management plan that achieves the following:

- Managing the information required by governmental and external agents.
- Managing internal information requirements.
- Security and confidentiality of information.
- Records retention.
- Patients' unique files documentation and completion

MOI.1. The home healthcare service defines, in a policy, the information that needs to be shared internally and with other external entities, and its format.

- MOI.1.1. The policy defines how patient demographics and medical information is shared among medical and administrative staff including paper format, electronic, or a combination.
- MOI.1.2. The policy identifies how the information is disseminated from leaders to staff and vice versa.
- MOI.1.3. The policy defines what information is required by the relevant external authorities, and the frequency of reporting.
- MOI.1.4. The policy defines what patient information, personal and medical, is required to be referred to a higher level of care.
- **MOI.1.5.** The policy identifies the staff security levels for accessing patient information.
- MOI.1.6. The policy identifies how various types of information are secured and safely stored.
- MOI.1.7. The policy highlights how long the home healthcare service is required to retain the various types of information as consistent with the applicable local rules and regulations.

Explanation

Communication failures are responsible for a third of morbidities and mortalities in healthcare. Identifying and organizing the flow of information inside the facility/ service and with external customers helps streamline communication and eliminate communication errors. All stakeholders collaboratively develop management of information plan that includes the following:

- Managing the patients' information (i.e. medical records) and defining its format (paper format, electronic, or combined).
- Management of internal communication between staff and the leaders, such as memoranda, management notifications, and staff complaints.
- Managing externally required information by the regulatory bodies.
- Managing how information is secured and safely stored.
- The information management plan identifies the level of security for each type of document and how staff can access the information he/she is authorized to view.
- The information management plan identifies how the information is backed up and restored if needed.
- The information management plan identifies the retention time of various documents and information relevant to the rules and regulations of the regulatory bodies.

MOI.2. All patients seen in the home healthcare service have unique medical records.

- MOI.2.1. The contents of the patients' medical records are arranged according to a standardized process.
- MOI.2.2. Medical record/file contains the required patient demographics including national identification number, contact information, emergency contacts, and insurance history.
- MOI.2.3. Medical record/file contains sufficient updated medical information to safely manage the patient and promote continuity of care including history, physical examination, plan of care, investigations, consultations, observations, consents, procedure/surgery reports, medications, allergies, and prior adverse reactions.

To ensure continuity of care, each patient cared for in the home healthcare service must have an individual medical record that has a unique medical record number. The medical record shall contain at a minimum all the elements specified in MOI.2.2 through MOI.2.3.

MOI.3. The home healthcare service has a policy for making entries in the patient medical records.

- **MOI.3.1.** The medical records policy identifies the category of staff allowed to write in the medical record.
- **MOI.3.2.** All entries in the patient's medical record are legible, dated, timed, and signed by the author.
- **MOI.3.3.** There is a uniform entry of data in medical records, whereby orders are written separately from assessments, care plans, and progress notes.
- **MOI.3.4.** Entries written in error in the medical record are not deleted or erased. Instead, a single line is passed through the error text, dated, timed, and signed by the author, or electronically the system allows for amendment tracing.
- **MOI.3.5.** Only standardized and approved abbreviations and symbols are used in medical records.
- **MOI.3.6.** The home healthcare service uses diagnosis codes and procedure codes including international classification of diseases (ICD) or current procedural terminology (CPT) consistent with the requirements of relevant authorities.

Explanation

Uniformity of writing in medical records ensures proper documentation and avoids misinterpretation of written information. Therefore, a policy should be developed and implemented based on the elements in MOI.3.1 through MOI.3.4.

Standardized diagnoses, procedures, and services codes help programs track pathology and standard procedures and comply with insurance companies requirements. Abbreviations and symbols could be interpreted differently, thus inadvertently changing the intended care plans.

MOI.4. The home healthcare service has a process for completing and storing patient medical records.

- **MOI.4.1.** The home healthcare service has a dedicated and secured storage method/ area for all medical records.
- **MOI.4.2.** The home healthcare service develops a policy and procedure for the clinical documentation improvement (CDI) program.
- **MOI.4.3.** Regular checks are made on returned files to ensure completion. The check includes but is not limited to demographics, medical information, and authentication.
- **MOI.4.4.** Noncompleted files are separated from completed ones in the storage area. They are completed in a time frame defined by the service.
- **MOI.4.5.** The home healthcare service keeps a record of the percentage of incomplete records over time and uses this information to improve staff compliance with record completion.

At the end of a patient's visit, the medical record is returned to the medical records store or electronically stored. This keeps the medical records safe, secure, and in good order. Upon its receipt, the medical record is checked for completeness according to a written process that includes complete demographics, medical information, and authentication. Every effort is made to complete any incomplete records within a time frame that the policy has identified. Each month, the home healthcare service should check a predefined percentage of its records for completion. The collected information is conveyed to staff and used to improve staff compliance with completion.

MOI.5. The home healthcare service develops a policy and procedure for the use of information technology.

- **MOI.5.1.** The policy and procedure on information technology highlight how generated information is stored and regularly backed up.
- **MOI.5.2.** The policy and procedure describe the manual procedures required to capture and record data in the event of system failure, maintenance, or repair.
- **MOI.5.3.** Staff can demonstrate the manual procedure to be used in the event of system failure, maintenance, or repair.

Explanation

Despite advances in infrastructure robustness, many HCFs/services still face database, hardware, and software downtime, lasting short periods or shutting down work for days. To maintain the completeness and comprehensiveness of data, an adequate data capturing process during downtimes is critical. Gaps in patient data may result in gaps in patient care. A complete manual system is prepared for use during any downtime period and includes managerial and clinical activities to prevent the interruption of care processes. End users involved in providing program services are trained on the planned manual system and know how to shift to the manual system if the electronic system is down. The downtime manual system is regularly assessed for effectiveness as well as after actual downtime incidents. Documented reports of this assessment are available and include actions taken in response to any deficiencies. Even though healthcare facilities/services may treat their stored media with care, it can still be damaged accidentally or on purpose, and medical records can be accidentally changed or erased. The creation of backup copies limits the amount of information lost. Backup media should be safely and securely stored. As part of information and data integrity, healthcare facilities/services are expected to have a precise mechanism for backing up data to ensure ease of retrieval. The backup process is regularly implemented to avoid any data loss or gaps in information that may affect gaps in the care and service provided and avoid misinformed decisionmaking by leaders.

MOI.6. The leaders ensure the integrity and security of telemedicine, teleradiology, and other diagnostic remote contracted services.

- **MOI.6.1.** Telemedicine, teleradiology, and other diagnostic remote contracted services are registered and comply with national health rules and regulations.
- **MOI.6.2.** The leaders ensure the credentialing and privileging of all healthcare providers involved in the process of providing diagnostic remote services before starting the service.
- **MOI.6.3.** The leaders ensure the security and confidentiality of patient information exposed because of the telecommunication process.

The provision of telemedicine and teleradiology, and other remote diagnostic services such as ECG interpretation, has been recently introduced in the Kingdom. These services are regulated and the services provider should be approved and registered with the Ministry of Health. The home healthcare service ensures the competency of the physicians providing the services by subjecting them to the home healthcare service's credentialing and privileging process like other practicing physicians in the home healthcare service. The confidentiality of patient information is secured by allowing access only to the relevant required information from the patient's file.

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Infection Prevention and Control (IPC)

Introduction

Home healthcare patients are vulnerable to the development of healthcare-associated infections because of multiple factors. The home healthcare service requires an evidence-based infection control program according to its scope of services to identify and reduce infection risks. The infection control program covers all related infection, prevention, and control activities to ensure maximum safety for patients and staff. The program is overseen by a person qualified in infection prevention and control practices through education, training, experience, or certification.

This chapter outlines the requirements for the following processes and activities related to infection prevention and control:

- Coordinated infection prevention and control program
- Infection prevention and control policies and procedures
 - o Hand hygiene program
 - o Insertion and removal of catheters and lines
 - Correct wound dressing
 - o Standard precautions
 - o Cleaning, decontamination, disinfection, and sterilization
 - o Reporting of communicable diseases
- Personal protective equipment
- · Safe disposal of medical waste
- Staff screening and immunization

IPC.1. The home healthcare service implements a coordinated program to reduce the risk of healthcare-associated infections.

- **IPC.1.1.** The home healthcare service leaders allocate adequate and appropriate resources to support the infection prevention and control program.
- **IPC.1.2.** A qualified individual, acting on a full-time or part-time basis, is responsible for the infection control program.
- **IPC.1.3.** The infection prevention and control program is updated annually based on current scientific knowledge, accepted practice guidelines, and applicable laws and regulations.
- **IPC.1.4.** The infection prevention and control program is integrated with quality and patient safety, and risk management programs.
- **IPC.1.5.** The infection prevention and control program's components are contained in a manual that is available to all staff members.

Explanation

The home healthcare service should establish an evidence-based infection control (IC) program according to its scope of services. The program must cover all related IC prevention and control activities that could ensure maximum safety for patients, staff, volunteers, contractors...etc. Infection prevention and control activities should be overseen by a person qualified in infection prevention and control practices through education, training, experience, or certification. This qualified staff member should directly report to higher administrative authority to ensure the presence of an independent administrative unit that oversees IC issues in the whole center.

IPC.2. The leaders develop and ensure the implementation of infection control policies and procedures targeting the most important infection risk processes during home visits.

- **IPC.2.1.** The home healthcare service has an established and implemented policy on hand hygiene.
- **IPC.2.2.** The home healthcare service has an established and implemented policy for the insertion and removal of catheters and lines.
- **IPC.2.3.** The home healthcare service has an established and implemented policy on the correct wound dressing.
- **IPC.2.4.** The home healthcare service has an established and implemented policy on practicing universal precautions for the handling of human blood and body fluids
- **IPC.2.5.** The home healthcare service has an established and implemented policy on cleaning, decontamination, and disinfection processes in the patient care area during home visits with a list of appropriate detergents and disinfectants.
- **IPC.2.6.** The home healthcare service has an established and implemented policy on reporting communicable diseases to the relevant authorities.

Explanation

The home healthcare service establishes an evidence-based infection control program according to its scope of services. The infection control program covers all related infection, prevention, and control activities to ensure maximum safety for patients, staff, volunteers, contractors, and others. Infection prevention and control activities are overseen by a person qualified in infection prevention and control practices through education, training, experience, or certification. This qualified staff member directly reports to a higher administrative authority to ensure an independent administrative unit that oversees IC issues in the entire program. The person assigned to oversee infection prevention and control fulfills program oversight responsibilities

as per standard requirements that are described in the job description. To ensure that the home healthcare service complies with the applicable regulatory requirements concerning the reporting of notifiable communicable diseases, the services should maintain evidence of reporting communicable diseases to relevant authorities as per the home healthcare service policy.

IPC.3.

Personal protective equipment is readily accessible and available and is used correctly by staff in all patient care areas.

- **IPC.3.1.** Written policies and procedures are available for the appropriate use of gloves, gowns, facemasks, and protective eyewear.
- **IPC.3.2.** Gloves are worn when the potential exists for contact with blood/body fluids.
- **IPC.3.3.** Gowns, masks, eyewear or face shields, and other protective equipment are worn during patient visits as required according to the infection control policy and procedures.

Explanation

Personal protective equipment (PPE) is a fundamental tool for proper infection prevention and control practices. The center identifies those situations in which masks, eye protection, gowns, or gloves are required in written policy, and provides a sufficient supply of PPEs as well as training in their proper use.



The home healthcare service supports its patients and, when appropriate their families, in the safe disposal of medical waste.

- **IPC.4.1.** When required, the home healthcare service provides its patients with sharp disposal containers and yellow bags for proper disposal of medical waste.
- **IPC.4.2.** The home healthcare service educates its patients and staff on the correct waste disposal including the use of sharps disposal containers and yellow bags.
- **IPC.4.3.** The home healthcare service collects the sharps disposal containers and yellow bags appropriately from their patients for final disposal.
- **IPC.4.4.** Waste disposal is done effectively within the facility or through an authorized contractor.

Explanation

To protect the public and the environment from infectious organisms, and to provide a safe, healthy environment to the patient and healthcare workers, the home healthcare service should implement a Medical Waste Management Program that regulates the segregation, handling, storage, and disposal of medical waste. The home healthcare service provides oversight to ensure implementation as per the program policy and the national laws and regulations. The home healthcare service ensures the availability of required supplies (yellow bags, red bags, medical waste containers, and so on). Medical waste workers are appropriately vaccinated as evidenced in their health records and trained on safe handling of medical waste as documented in their personnel file.

IPC.5.

The home healthcare service develops policies and procedures that address employees' screening, immunization, and post-exposure management.

- **IPC.5.1.** Employees' screening, immunization, and post-exposure management are consistent with the laws and regulations, and recommendations of professional organizations.
- **IPC.5.2.** All employees have baseline screening for hepatitis B, hepatitis C, HIV, and tuberculosis.
- **IPC.5.3.** The immune status of newly hired staff against hepatitis B is determined by serological testing and appropriate vaccine(s) are administered to those who are non-immune.
- **IPC.5.4**. The response to hepatitis B vaccination is monitored in vaccinated employees four weeks after completing the vaccine series. Non-responders to the hepatitis B vaccine are offered at least a second series of the vaccine.

Explanation

Home healthcare staff are at risk of encountering infection from patients and their protection must be a high priority. The home healthcare service must develop and implement an evidence-based policy governing staff vaccination and post-exposure management.

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Facility Management and Safety (FMS)

Introduction

A safe, functional, and effective environment for patients, staff, and other individuals is crucial to prevent or minimize risks in the environment of care. The service leadership must provide all necessary support and resources to improve safety in the workplace in alignment with regulatory requirements.

The home healthcare service must maintain plans for managing the safety of the environment and must implement these plans. The service must collect and analyze data to determine the effectiveness of the plans and facilitate continuous quality improvement.

Staff members must also receive education about their responsibilities. Education must commence at orientation and continue regularly thereafter.

Important aspects of facility management and safety that this chapter addresses include the following:

- Safety
- Security
- · Fire safety
- Emergency
- · Medical equipment
- · Hazardous materials
- Utilities

FMS.1. The leaders establish and support a facility management and safety program.

- FMS.1.1. A qualified individual is responsible for the facility management and safety program as a full-time or part-time employee.
- FMS.1.2. The safety management program includes plans for emergency management and management of utility systems, hazardous materials, fire safety, medical equipment, building safety, and security.
- FMS.1.3. The FMS Officer conducts a facility inspection round at least four times per
- FMS.1.4. The resulting information of the facility inspection rounds is documented and used for corrective actions, planning, and budgeting.
- FMS.1.5. Data related to safety concerns are reviewed and analyzed and proper actions are taken to prevent reoccurrences.
- FMS.1.6. All home healthcare staff including new hires, volunteers, and trainees receive education about the facility management and safety program.

Explanation

The center develops individual programs or one master's program that includes the following components:

- Safety and Security
 - Safety—The degree to which the center's buildings, grounds, and equipment do not pose a hazard or risk to patients, families, and staff.
 - Security—Protection from loss, destruction, tampering, or unauthorized access or use.
- Hazardous materials—Handling, storage, and use of hazardous materials are controlled, and hazardous waste is safely disposed of.
- Emergencies—Response to disasters and emergencies is planned and effective.
- Fire safety—The property and it's occupants are protected from fire and smoke.
- Medical technology—Technology is selected, maintained, and used in a manner that reduces risks.
- Utility systems—Electrical, water, and other utility systems are maintained to minimize the risks of operating failures. A backup system is available in case of

Such programs are written and up to date in that they reflect actual conditions within the center's environment. A process exists for their periodic review and updating. When the center has other entities within the facilities to be surveyed (e.g., coffee shop or gift shop), the center has an obligation to ensure that these independent entities comply with the facility management and safety program. Safety rounds by the safety team and other disciplines should take place regularly in the home healthcare service. The rounds are designed to discover any inconsistencies and to identify existing safety or security hazards related to settings and environment. The results of rounds are formally documented and corrective actions are taken to ensure that safety requirements are met. The home healthcare service should be able to establish a systematic approach for the necessary safety expenditures (allocated budget).

FMS.2. The leaders ensure that the home healthcare service environment is safe for patients and staff.

- FMS.2.1. The leaders ensure that the building and its services comply with national standards, environmental protection standards, laws and regulations, and the recommendations of professional centers.
- FMS.2.2. The home healthcare service has adequate parking spaces, waiting areas, and toilets.

- FMS.2.3. The home healthcare service has an appropriate storage area for medical supplies.
- FMS.2.4. Medical supplies and consumables are stored in an organized way with labels showing the item's name and expiry date.
- FMS.2.5. The home healthcare service ensures the availability of safe transportation of healthcare providers to home visits.

Explanation

To ensure occupants' safety and manage the risks within the healthcare environment, all centers, regardless of size and resources, must comply with national standards, environmental protection standards, laws and regulations, and the recommendations of professional agencies. The leadership is responsible for the following:

- The building and its surroundings should be free of hazards such as; potentially loose objects, exposed outlets or wiring, slippery floors, sharp ends, and holes in the ground.
- The home healthcare service leaders should have knowledge regarding which national and local laws, regulations, and other requirements apply to the center's
- Planning and budgeting for the necessary upgrading or replacement as identified by monitoring data and providing evidence of progress toward implementing the improvements.

The home healthcare service must develop and implement a plan for periodic preventive and corrective maintenance for the center's setting, including electrical and mechanical systems. Maintenance records are kept for all mechanical and electrical equipment, such as air conditioning, power, and equipment to inform decision-making regarding replacement or upgrades. No medical supply is located on the floor or stacked over top shelves, with a minimum distance of 45 centimeters from the ceiling.

FMS.3. The leaders develop and monitor the implementation of a fire prevention program.

- FMS.3.1. At least annually, home healthcare staff are trained on emergency drills, fire drills, and evacuation plans. Training records are kept in staff personal
- FMS.3.2. Egress routes, corridors, and fire escapes are marked and free from obstacles.
- FMS.3.3. Fire systems, including the fire alarm and fire equipment, are in place and functioning.
- FMS.3.4. Fire extinguishers are tested and distributed in the center according to the type of extinguisher required.
- FMS.3.5. The fire alarm system is maintained and tested and all maintenance records are maintained.
- FMS.3.6. A "No Smoking" policy is approved and enforced.
- FMS.3.7. "No Smoking" signs are posted at all entrances and waiting areas.

Explanation

The fire safety of the center and its occupants must be ensured through a number of facility control measures. In addition, staff training must be conducted through fire drills including the use of acronyms such as RACE/PASS and evacuation techniques. These measures must include the procurement of fire-rated materials such as furniture and curtains (proven through the materials' specifications) and the establishment of fire and smoke compartments, especially for high-risk areas like the laboratory. Fire rating should also include windows, glass, and doors along the compartment. Also,

a staff training schedule on fire extinguisher use should be provided and include different types of fire extinguishing systems. The fire alarm system is to be maintained and tested, and all maintenance records are to be kept and updated. The National Fire Protection Association rates cigarette smoking as one of the three main causes of fire in healthcare facilities. Cigarette smoking also poses a health risk for others in the form of passive smoking." No smoking signs are posted and a no smoking policy is enforced.

FMS.4. The leaders develop a hazardous material (HAZMAT) plan.

- **FMS.4.1.** The leaders keep an updated register of all hazardous materials in the home healthcare service, along with their "Safety Data Sheets".
- FMS.4.2. Staff are trained in dealing with available hazardous materials.
- **FMS.4.3.** Hazardous materials are stored, handled, transported, used, and disposed of as per the "Safety Data Sheets".
- FMS.4.4. Fire-rated cabinets are used for flammable hazardous materials.

Explanation

The home healthcare service must protect its occupants from the effects of hazardous materials. A hazardous materials plan is in place that includes identifying and safely controlling hazardous materials and waste throughout the facility. A hazardous material is any solid, liquid, or gas that can harm people, other living organisms, property or the environment. Hazardous materials may be radioactive, flammable, explosive, toxic, corrosive, oxidizers, asphyxiants, pathogens, or allergens, or may have other characteristics that render them hazardous in specific circumstances. The hazardous materials program includes processes for:

- Inventory of hazardous materials.
- Handling, storage, and use of hazardous materials.
- Proper protective equipment and procedures to use and follow during use, spill, or exposure.
- Proper labeling of hazardous materials and waste.
- · Reporting and investigation of spills, exposures and other incidents.
- Documentation, including any permits, licenses or other regulatory requirements.
- Education and training on the signs and symptoms of exposure to hazardous materials and the appropriate treatment according to Safety Data Sheets (SDSs).

Information regarding procedures for handling or working with hazardous materials in a safe manner must be immediately available at all times, and include the physical data of the material (such as its boiling point, flash point, etc.), its toxicity, its health effects, identification of proper storage and disposal after its use, the type of protective equipment required during its use, and spill-handling procedures, including the required first aid for any type of exposure.

FMS.5. The leaders develop a plan for the inspection, testing, and maintenance of medical equipment.

- **FMS.5.1.** An updated inventory list is available for all medical equipment.
- **FMS.5.2.** Medical equipment is installed following the manufacturer's recommendations and safety requirements.
- **FMS.5.3.** A periodic/planned preventive maintenance (PPM) program is implemented for all medical equipment according to the supplied and available manufacturer's service manual. Records are kept documenting this maintenance.
- FMS.5.4. Medical equipment is tagged with a label denoting the date of the next PPM.

- **FMS.5.5.** All defective medical equipment is labeled and banned from use until repaired.
- **FMS.5.6.** Medical equipment is discontinued, according to a clear policy, for reasons including lifespan, beyond economic repair, and vendor or governmental recalls. Equipment is disposed of as per government rules and regulations.

Explanation

The medical equipment management program must be supported by policies and procedures that mitigate the risks associated with introducing new medical equipment, the tagging of medical equipment, the removal of equipment from service, agent/sub-contractors repairs, and the correct use of extension cords and cellular phones. The policy includes procedures to ensure that medical equipment is safe to use through proper installation, regular inspection, and maintenance, and testing. A comprehensive medical equipment management program is implemented and includes:

- 1. An inventory of medical equipment that covers, at a minimum, the equipment name, its manufacturer, its model, its serial number, its location, its organization number, and its maintenance history.
- 2. Installation requirements, including modification of HVAC requirements and safety precautions (for some types of equipment).
- 3. The availability of a system for medical equipment alerts and recall monitoring through the SFDA and manufacturer notifications and the reporting of medical equipment failures in a severe injury or illness to SFDA.
- 4. The availability of a necessary service and operation manual, whether a hardcopy or softcopy, for reference when needed.
- 5. The availability of all necessary calibration equipment to insure proper calibration of medical equipment.
- 6. A risk-assessment-based backup plan for failed medical equipment.

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Glossary

Glossary

Adverse Drug Reaction

A response to a medicinal product that is noxious and unintended and that occurs at doses normally used in a human for the prophylaxis, diagnosis, or therapy of disease or for the restoration, correction, or modification of a physiological function.

Clinical Practice Guidelines

Systematically developed statements that help practitioners and patients choose appropriate healthcare for specific clinical conditions.

Continuity of Care

The degree to which patient care is coordinated among practitioners and organizations and over time, without interruption, cessation, or unnecessary repetition of diagnosis or treatment.

Credentialing

The process of obtaining, verifying, and assessing a healthcare professional's qualifications to determine whether that individual can provide patient care services in or for a healthcare organization.

Critical Test

A stat test with critical values/results or other results that the laboratorian, radiologist, or other diagnostician has determined to be critical to the patient's subsequent treatment decisions.

Governance

The function of determining the organization's direction, setting objectives, and developing policy to guide the organization in achieving its mission.

Governing Body

In healthcare, it represents the individual(s), group, or agency with ultimate authority, responsibility, and accountability for the overall strategic direction, methods of operation (management and planning), establishment of policies, and maintenance of the safety and quality of care that the facility provides.

Healthcare Organization

A generic term used to describe many types of organizations that provide healthcare services.

Incidents

Events that are unusual, are unexpected, may have an element of risk, or may have a negative effect on patients, staff, or the hospital.

Information Management

A term used to designate the manual or computer-based conveying of information throughout the department/organization, or the creation, use, sharing, and disposal of data or information across an organization. This practice is critical to the effective and efficient operation of organization activities.

Informed Consent

A person's voluntary agreement of one who has sufficient mental capacity with full knowledge of the risks involved, probable consequences, and alternatives to make an informed decision. It allows a patient to balance the probable risks against the probable benefits of any potential care.

Job Description

A written statement that describes the list of rules, duties, responsibilities, and required qualifications of candidates, and the reporting relationship and coworkers of a particular job.

Key Performance Indicators (KPIs)

Measures of performance that are central to success.

Licensure

A legal right granted or evidenced by documentation issued by SCFHS (such as a physician, nurse, psychiatrist, or clinical social worker, or the operation of a health facility) in the form of a license, registration, or certification.

Medical Device

Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related article that the manufacturer intends to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s): diagnosis, prevention, monitoring, treatment or alleviation of disease, alleviation of or compensation for an injury, investigation, replacement, modification, support of the anatomy or a physiological process, and the support or sustaining of life.

Note: Products that may be considered medical devices in some jurisdictions but not in others include: disinfection substances, aids for persons with disabilities, devices incorporating animal and/or human tissues, devices for in-vitro fertilization, or assisted reproduction technologies.

Medical Equipment

Equipment used for the specific purposes of diagnosing and treating disease or for rehabilitation following disease or injury. It can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment (e.g., EKG machines, diagnostic ultrasounds, surgical lights, patient beds, surgical tables, anesthesia machines, and defibrillators).

Medication Error

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is under the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

Medication Management

The overall effort by facilities and manufacturers to reduce medication errors that can occur throughout the various stages of the medication use cycle: selection, procurement, prescription, transcription, dispensing, distribution, administration, and monitoring.

Medication Reconciliation

The process of creating the most accurate list possible of all medications the patient is taking – including drug name, dosage, frequency, and route – and comparing that list against the physician's admission, transfer, and/or discharge orders with the goal of providing correct medications to the patient at all transition points within the hospital.

Patient Satisfaction

A measurement that obtains reports or ratings from patients about services received from an organization, hospital, physician, or healthcare provider.

Personnel File

Collection of information about a staff member, covering licensure, certifications, leaves, appraisal reviews, job description and others.

Care Plan (Plan of Care)

A treatment plan especially designed for each patient, based on individual strengths and needs. The caregiver(s) develop(s) the plan with input from the family and communication with each other. The plan establishes goals and details appropriate treatment and services to meet the patient's special needs. The planning is an interdisciplinary process.

Privileging

The process of reviewing an individual's credentials through a credentials body to determine the authority and responsibility to be granted to a practitioner for making independent decisions to diagnose, initiate, alter, or terminate a regimen of medical or dental care. Privileging determines the physician's scope of practice in the organization determined by his/her competencies.

Probationary Period

The time period that the labor law specifies for determining whether the employee is competent to perform his/her duties and continue employment with the organization. Generally, the time period for probation is three months.

Program

Organizational activities aimed at achieving broader organization objectives by coordinating a group of projects.

Protocols

A plan, or set of steps, to be followed in a study, an investigation, or an intervention.

Risk

The combination of the assessment of the magnitude of an injury, or potential injury, with the probability that certain actions/events will occur.

Scope of Services

The range of activities provided to patients and/or other customers by the leadership, clinical, and support personnel.

Sentinel Event

An event requires intensive assessment and prompt response. An unexpected occurrence involving death, serious physical or psychological injury, or the risk thereof, and any event that might cause embarrassment or risk to the healthcare organization, with potential legal ramifications and/or media inquiries or coverage.

Transfer

The formal shifting of responsibility for the care of a patient from one care unit to another, one clinical service to another, one qualified practitioner to another, or one organization to another.

Transport

The movement of an individual from one place to another using a transport aid or vehicle, either motorized or manual (wheelchair, trolley, bed).

About This Manual

This first edition of the National Standards for Home Healthcare Services was developed through a consensus process which entailed the participation of all the relevant stakeholders. From the beginning, the aim was to have a set of standards that are detailed and descriptive, assembled around the key elements of Home Healthcare Services, based on the current best healthcare practices. The goal of this manual is to be used as a reference for achieving the optimal care for patients and their families, given the national challenges that we are facing today.

About CBAHI

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is a non-profit organization emerging from the Saudi Health Council and is responsible for setting and assessing the healthcare quality and patient safety standards in Saudi Arabia. CBAHI began a few years ago with only a few hospitals enrolled in the accreditation process and a limited number of surveyors and staff. Today, CBAHI is proud to have a comprehensive set of evidence-based standards that are utilized for the assessment of thousands of healthcare facilities across the country.

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