

## GAHAR HANDBOOK FOR

# AMBULATORY HEALTHCARE ACCREDITATION STANDARDS

# **GAHAR HANDBOOK FOR AMBULATORY HEALTH CARE ACCREDITATION STANDARDS**

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## Foreword

As an essential step towards implementing the comprehensive healthcare recovery in Egypt, here is the GAHAR Handbook for Ambulatory Healthcare Centers Standards – Edition 2022 issued by the General Authority for Healthcare Accreditation and Regulation (GAHAR). This edition is a continuation of the efforts started in the last century for improving healthcare services in the country through standardization. The development of these standards is a valuable eventual product of collaborative efforts of representatives from the different health sectors in Egypt, including the Ministry of Health and Population, the private sector, universities, military sectors and professional syndicates.

This book of standards handles healthcare delivery from two main perspectives, the patient-centered perspective and organization-centered perspective. Each perspective is handled thoroughly in a separate section and discusses in details the minimum requirements for accrediting organizations based on them. The first section discusses accreditation prerequisites and conditions. The second section discusses patient-centered standards and adopts Picker's model for patient-centered care to ensure responsiveness of organizations to patients' needs. The third section discusses organization-centered standards, highlighting many aspects required workplace suitability to provide safe and efficient healthcare. The third section also adopts the Health WISE concepts.

Although this handbook is relatively, compact and directed toward all ambulatory health care services in a general means. Annex (A) offers a detailed background information on the required practice in the community pharmacies. Annex (B) offers a comprehensive framework and requirements needed to be implemented in the private clinics in Egypt.

While these standards were carefully tailored to steer the current situation of Egyptian healthcare in the direction of Egypt's 2030 Vision, they have been finely compared to international standards and found to meet their basic intent that applies to Egyptian laws, regulations, and culture. It is expected that the standards shall be a catalyst for applying change and improvement in both the culture and practice of healthcare in Egypt.

## Introduction

Patient-centered care is the healthcare that respects and responds to the preferences, needs, and values of patients and consumers. The widely accepted dimensions of patient-centered care are respect, emotional support, physical comfort, information and communication, continuity and transition, care coordination, family involvement, and access to care. Surveys measuring patients' experience of health care are typically based on these domains. Research demonstrates that patient-centered care improves patient care experience and creates public value for services. When healthcare administrators, providers, patients, and families work in partnership, the quality and safety of health care improve, costs decrease, provider satisfaction increases, and patient care experience is successfully achieved.

Patient-centered care can also positively affect business metrics, such as finances, quality, safety, satisfaction, and market share. Patient-centered care is recognized as a dimension of high-quality healthcare and is identified in the Institute of Medicine Report Crossing the Quality Chasm as one of the six quality aims for improving care. In recent years, strategies used worldwide to improve overall healthcare quality, such as public reporting and financial incentives, have emerged as policy-level drivers for improving patient-centered care.

Patients are not the only customers of healthcare systems. Healthcare providers and workers face risks, as well. Although debate continues regarding whether worker wellbeing should be considered as part of the patient safety initiatives, many organizations think about it that way, including major players in the healthcare industry worldwide. Three major aspects may affect the worker's wellbeing: safety, stress, and organizational structure.

This book defines the minimum requirements for healthcare organizations to comply with patient safety and centeredness while maintaining a safe, structured, and positive work environment.

## **Scope of this Handbook**

These standards apply to Ambulatory healthcare centers seeking to be accredited by the General Authority for Healthcare Accreditation and Regulation (GAHAR).

The scope of the GAHAR standards for ambulatory healthcare centers includes all healthcare facilities that provide care for patients with short length of stay less than 24 hours; this care may be general or specialized, urgent or planned. The services provided in settings such as dialysis centers, day surgery centers, private clinics (i.e. Solo medical care practice), polyclinics, dental care centers, ophthalmology centers, community pharmacies and others

## Purpose

GAHAR standards describe the competent level of care in each phase of the patient care process. They reflect a desired and achievable level of performance against which ambulatory healthcare center's actual performance can be compared. The main purpose of these standards is to direct and maintain safe healthcare practice through the accreditation standards.

These standards also promote and guide organization management. They assist staff, management team, and the ambulatory healthcare center as a whole to develop safe staffing practices, delegate tasks to licensed and unlicensed staff members, ensure adequate documentation, and even create policies for new technologies.

Compliance with GAHAR standards guarantees ambulatory healthcare center accountability for its decisions and actions. Many standards are patient-centered and safety-focused to promote the best possible outcome and minimize exposure to the risk of harm. These standards encourage the ambulatory healthcare center staff to enhance persistently their knowledge base through experience, continuous education, and the latest guidelines. These standards can be used to identify areas for improvement in clinical practice and work areas, as well as to improve patient and workplace safety.

## Reading and Interpretation of the book

- The General Authority for Healthcare Accreditation and Regulations evaluates organizations' structure, processes, and/or outcomes by setting standards that address these concepts.
- This book is divided into three sections, in addition to the foreword, introduction, Scope of this handbook, Purpose, Use, Acknowledgments, Acronyms, Survey activities and readiness, Glossary and References, additionally this book contains two annexes one for the community pharmacy standards and the other for the private clinics standards.
- Each section is divided into chapters when applicable.
- Each chapter has:
  - an introduction that contains an overall intent.
  - Implementation guiding documents that need to be checked in order to achieve the full compliance with the standards.
  - Purpose which clarify the introduction, and each purpose has a standard or more in the chapter
  - purpose that details follow the introduction, and each one has a standard or more.
- A standard is a level of quality or achievement, especially a level that is thought to be acceptable; it is composed of a standard statement, keywords, intent, survey process guide, evidence of compliance, and related standards paragraphs.

### Standard Component

- **Standard Statement:**
  - In this handbook, each standard is written as a standard statement preceded with a code.
  - Each standard is followed by a *non-black-scripted statement* that describes the essential quality dimension(s) addressed by the standard.
- **Keywords:**
  - To help organizations understand the most important element of the standard statements, as these are words or concepts of great significance. They answer the question of WHAT the standard is intended to measure.
- **Intent:**
  - Standard intent meant to help organizations understand the full meaning of the standard.
  - The intent is usually divided into two parts:
    - Normative: that describes the purpose and rationale of the standard and provides an explanation of how the standard fits into the overall program. It answers the question of WHY the standard required to be met.

- Informative: is meant to help organizations identify the strategy to interpret and execute the standard. It answers the question of HOW the standard is going to be met.
- Some standards require the implementation of minimum components of processes to be documented, implemented, recorded, and/or monitored. These components are usually preceded with the phrase “at least the following”, followed by a numbered/ lettered list of requirements. Hence, these elements are considered essential, indivisible parts of compliance with the minimum acceptable standard.
- **Evidence of compliance (EOCs):**
  - Evidence of compliance of a standard indicates what items will be reviewed and assigned a score during the on-site survey process.
  - The EOCs for each standard identify the requirements for full compliance with the standard as scoring is done in relation to EOCs.
- **Survey process guide:**
  - Facilitates and assists the surveyors in the standard’s rating for the required EOCs.
- **Related standards:**
  - As healthcare is a complex service, each standard measures a small part of it. To understand what each standard means in the overall context of healthcare standards, other standards need to be considered as well.
- **Standards are categorized and grouped into three sets of groups:**
  - Chapters, where standards are grouped as per uniform objective.
  - Quality dimensions, where each standard addresses a particular quality dimension, and strategic categorization of standards to analyze their quality characteristics.
  - Documentation requirements, where some standards require certain types of documents

## Used Language and Themes

This handbook used certain themes and vocabulary to ensure uniformity and clarity; these are the most important ones that will help ambulatory healthcare centers to interpret the standards:

**Process, Policy, Procedure, Program, Plan, Guideline, Protocol**

Whenever 'Process' is used in a standard, it indicates a requirement that is necessary to follow.

- **Process**  
A series of actions or steps taken in order to achieve a particular end.
- **Documented Process**  
A document that describes the process and can be in the form of policy, procedure, program, plan, guideline, or protocol.
- **Policy:**
  - A principle of action adopted by an organization.
  - It usually answers the question of what the process is.
  - It is stricter than guidelines or protocols.
  - It does not include objectives that need to be met in a certain timeframe.
- **Procedure:**
  - An established or official way of doing something.
  - It usually answers the question of how the process happens.
  - It is stricter than guidelines or protocols.
  - It does not include objectives that need to be met in a certain timeframe.
- **Program:**
  - A plan of action aimed at accomplishing a clear business objective, with details on what work is to be performed, by whom, when, and what means or resources shall be used.
- **Plan:**
  - A detailed proposal for doing or achieving something.
  - It usually answers the question of what is the goal, why, how it is going to be achieved, and when.
  - It includes objectives that need to be met in a certain timeframe.
- **Guideline:**
  - A general rule, principle, or piece of advice.
  - It usually answers the question of what the process is and how it should happen.
  - Usually, it is more narrative than protocol.



- Protocol:
    - A best practice protocol for managing a particular condition, which includes a treatment plan founded on evidence-based strategies and consensus statements.
    - Usually, it has graphs, flow charts, mind maps, and thinking trees.
1. Document versus Record
    - Document:  
Created by planning what needs to be done.
    - Record:  
Created when something is done.
  2. Physician Versus Medical staff member
    - Physician:  
A professional who practices medicine
    - Medical Staff member:  
A professional who practices medicine, dentistry, and other independent practitioners.

## Accreditation Overview

This chapter aims to set the rules and requirements to obtain GAHAR accreditation for the ambulatory health care centers, which includes, but not limited to, the following:

1. Compliance with licensure requirements for licensing the ambulatory centers as mandated by laws and regulations and regulatory ministerial decrees.
2. Compliance with the National Safety Requirements for ambulatory centers, (herein included), to ensure the safety of the patients, families, visitors, and staff.
3. Compliance with the requirements of the standards according to Accreditation Decision Rules in this handbook.

### A) General rules:

- Determining which set of accreditation manuals is applied to the applicant's facility is done by matching the facility scope of services provided. The Authority must be informed of any change in the field of services provided (adding a new service, canceling an existing service, or increasing the volume of an existing service by more than 15%) in writing to the e-mail [reg@gahar.gov.eg](mailto:reg@gahar.gov.eg). at least one month prior to the actual implementation of this change.
- Facilities that desire to obtain GAHAR's accreditation have to apply starting from the date of entering the governorate under the scope of universal health insurance law implementation, within a maximum period of three years. For facilities in the governorates that have not fall yet under the scope of the law application, they have to apply within three years from the date of application submission.
- The facility shall ensure the validity of the documents and data provided at all stages of the accreditation process. If there is evidence that the submitted documents are proven to be inaccurate, the facility is at risk for rejection of accreditation.
- The facility is not permitted to use GAHAR's certificate or logo in a misleading manner.
- The accreditation may be withdrawn or at risk of rejection, if there is an evidence that the facility has falsified or withheld or intentionally misleading the information submitted to GAHAR.
- GAHAR shall inform the facility about the accreditation decision within a period not exceeding 15 working days starting from the date of completion of the survey visit.
- GAHAR has the right to publish the results of survey visit, accreditation suspension or rejection, according to the requirements of Law No. 2 of 2018.
- The facility has to complete at least 60% of its staffing plan, and to register at least 60% of each category of health professional members before the survey visit, provided that the remaining registration process has to be completed within three months starting from the date of accreditation.

- In case of sentinel event or any serious adverse event, GAHAR shall be notified within 7 days of its occurrence, or via email notification using the following link; [reg@gahar.gov.eg](mailto:reg@gahar.gov.eg). The root cause analysis shall be submitted no later than 45 days starting from the date of the occurrence or its notification with the appropriate corrective plan to prevent / reduce its recurrence according to the nature of the event. (Refer to standard no. QPI.07 for more information).

**B) Compliance to current relevant laws, regulations, licensures requirements and their updates as follows;**

► **For Governmental ambulatory center:**

- Radioactive materials usage license
- Blood bank license
- Laser usage License
- Dialysis unit License
- Cardiac catheterization unit license
- Ionizing radiation equipment license
- Hazardous waste handling license
- Certificate of conformity with the civil protection requirements.
- Elevator license (if any)
- Electric generator License (in accordance with Article 2 and Article 3 of Law No. 55 of 1977 regarding the establishment and management of thermal machines and steam boilers).

► **For Non- governmental ambulatory center:**

- Unit/Center/Facility license.
- Pharmacy license.
- Laboratory license
- Physiotherapy center license
- Radioactive materials usage license
- Blood bank license
- Laser usage License
- Dialysis unit License
- Cardiac catheterization unit license
- Ionizing radiation equipment license
- Hazardous waste handling license
- Certificate of conformity with the civil protection requirements.
- Elevator license (if any)
- Electric generators license (in accordance with Article 2 and Article 3 of Law No. 55 of 1977 regarding the establishment and management of thermal machines and steam boilers).

► **For private clinics**

- Clinic license.

► **For community pharmacies**

- Pharmacy license.

**C) Accreditation may be suspended (for a period not exceeding 6 months) if:**

- The facility fails to pass unannounced survey,
- The facility fails to comply with GAHAR circulars when applicable.
- The facility data in the application form does not match its status upon unannounced evaluation visits.
- Sentinel events related to the safety of patients, healthcare providers or visitors that had not reported to GAHAR within 7 days of its occurrence or 45 days of its discovery.
- The GAHAR has not been notified of any changes in the scope of services provided (e.g. adding a new service, canceling an existing service, or increasing the volume of an existing service by more than 15%) within at least one month before the actual implementation of this change.
- The facility did not register at least 60% of their medical professionals' members.

**D) Accreditation may be withdrawn or at risk of rejection if:**

- The facility fails to pass follow up surveys in case of conditioned accreditation,
- GAHAR team discover any falsification, withhold or intentionally misleading the information submitted during or after the survey visit, or it is proven that the attached and submitted documents are inaccurate.
- The facility prevents GAHAR regulatory team/inspectors from doing their duties, such as refusal or preventing them from obtaining documents and data related to the scope of their duties.
- The facility refuses to meet the auditors' team or GAHAR surveyors in the announced / unannounced evaluation visits.
- A legal document issued by an administrative agency or Supreme Court rules against the facility either by permanent or temporary closure.
- Moving the facility from its actual place mentioned in the application form, or when the facility is demolished, reconstructed or rebuilt without any pre notification to GAHAR.
- Exceeding the period prescribed for suspension of accreditation without correcting the reasons for this suspension.

## Applying for a GAHAR survey

Ambulatory healthcare center seeking GAHAR accreditation begins by:

- Applying to join the program via [www.gahar.gov.eg](http://www.gahar.gov.eg) or by sending an email to [reg@gahar.gov.eg](mailto:reg@gahar.gov.eg)
- GAHAR is going to respond by sending an application form attached to the email. The ambulatory healthcare center will complete the application form and upload the required documents.
- Ambulatory healthcare center documents will be reviewed by GAHAR.
- GAHAR will determine survey financial fees, and bank account details will be shared.
- The ambulatory healthcare center will make the payment to the Central Bank of Egypt on the bank account, and it will send the receipt back via email.
- An appointment for the survey visit will be determined for the ambulatory healthcare center.
- GAHAR's surveyor team will evaluate the ambulatory healthcare center according to the GAHAR Handbook for Ambulatory Healthcare Center standards.
- The survey report is submitted to the accreditation committee to review and decide based on the decision rules.
- The ambulatory healthcare center is notified of the decision of the accreditation committee. The ambulatory healthcare center has 15 days to submit an appeal. If no appeal is submitted, the chairperson of GAHAR approves the decision, and a final certificate is issued.

## **Look back period**

Surveyors are required to review standards requirements and evaluate organization compliance to them over a look back period.

Look back period: It is the period before the survey visit during which any ambulatory healthcare center is obliged to comply with the GAHAR accreditation standards. Failure to comply with this rule affects the accreditation decision.

Look back period varies from one ambulatory healthcare center to another, depending on accreditation status.

### **An ambulatory healthcare center seeking accreditation will:**

- Comply with the GAHAR Handbook for Ambulatory Healthcare Center Standards as applicable for at least four months before the actual accreditation survey visit.

### **Ambulatory healthcare center seeking re-accreditation:**

- For GAHAR accredited ambulatory healthcare centers, compliance with the GAHAR Handbook for Ambulatory Healthcare Center Standards from receiving the approval of the previous accreditation until the next accreditation survey visit.

## Scoring Guide

During the survey visit, each standard is scored for the evidence of compliance (EOC).

These are mathematical rules that depend on summation and percentage calculation of scores of each applicable EOCs as follows:

- **Met** when the ambulatory healthcare center shows 80% or more compliance with requirements during the required lookback period with a total score of 2
- **Partially met** when the ambulatory healthcare center shows less than 80% but more than or equal to 50% compliance with requirements during the required lookback period with a total score of 1
- **Not met** when the ambulatory healthcare center shows less than 50% compliance with requirements during the required lookback period with a total score of 0
- **Not applicable** when the surveyor determines that, the standard requirements are out of the organization scope (the score is deleted from the numerator and denominator)
- While most EOCs are independent, stand-alone units of measurement that represent the structure, process, and/or outcome, few EOCs are dependent on each other. Dependence means that compliance with one EOC cannot be achieved (or scored) without ensuring compliance with other EOCs.

### Scoring of each standard

- **Met:** when the average score of the applicable EOCs of this standard is 80% or more.
- **Partially met:** when the average score of the applicable EOCs of this standard is less than 80% or but not less than 50%.
- **Not met:** when the average score of the applicable EOCs of this standard is less than 50%.

### Scoring of each chapter

Each chapter is scored after calculating the average score of all applicable standards in this chapter.

### Scoring of each Annex:

Each Annex is scored separately after calculating the average score of all applicable standards in this annex.

## Accreditation Decision Rules

Ambulatory healthcare center can achieve accreditation by demonstrating compliance with certain accreditation decision rules. These rules mandate achieving certain scores on a standard level, chapter level, and annex level (as applicable) and overall level as the accreditation decision is composed of four decisions.

### 1<sup>st</sup> Decision: Status of Accreditation for ambulatory healthcare center (3 years).

- Overall compliance of 80% and more, and
- Each chapter/annex should score not less than 70%, and
- No single whole standard is scored as not met.

### 2<sup>nd</sup> Decision: Status of Conditioned Accreditation for ambulatory healthcare center (2 years).

- Overall compliance of 70% to less than 80%, or
- Each chapter/annex should score not less than 60%, or
- Up to one standard not met per chapter, and
- No single not met NSR standard. (not applied for handbook annexes)

### 3<sup>rd</sup> Decision: Status of Conditioned Accreditation for ambulatory healthcare center (1 year).

- Overall compliance of 60% to less than 70%, or
- Each chapter/annex should score not less than 50%, or
- Up to two standards not met per chapter, and
- No single not met NSR standard. (not applied for handbook annexes)

### 4<sup>th</sup> Decision: Rejection of Accreditation

- Overall compliance of less than 60%, or
- One chapter/annex scored less than 50%, or
- More than two standards not met per chapter, or
- Not met NSR standard. (not applied for handbook annexes)

The facilities having status of accreditation or conditioned accreditation (with elements of non-compliance) are requested to:

- Submit a corrective action plan for unmet EOCs and standards within 90 days for 1st decision, 60 days for 2nd decision and 30 days for 3rd decision to the email [reg@gahar.gov.eg](mailto:reg@gahar.gov.eg).
- Apply and pass the accreditation survey in 2 years for 2nd Decision and 1 year for 3rd Decision.



## Acknowledgments

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## Acronyms

Code	Meaning
APC	Accreditation Prerequisites and Conditions
NSR	National Safety Requirements
PCC	Patient-Centeredness Culture
ACT	Access, Continuity, and Transition of Care
ICD	Integrated Care Delivery
DAS	Diagnostic and Ancillary Services
SAS	Surgery, Anesthesia, and Sedation
MMS	Medication Management and Safety
EFS	Environmental and Facility Safety
IPC	Infection Prevention and Control
OGM	Organization Governance and Management
WFM	Workforce Management
IMT	Information Management and Technology
QPI	Quality and Performance Improvement
CPS	Community Pharmacy Standards
PCS	Private Clinic Standards

## **SECTION 1**

### **ACCREDITATION PREREQUISITES AND CONDITIONS**



## Section 1: Accreditation Prerequisites and Conditions

### Section Intent:

This chapter aims at providing a clear ethical framework that the ambulatory healthcare centers as well as community pharmacies and private clinics must follow in order to comply with the GAHAR survey process. Scores of these standards are always to be met in order to continue the survey process. One partially met or not met evidence of compliance is to be dealt with on the GAHAR accreditation committee level and may result in rejection or suspension of accreditation.

### Compliance with GAHAR accreditation prerequisites

**APC.01 The ambulatory healthcare center ensures full compliance with national regulations and licensure requirements.**

*Safety*

### Keywords:

National regulations and licensure requirements.

### Intent:

Regulation and licensure requirements are considered a basic requirement to ensure minimum level of compliance for any ambulatory healthcare center or other facility providing healthcare services and aiming to be enrolled in the Universal Health Insurance system or achieving the accreditation or to be accredited by GAHAR. When the ambulatory healthcare center is applied for accreditation, it is expected to sustain or improve the same level of quality scored during the accreditation visit.

Licensure requirements shall be met by the ambulatory healthcare according to the scope of services provided.

### Survey process guide:

During the GAHAR survey, the surveyors may review facility licenses that match the national laws and regulations.

### Evidence of compliance:

1. The ambulatory healthcare center has a clear process of frequent assessment of compliance with the national, applicable regulation requirements.
2. When a gap is identified, the ambulatory healthcare center has developed a corrective action plan describing all necessary measures needed to improve performance and sustain the full compliance.
3. The ambulatory healthcare center reports to GAHAR any challenges that affect compliance with the national regulation requirements.



**Related standards:**

OGM.01 Governing body Structure and clear responsibilities, WFM.01 Workforce Laws and regulations,  
EFS.01 Ambulatory healthcare center environment and facility safety structure,  
DAS.01 Planning and provision the medical imaging services, DAS.08 Laboratory services planning and management, DAS.19 Uniform Blood Transfusion services and planning

**APC.02 The ambulatory healthcare center ensures safe medical provision through complying with GAHAR Healthcare Professionals Registration.**

*Safety*

**Keywords:**

Registration of staff.

**Intent:**

Healthcare Professionals registration process aims to ensure the competencies of healthcare professionals by matching their qualifications and experience to the accredited ambulatory healthcare center scope of medical services. In return, this process will improve the quality of healthcare services provided to the community. The ambulatory healthcare center is expected to register 100% of all current members of the following healthcare professions' categories if present:

- a. Physicians
- b. Dentists
- c. Pharmacists
- d. Physiotherapists
- e. Nurses
- f. Nursing technicians
- g. Health technicians
- h. Chemists and physicists
- i. Veterinary doctors

The ambulatory healthcare center shall create a process to register all applicable newly hired staff members within 1-3 months.

**Survey process guide:**

During the GAHAR survey, the surveyor may review healthcare professional registration records including both the current and new staff.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved process for registering all members of the required medical professionals including both current and newly hired members.
2. All contracts/ agreements either full-time, part-time, visiting, or other types of employment contracts with the healthcare professionals mentioned in the intent from (a) to (i) are to

be submitted in GAHAR healthcare professionals' registration process.

3. The ambulatory healthcare center has a process to report to GAHAR, other healthcare authorities, and professional syndicates of any findings that affected patient safety such as, fake, or falsified credentials.

**Related standards:**

WFM.03 Job Description, WFM.04 Verifying credentials

**Transparent and ethical relationships**

**APC.03 The ambulatory healthcare center provides GAHAR with accurate and complete information through all phases of the accreditation process.**

*Effectiveness*

**Keywords:**

Accurate and complete information

**Intent:**

During accreditation processes, there are many points at which GAHAR requires data and information. When an ambulatory healthcare center is accredited, it lies under GAHAR's scope to be informed of any changes in the ambulatory healthcare center/facility and any reports from external evaluators. Ambulatory healthcare centers may provide information to GAHAR verbally, through direct observation, an interview, application, or any other type of communication with a GAHAR employee. Relevant accreditation policies and procedures inform the ambulatory healthcare center of what data and/or information are required and the period for submission. The ambulatory healthcare center is expected to provide timely, accurate, and complete information to GAHAR regarding its structure, scope of work, building, governance, licenses, and evaluation reports by external evaluators. GAHAR requires each ambulatory healthcare center, whether, accredited, or just interested in engaging in the accreditation process with honesty, integrity, and transparency.

**Survey process guide:**

- GAHAR surveyors may review reports of accreditation, licensure, inspection, audits, legal affairs, reportable sentinel events, and reportable measures.
- GAHAR surveyors may observe accreditation process to check the honesty, integrity, and transparency.

**Evidence of compliance:**

1. The ambulatory healthcare center has a process to verify all reports for accuracy and completion prior to GAHAR submission, throughout all stages of accreditation process.
2. The ambulatory healthcare center is aware of their commit to report any structural changes in the ambulatory healthcare center scope of work of addition or deletion of medical services by more than 15% within 30 days.

3. The ambulatory healthcare center provides GAHAR access to evaluation results and reports of any evaluating organization.

**Related standards:**

OGM.01 Governing body Structure and clear responsibilities, IMT.01 Documentation management system

**APC.04 The ambulatory healthcare center uses the accreditation process to improve safety and effectiveness.**

*Safety*

**Keywords:**

Accreditation process value.

**Intent:**

GAHAR accreditation implies that an ambulatory healthcare center is a place that maintains high safety standards. Public, governmental bodies, staff, third party payers, among others, will assume credibility in accredited ambulatory healthcare center processes. Thus, GAHAR has the right to obtain any information to confirm standards and accreditation policy compliance and/or evaluate patient safety and quality concerns at any time during all phases of accreditation. When external bodies other than GAHAR evaluate areas related to safety and quality such as fire safety inspections, police criminal investigations, court allegations checking, staff working conditions inspections, and evaluation of safety incidents or quality complaints. These evaluations complement accreditation reviews but may have a different focus or emphasis. Creating a safe culture is not an easy task; it requires everyone to be aware of safety issues and able to report them.

The ambulatory healthcare center improves safety by sharing knowledge with GAHAR about any challenges identified through internal or external processes. The ambulatory healthcare center's website, advertising and promotion, brochures, newspapers, and other information made available to the public accurately and reflect the scope of services provided. as well as the methods of reporting any safety issues which affect the patients or the healthcare professionals or practitioners.

**Survey process guide:**

- GAHAR surveyors may review any reports or concerns related to safety issues.
- GAHAR surveyors may interview responsible staff and patients to check their awareness of the mechanisms of reporting safety issues to GAHAR.

**Evidence of compliance:**

1. The ambulatory healthcare center permits GAHAR to perform on-site evaluations of compliance or verification of quality and safety concerns, reports, or any regulatory authority sanctions.

2. The ambulatory healthcare center accurately represents its accreditation status and scope.
3. The ambulatory healthcare center has a process to inform staff and patients on mechanisms to report safety issues to GAHAR.

**Related standards:**

QPI.01 Quality management program, QPI.02 Performance Measures, QPI.08 Performance improvement and patient safety plan

**APC.05 The ambulatory healthcare center maintains professional standards during the survey.**

*Equity*

**Keywords:**

Professional standards during surveys.

**Intent:**

The surveyors' aim is to perform their duties and responsibilities and to attain the highest levels of performance by the ethical requirements generally to meet the public interest and maintain the reputation of GAHAR. To achieve these objectives, the survey process has to establish credibility, professionalism, quality of service, and confidence. The ambulatory healthcare center is expected to maintain professional standards in dealing with surveyors. The ambulatory healthcare center is expected to report to GAHAR if there is a conflict of interest between a surveyor and the ambulatory healthcare center that could affect any of the following:

- a. Integrity
- b. Objectivity
- c. Professional competence
- d. Confidentiality
- e. Respect

The ambulatory healthcare center ensures that there are no immediate risks for surveyors' safety and security. The ambulatory healthcare center respects the confidentiality and sensitivity of the survey process.

**Survey process guide:**

During the GAHAR survey, surveyors may observe all aspects towards the safety, security, confidentiality, privacy, respect, integrity, objectivity, professional competence values and proper ethical management implementation.

**Evidence of compliance:**

1. Any conflict of interest is directly reported to GAHAR with evidence. (if present).
2. The ambulatory healthcare center maintains professional standards on dealing with surveyors.

3. The ambulatory healthcare center ensures that the environment does not pose any safety or security risks to surveyors during the survey.
4. Social media releases are not allowed without GAHAR's prior approval and notification.

**Related standards:**

OGM.12 Ethical Management.

## SECTION 2

### PATIENT-CENTERED STANDARDS



## Section 2: Patient-Centered Standards

Patient-centered care represents a paradigm shift in how patients, healthcare professionals, and other participants think about the processes of treatment and healing. It is defined by the Institute of Medicine as the act of providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions. The rise of patient-centered care paves the way for a healthcare system designed to optimize the benefit and comfort of the most important and vulnerable people in the equation: patients, their families, and their communities.

Over the past two decades, patient-centered care has become internationally recognized as a dimension of the broader concept of high-quality healthcare. In 2001, the semiannual US Institute of Medicine's (IOM), *Crossing the Quality Chasm: A New Health System for the 21st century*, defined good-quality care as safe, effective, patient-centered, timely, efficient, and equitable.

The report sets out several rules to redesign and improve patient-centered care, including ensuring that care is based on continuous, healing relationships; customizing care based on patients' needs and values; ensuring the patient is the source of control; sharing knowledge and information freely; and maintaining transparency.

The IOM report defined four levels that further define quality care and the role of patient-centered care in each level:

1. The experience level refers to an individual patient's experience of their care. Care should be provided in a way that is respectful, informative, and supportive for the participation of patients and families
2. The clinical micro-system level refers to the service, department, or program level of care. Patients and families should participate in the overall design of the service, department, or program.
3. The ambulatory healthcare center-level refers to the ambulatory healthcare center as a whole. Patients and families should participate as full members of key ambulatory healthcare center committees
4. The environment level refers to the regulatory level of the health system. Patients and families can inform local authorities.

According to Charmel and Frampton, the IOM report reinforces patient-centered care not only as a way of creating a more appealing patient experience but also as a fundamental practice for providing high-quality care in the US.

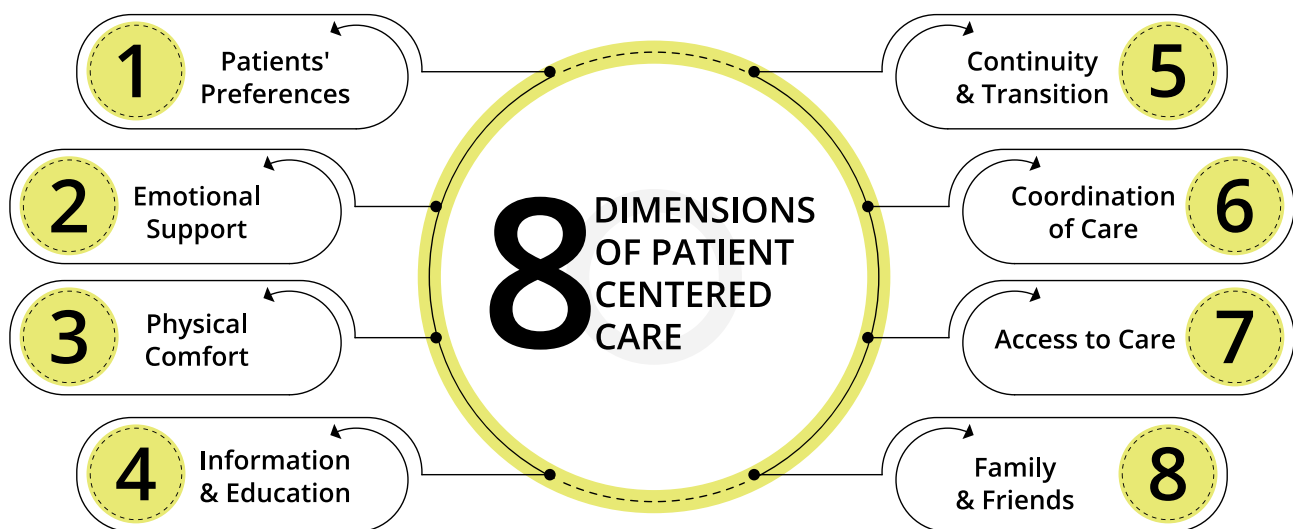
Practically, many Egyptian ambulatory healthcare centers could readily put patients' medical record and informed consent policies in place, but many find it hard to actively change the way care is delivered, and struggle to involve patients and learn from their experience. Key



strategies from leading patient-centered care organizations worldwide include demonstrating committed senior leadership; regular monitoring and reporting of patient feedback data; engaging patients and families as partners; resourcing improvements in care delivery and environment; building staff capacity and a supportive work environment; establishing performance accountability; and supporting a learning organization culture.

Internationally, healthcare services use a range of strategies to promote patient-centered care, including staff development, leadership, collecting and reporting patient feedback, redesigning and co-designing service delivery, implementing patient rights bills, and engaging patients and families as partners in improving care.

There are Eight Principles of Patient-Centered Care as defined by Picker's Institute:



## 1. Patients' Preferences

At every step, patients should be given the needed information to make thoughtful decisions about their care. Those preferences should always be considered when determining the best course of action for that patient. The expertise and authority of healthcare professionals should complement and enhance the patient perspective. Assessment and care should be in a way that maintains patients' dignity and demonstrates sensitivity to their cultural values healthcare professionals need to focus on the person's quality of life, which may be affected by their illness and treatment. Everyone involved is always on the same team, working toward the same goal.

## 2. Emotional Support

Challenges of treating and healing the body can also take their toll on the mind and the heart. Practicing patient-centered care means recognizing the patient as a whole person, having a multi-dimensional human experience, eager for knowledge and human

connection, who may need extra, specialized help in keeping up the spirit of optimism. It helps to alleviate fear and anxiety the person may be experiencing with respect to their health statute (physical status, treatment, and prognosis), the impact of their illness on themselves and others (family, caregivers, etc.), and the financial impacts of their illness.

### **3. Physical Comfort**

Patients shall summon the courage to face circumstances that are scary, painful, lonely, and difficult. Strong pain relief and a soft pillow can go a long way. Healthcare professionals should work to ensure that the details of patients' environments are working for them, rather than against them. Patients should remain as safe and comfortable as possible through difficult straits, surrounded by people equipped to care for them.

### **4. Information and Education**

Providing complete information to patients regarding their clinical status, progress, and prognosis; the process of care; and information to help ensure their autonomy and their ability to self-manage and to promote their health. When patients are fully informed, given the trust and respect that comes with sharing all relevant facts, they will feel more empowered to take responsibility for the elements of their care that are within their control.

### **5. Continuity and Transition**

A transition from one phase of care to the next should be as seamless as possible. Patients should be well informed about what to expect. Treatment regimens, especially medication regimens, should be clearly defined and understood. And everyone involved should be able to plan and understand what warning signs (and positive indicators) to look out for.

### **6. Coordination of Care**

Every aspect of care depends on every other aspect working as efficiently and effectively as possible. Treatment and patient experience shall be considered as an integrated whole, with different moving parts working in concert to reduce feelings of fear and vulnerability. Healthcare professionals shall cooperate in the interest of the patient's overall wellbeing.

### **7. Access to Care**

To the extent that it is possible, patients should have access to all the care they need, when they need it, in a manner that's convenient and doesn't inflict too much stress. It should be simple to schedule appointments, stick to medication regimens, and practice self-care.

### **8. Involvement of Family and Friends**

Patient-centered care encourages keeping patients involved and integrated with their families, their communities, and their everyday lives by:

- Accommodating the individuals who provide the person with support during care.
- Respecting the role of the person's advocate in decision making.
- Supporting family members and friends as caregivers, and recognizing their needs.

## National Safety Requirements

### Chapter intent:

The World Health Organization (WHO) defines patient safety as the reduction and mitigation of unsafe acts within the healthcare system, as well as through the use of best practices shown to lead to optimal patient outcomes. Healthcare is a complex environment where errors can lead to injury or death. Usually, the safeguards work. However, each layer of defenses such as alarms, standardized procedures, and trained health professionals has weak spots.

Advances and commitment to patient safety worldwide have grown since the late 1990s, which leads to a remarkable transformation in the way patient safety is viewed.

When multiple system failures occur, mistakes that would usually be caught slip through, the price we pay when such situations occur is often high, on both human and health-system level.

Measuring patient safety initiatives and adverse events is essential when monitoring the progress of these strategies, tracking success, and helping to flag issues or identify potential areas for improvement.

As part of the GAHAR accreditation process, Ambulatory healthcare centers have to show commitment to patient safety. This requires compliance with each of the National Safety Requirements (NSRs). During surveys, surveyors evaluate that safe and efficient implementation of each of the NSRs is maintained in all relevant practices. The application of the standards should be according to the applicable Egyptian laws and regulations.

### Chapter purpose:

1. To address all the National Safety Requirements.
2. To ensure that the organizations provide and maintain the patient safety program effectively.

### Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

1. Egyptian Constitution
2. Egyptian code of medical ethics 238/2003
3. Egyptian code of nursing ethics
4. Jeddah Declaration on Patient Safety 2019
5. WHO Patient Safety Assessment Manual
6. WHO Surgical Safety Checklist
7. WHO Patient Safety Friendly Initiatives

No standards are scored under this chapter; all National Safety Requirements will be scored in their corresponding chapters.

Code	NSR Keyword	Code in this book
<b>GENERAL PATIENT SAFETY</b>		
NSR.01	Patient Identification	ACT.02
NSR.02	Verbal and telephone orders	ICD.10
NSR.03	Hand Hygiene	IPC.05
NSR.04	Catheter and tube misconnections	ICD.12
NSR.05	Fall screening and prevention	ICD.06
NSR.06	Handover Communication	ACT.08
NSR.07	Critical Results	ICD.11
<b>MEDICATION MANAGEMENT AND SAFETY</b>		
NSR.08	Medication storage and labelling	MMS.02
NSR.09	High alert medications and concentrated electrolytes Look-Alike and Sound-Alike Medication	MMS.03
<b>SURGICAL, ANESTHESIA AND SEDATION</b>		
NSR.10	Pre-operative Verification process	SAS.12
NSR.11	Time-out	SAS.13
NSR.12	Pre and post procedure count verification process	SAS.16
<b>ENVIRONMENTAL AND FACILITY SAFETY</b>		
NSR.13	Fire and smoke Safety	EFS.02
NSR.14	Fire Drill	EFS.04
NSR.15	Hazardous Material Safety	EFS.05
NSR.16	Safety Management Plan	EFS.06
NSR.17	Medical Equipment Safety	EFS.09
NSR.18	Critical Alarms	EFS.10
NSR.19	Utilities Safety	EFS.11
<b>DIAGNOSTIC AND ANCILLARY SERVICES</b>		
NSR.20	Radiation Safety Program	DAS.07
NSR.21	Laboratory Safety Program	DAS.17
<b>INFORMATION TECHNOLOGY AND MANAGEMENT</b>		
NSR.22	Abbreviations	IMT.02

## Patient-Centeredness Culture

### Chapter intent:

In patient-centered care, a patient's specific health needs and desired health outcomes are the driving force behind all healthcare decisions and quality measurements. As many patients are unable to evaluate a healthcare professional's level of technical skill or training, criteria for judging a particular service are non-technical, personal and include aspects like comfort, friendly service, healthcare professional's communication, soft skills, and on-time schedules.

This requires that healthcare professionals develop good communication skills and address patient needs effectively and timely. Patient-centered care also requires that the healthcare professional becomes a patient advocate and strives to provide care that is not only effective but also safe.

The goal of patient-centered healthcare is to involve and empower patients and their families to become active participants in their care not only from a clinical perspective, but also from an emotional, mental, spiritual, social, and financial perspective.

Globally, the universal declaration of human rights article 25 emphasized the human right to a standard of living adequate for the health and wellbeing of himself and of his family, which includes medical care and the right to security in the event of sickness or disability. In 1990, the Cairo declaration on human rights in Islam clearly stated in article 20 that no human should be a subject in clinical research without his/her consent provided that there is no harm to the subject's health or life.

Locally, Egyptian legal and ethical frameworks supported patient-centered care as well. According to the Egyptian constitution, comprehensive quality-standardized healthcare is a right for Egyptians. Egyptian codes of medical, nursing, pharmaceutical, and other healthcare professionals' ethics emphasized multiple aspects of patient's rights and healthcare professional's obligations towards patients.

In addition, Egyptian laws clearly describe the mechanism to obtain legal consents. During the past few years, the Egyptian parliament discussed some laws that are pertinent to the rights of some groups of Egyptian society, such as women, children, and handicapped and elderly. Egyptian government identified multiple methods for the public to voice complaints from ambulatory healthcare centers, including hotlines in the ministry of health and population.

Practically, Ambulatory healthcare centers need to ensure infrastructure for uniform patient-centered care policies and procedures. Organizations shall not stop their patient-centered care processes at just printing patient rights and responsibilities brochures and handing them to patients. Policies and procedures need to identify mechanisms to establish and sustain patient-centered care culture. Education and techniques to encourage patient-centeredness behaviors are needed.

During the GAHAR Survey, Surveyors shall be able to measure how organizations define their patient-centeredness culture and work to sustain it through reviewing documents pertinent to this chapter, reviewing the implementation of direct patient management, during patient tracers, and interviewing staff. The leadership interview session may touch on this topic, as well.

**Chapter purpose:**

1. To describe the patient centeredness culture needed to comply with the chapter requirements.
2. To describe basic patient rights and responsibilities.
3. To emphasis on the techniques and cultural changes that organizations need to address while building a patient-centeredness culture.

**Implementation guiding documents:**

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

1. The Egyptian Constitution
2. The Universal Declaration on Human Rights, 1964
3. Cairo Declaration on Human Rights in Islam, 1990
4. Law 126/2008 on the Egyptian child
5. Law 10/2018 on the rights of handicapped
6. Drafted Egyptian law for Elderly care
7. Law 181/2018 on Egyptian Consumer Protection
8. Law 206/2017 on advertisement for healthcare services
9. Egyptian code of medical ethics 238/2003
10. Egyptian code of nursing ethics (Nursing Syndicate Publications)
11. Code of ethics and behavior for civil service staff,2019, if applicable
12. Egyptian Criminal code 58/1937
13. Egyptian consent laws
14. MOH Ministerial decree 186/2000, Management of emergency cases
15. MOHP Ministerial decree 216/1982, Healthcare facilities organization
16. MOHP Ministerial 186/2001, A patient's right to know the expected cost of care

## Planning and protecting the patient-centeredness culture

**PCC.01 The ambulatory healthcare center advertisements are clear and comply with applicable laws, regulations, and ethical codes of the healthcare professionals' syndicates.**

*Patient-centeredness*

**Keywords:**

Ambulatory healthcare center advertisement

**Intent:**

Usually, ambulatory healthcare centers use advertisements as an important tool to improve the utilization of services. Good advertisement aims to help the community having a better understanding of the available health services. Ambulatory healthcare centers might use newspapers, TV advertisements, banners, brochures, pamphlets, websites, social media pages, call centers, SMS messaging, mass emailing, or other media to advertise provided services. According to Egyptian laws and regulations, an advertisement for healthcare services should be done honestly. Medical syndicate, nursing syndicate, pharmacists syndicate, and others addressed honesty and transparency as high values in their codes of ethics. The ambulatory healthcare center can start complying with this standard by exploring the relevant to ethical codes and finding out how they apply to the ambulatory healthcare center advertisement/communication plan. Information must be accurate, updated, and clearly communicated about types of services, healthcare professionals, cost of services, and working hours.

**Survey process guide:**

GAHAR surveyor may check ambulatory healthcare center website, social media, or other forms of advertisement at any time from the receiving of application and assigning of surveyors until sending the survey report. Advertisements may be matched with the application information and with survey visit observations.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy guiding the process of providing clear, updated, and accurate advertisements of services.
2. Advertisements are done in compliance with ethical codes of healthcare professionals' syndicates.
3. Patients and their families receive clear, updated, and accurate information about the ambulatory healthcare center's services, healthcare professionals, and working hours.

**Related standards:**

PCC.02 Patient and family rights, OGM.12 Ethical Management, OGM.04 Scope of services, ACT.01 granting access.



## **PCC.02 Patient and family rights are protected and informed to patients and families.**

*Patient-centeredness*

### **Keywords:**

Patient and family rights

### **Intent:**

Seeking and receiving care and treatment at the ambulatory healthcare center can be overwhelming for patients, making it difficult for them to act upon their rights and understand their responsibilities in the care process. Patients should be able to understand their rights and know how to use them. If for any reason, a patient does not understand his/her right, the ambulatory healthcare center is committed to help the patient to gain knowledge about his/her rights. The ambulatory healthcare center provides direction to staff regarding their role in protecting the rights of patients and families. Patient emotional, religious, spiritual needs and other preferences shall be addressed and recognized. Whenever appropriate, provide separate facilities and services for women and men according to their cultural needs. Patient and family rights shall be defined by laws and regulations, and the ethical code of healthcare professionals' syndicates.

The ambulatory healthcare center shall develop a policy and procedures to ensure that all staff members are aware of and respond to patient and family rights issues when they interact with and care for patients throughout the ambulatory healthcare center. The policy addresses at least the following:

- a) Patient and family right to access care if provided by the ambulatory healthcare center.
- b) Patient and family right to know the name of the treating, supervising, and/or responsible medical staff member.
- c) Patient and family right to receive care that respects the patient's personal values, beliefs and personal preferences.
- d) Patient and family rights to be informed and participate in making decisions related to their care.
- e) Patient and family right to refuse care and discontinue treatment.
- f) Patient and family right to have security, personal privacy, confidentiality, and dignity.
- g) Patient and family right to have pain assessed and treated.
- h) Patient and family right to make a complaint or suggestion without fear of retribution.
- i) Patient and family right to know the price of services and procedures.
- j) Patient and family right to seek a second opinion either internally or externally.
- k) Patient and family right to have protection from any violations or abuse.

### **Survey process guide:**

- The GAHAR surveyor may review patient rights policy and interview staff members to check their awareness.
- The GAHAR surveyor may observe patient rights statements availability in the ambulatory healthcare center may also observe how patients receive information about their rights



and may check conditions under which patient rights are protected.

- GAHAR surveyor may interview staff to check their awareness on how to manage violations or predict violation as one of the patient and family rights.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that describe the process of defining patient and family rights, as mentioned in the intent from a) through k).
2. All staff members are aware of patient and family rights.
3. An approved statement on patient rights and family is available in all public areas in the ambulatory healthcare center.
4. Patient and family rights are protected in all areas and at all times.
5. Any violations to patient rights are managed and reported through a defined process.
6. Information about patient rights is provided in writing or in another manner in which the patients and their families understand.

**Related standards:**

PCC.03 Patient and family responsibilities, PCC.04 Patient and family education process, PCC.07 Patient and family feedback, PCC.08 Complaints and suggestions EFS.08 Security Plan, PCC.05 informed consent, OGM.08 billing system

**PCC.03 Patients and families are empowered to assume their responsibilities.**

*Equity*

**Keywords:**

Patient and family responsibilities

**Intent:**

Patients and their families should be able to identify responsibilities related to the care process. If, for any reason, a patient/family does not understand his/her responsibilities, the ambulatory healthcare center is committed to help him to gain relevant knowledge. The inability to identify these responsibilities might affect the care or the management processes of the patients themselves, their families, and other patients or staff members. The ambulatory healthcare center is responsible for making the patients' responsibilities visible to patients and staff members at all times. The ambulatory healthcare center shall develop and implement a policy and procedures to ensure that patients are aware of their responsibilities.

The policy addresses at least the following:

- a. Patients and their families have the responsibility to provide clear and accurate information on the disease/condition including the current and past medical history.
- b. Patients and their families have the responsibility to comply with the policies and procedures of the ambulatory healthcare center.
- c. Patients and their families have the responsibility to comply with financial obligations

according to laws and regulations and ambulatory healthcare center policy.

- d. Patients and their families have the responsibility to show respect to other patients and healthcare professionals.
- e. Patients and their families have the responsibility to follow the recommended treatment plan.

**Survey process guide:**

- GAHAR surveyor may review patient responsibilities policy and interview staff members to check their awareness.
- During the GAHAR survey, the surveyor may observe patient responsibility statements availability in the ambulatory healthcare center. The surveyor may also observe how patients receive information about their responsibilities.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that describe the process of defining patient and family responsibilities as mentioned in the intent from a) through e).
2. All staff members are aware of patients and families responsibilities.
3. An approved statement on patient and family responsibilities is available in all public areas in the ambulatory healthcare center.
4. Information about patient responsibilities is provided in writing or in another manner that the patient understands.

**Related standards:**

PCC.02 Patient and family rights, PCC.04 Patient and family education process, PCC.08 Complaints and suggestions, PCC.05 informed consent, ICD.08 plan of care.

**Empowerment and involvement of patients and their families**

**PCC.04 The ambulatory healthcare center ensures that patients and families' education is provided clearly.**

*Patient-centeredness*

**Keywords:**

Patient and family education process

**Intent:**

Patient and family education helps to understand the care process and empower patients and families taking informed decisions. Multiple disciplines contribute to the process of educating patients and families during the course of care processes. The ambulatory healthcare center shall develop and implement a policy and procedures to define the process of patient and family education. All Patient education activities required shall recorded in the patient's medical record. The policy addresses at least the following:

- a. Identifying patient and family educational needs.
- b. Multidisciplinary responsibility to educate patients and families.

- c. Method for education provided, according to patient and family values and level of learning, and in a language and format that they understand.
- d. Process of recording patient's educational activities.

The multidisciplinary team identifies all the educational needs, which may vary from a patient to another; however, at least the following needs are to be addressed for all patients:

- i. Diagnosis and current condition explanation.
- ii. Plan of care, expected outcome of care, and alternative to the planning of care.
- iii. Discharge/home instructions.

#### **Survey process guide:**

- The GAHAR surveyor may review a policy describing the patient and family education process.
- The GAHAR surveyor may interview staff members to check their awareness of patient and family education process
- The GAHAR surveyor may check patient and family education records to assess completion.
- The GAHAR surveyor may check the availability of patient education materials.

#### **Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy guiding the process of patient and family education and includes at least item a) to d) in the intent.
2. All staff members are aware of patients and families' education process.
3. Patients receive education relevant to their condition.
4. Patient education activities such as patient education needs, the responsibility of providing education, and the method used are recorded in the patient's medical record.
5. Appropriate patient education materials are available as per center's policy.

#### **Related standards:**

PCC.02 Patient and family rights, PCC.03 Patient and family responsibilities, PCC.05 Informed consent, PCC.08 Complaints and suggestions, ICD.08 plan of care.

#### **PCC.05 The ambulatory healthcare center has a defined process to obtain informed consent for certain medical processes.**

*Patient-centeredness*

#### **Keywords:**

Informed consent

#### **Intent:**

One of the main pillars to ensure patients' involvement in their care decisions is by obtaining informed consent. To give consent, a patient should be informed about many factors related to the planned care. These factors are required to make an informed decision. Informed consent is a process of getting permission before performing a healthcare intervention on a person, or for disclosing personal information. The informed consent shall include the

likelihood of success and the risk of not doing the procedure or intervention, benefits, and alternatives for performing that particular medical process.

The ambulatory healthcare center shall develop and implement a policy and procedures to describe how and where informed consent is used. The policy includes at least the following:

- a. The list of medical processes when informed consent is needed, this list includes:
  - i. Surgery and invasive procedures.
  - ii. Anesthesia, moderate and deep sedation.
  - iii. Use of blood and donation of blood.
  - iv. High-risk procedures or treatments including but not limited to (electroconvulsive treatment, radiation, therapy, and chemotherapy.....)
  - v. Research, if applicable.
  - vi. Photographic and promotional activities, for in which the consent could be for specific time or purpose

Certain situations when consent can be given by someone other than the patient, and mechanisms for obtaining and recording it according to applicable laws and regulations and approved ambulatory healthcare center policies. Specific informed refusal consent shall be used to document the refusal process. In case of refusing or discontinuing a step or steps in the medical care process, the patient informed refusal consent should be used to document the refusal process.

- b. Consent forms availability in all applicable, relevant locations.
- c. The validity requirements for informed consent.

#### **Survey process guide:**

- The GAHAR surveyor may review a policy describing the patient informed consent process.
- The GAHAR surveyor may check patient consent to assess completion.
- During the GAHAR survey, the surveyor may check the distribution and availability of consent forms in areas where they are mostly needed, such as operating room, dental clinic, endoscopy unit, and others.

#### **Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy guiding the process of informed consent that includes all elements mentioned in the intent from a) through c).
2. The informed consent forms are available in all relevant areas as per center' policy.
3. Informed consent is obtained in a manner and language that the patient understands.
4. Informed consent is recorded and kept in the patient's medical record.
5. The most responsible physician obtaining the informed consent signs the form with the patient.
6. All relevant staff members are aware of the consent process.

**Related standards:**

PCC.02 Patient and family rights, PCC.04 Patient and family education process, ACT.07 Patient's care responsibility

**PCC.06 The ambulatory healthcare center's responsibility towards the patient's belongings is defined.**

*Patient-centeredness*

**Keywords:**

Patient's belongings

**Intent:**

Patient's belongings may include clothing, dentures, hearing aids, eyeglasses or contact lenses, or valuables such as jewelry, electronic devices, cash, and credit/debit cards. The ambulatory healthcare center shall develop and implement a policy and procedures to accept custody of patients' belongings or not. Ambulatory healthcare centers shall accept custody of patient's belongings for the patient's best interests; and especially if the patient is not capable of being responsible for the belongings and family is unavailable to take custody for their belongings. Ambulatory healthcare center policy address at least the following:

- a. Clarify the accountability of staff who have the responsibility for managing patient's property.
- b. Ensure that there are safe and appropriate procedures in place to manage patient's property.
- c. Define lost and found process, lost and found items shall be recorded, protected, and returned when possible; the ambulatory healthcare center shall define a clear process to follow when items are not returned within a defined timeframe.

**Survey process guide:**

- The GAHAR surveyor may review the policy that guides ambulatory healthcare center responsibilities for patient's belongings.
- The GAHAR surveyor may interview staff members to check their awareness of the ambulatory healthcare center policy.
- During the GAHAR survey, the surveyor may observe posters, brochures, or other means of communication that inform patients about ambulatory healthcare center responsibility.
- The GAHAR surveyor may review security records and cabinets where patient belongings are kept and recorded.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy guiding ambulatory healthcare center responsibilities for patient's belongings from a) through c) in the intent.
2. Responsible staff members are aware of the ambulatory healthcare center's policy.
3. Records of patient's property management are available and matching the cabinet's contents.

**Related standards:**

PCC.02 Patient and family rights, PCC.03 Patient and family responsibilities, EFS.08 Security Plan.

**Responsiveness to patients' and families' voices**

**PCC.07 The ambulatory health care center improves its provided services based on measured patient and family feedback.**

*Patient-Centeredness*

**Keywords:**

Patient and family feedback.

**Intent:**

Patient and family feedback could include concerns, compliments and formal complaint through surveys that may help ambulatory healthcare center to identify ways of improving clinical and non-clinical performance. Ambulatory healthcare center can solicit feedback from patients in a variety of ways: phone surveys, written surveys, focus groups, or personal interviews. Many ambulatory healthcare centers shall use written surveys, which tend to be the most cost-effective and reliable approach. The ambulatory healthcare center shall develop and implement a policy and procedures to guide the process of managing patient feedback.

The ambulatory healthcare center shall define if the process addresses the measurement of patient experience or patient satisfaction.

For patient experience, the ambulatory healthcare center shall assess whether something that should happen in a healthcare setting (such as clear communication with a healthcare professional) actually happened or for how long it happened. While for patient satisfaction, the ambulatory healthcare center shall measure whether a patient's expectations about a health encounter were met. Two people who receive the exact same care, but who have different expectations for how that care is supposed to be delivered, can give different satisfaction ratings because of their different expectations. Measuring alone is not enough. Ambulatory healthcare centers need to analyze and interpret information obtained from measured feedback and identify potential improvement projects.

**Survey process guide:**

- The GAHAR surveyor may review the policy of patient and family feedback.
- The GAHAR surveyor may observe the process of using patient and family feedback for performance improvement

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy guiding the process of patient and family feedback measurement.
2. There is evidence that the ambulatory healthcare center has received, analyzed, and

interpreted feedback from patients and families.

3. The interpreted feedbacks have been communicated with the concerned staff members and used for services improvement.
4. There is evidence that patient and family feedback is used to improve the quality of service.

**Related standards:**

PCC.02 Patient and family rights, PCC.03 Patient and family responsibilities,  
PCC.08 Complaints and suggestions, QPI.02 Performance Measures,  
QPI.08 Performance improvement and patient safety plan

**PCC.08 Patients and families are able to make oral, written complaints or suggestions through a defined process.**

*Patient-Centeredness*

**Keywords:**

Complaints and suggestions.

**Intent:**

While Ambulatory health care center shall be able to proactively measure and use patient's feedback, patients and families may also want to give oral or written anonymous complaints or suggestions about their care and to have those complaints or suggestions reviewed and acted upon. The Ambulatory health care center shall develop and implement a policy and procedures to create a uniform system for dealing with different complaints and suggestions from patients and/or their families to make it easy to follow up, monitor, and learn from practices. Ambulatory health care center policy shall address at least the following:

- a. Mechanisms to inform patients and families of communication channels to voice their complaints and suggestions.
- b. Tracking processes for patient and family complaints and suggestions.
- c. Responsibility for responding to patient complaints and suggestions.
- d. Timeframe for giving feedback to patients and families about voiced complaints or suggestions and advising the patient of progress and outcome.

**Survey process guide:**

- The GAHAR surveyor may review the policy of managing patient complaints and suggestions.
- The GAHAR surveyor may interview staff to check their proper awareness.

**Evidence of compliance:**

1. The ambulatory health care center has an approved policy guiding the process of managing patients' complaints and suggestions as mentioned in the intent from a) through d).
2. The ambulatory health care center allows the complaining process to be publically available.

3. Complaints and suggestions are investigated and analyzed by the ambulatory health care center.
4. Patients and families receive feedback about their complaints or suggestions within approved timeframes and according to the level of urgency of the complaint.
5. Staff is aware of complaints and suggestions process.

**Related standards:**

PCC.02 Patient and family rights, PCC.03 Patient and family responsibilities,  
PCC.07 Patient and family feedback, QPI.02 Performance Measures,  
QPI.08 Performance improvement and patient safety plan.



## Access, Continuity, and Transition of Care

### Chapter intent:

Access is the process by which a patient can start receiving healthcare services. Facilitating access to healthcare is concerned with helping people to command appropriate healthcare services in order to preserve or improve their health. Access is a complex concept, and at least four aspects require evaluation: availability, affordability, acceptability, and physical accessibility. Continuity of care becomes increasingly important for patients as community ages develop multiple morbidities and complex problems.

Transitional care refers to the coordination and continuity of healthcare during a movement from one healthcare setting either to another one or to home, between healthcare professionals in the same or different settings, as their condition and care needs change during the course of a chronic or acute illness.

Locally, the Egyptian constitution focuses on the importance of granting access to healthcare services to all Egyptians, with a special emphasis on providing emergency life-saving care. Egyptian laws for establishing ambulatory healthcare centers defined the minimum requirements for licensure and for access pathways. The medical code of ethics defined the framework of doctors' responsibilities towards patients. Currently, a new law for medical accountability is under discussion, where a clear direction on physician care responsibility is expected. In addition, the Egyptian government has announced a major initiative to transform the healthcare services in Egypt, where payers and healthcare professionals shall be separated, and a body of accreditation shall measure the quality of provided services. All this shall be under the umbrella of the Universal Health Insurance, where eligibility criteria are set for patient access, and referral mechanisms shall be established.

Practically, Ambulatory healthcare centers need to consider all the accesses to services, even on the pre-ambulatory healthcare center level, when applicable. Building a Most Responsible Physician culture is important as well. Establishing organization policies on patient flows and studying the flow bottlenecks help organizations to better use available resources and safely handle patient care.

During a GAHAR survey, the GAHAR surveyor is going to assess the smooth flow of patients to/from the ambulatory healthcare center and assess the process and its implementation. In addition, they will be interviewing staff and reviewing documents related to the standards to assure that equity, effectiveness, and efficient processes are in place.

### Chapter purpose:

1. To ensure that organizations provide and maintain equitable, effective access to patient care services in a safe and efficient way.

2. To describe the patient journey from start access to healthcare services through either the emergency room, outpatient department, admission office, dialysis unit, daycare unit, or registration/admission offices.
3. To ensure assigning responsibility for the patient's plan of care all through the patient journey.
4. To describe situations that need care plan changes or request further consultation and the clear process needed to be followed.
5. To develop a process to avoid risks that may arise when patients need to physically transported from one place to another which may entail a risk of mishandling and missing some information.
6. To document clear information, upon discharge, transfer, or referral to a service outside the ambulatory healthcare center.

**Implementation guiding documents:**

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

1. Egyptian constitution
2. Universal Health Insurance Law 2/2018
3. Prime Minister decree, 1063/2014 Management of Emergency cases
4. Ministerial decree 186 / 2001 Management of emergency cases
5. The transition of care, WHO, 2016
6. Law 10/2018 on the rights of handicapped
7. Egyptian code of building for handicapped
8. Nursing Syndicate Publications – Nursing Guidelines
9. MOHP Ministerial decree number 216 / 1982 Healthcare facilities organization
10. MOHP Ministerial decree 254/2001 Discharge summary requirements
11. Publications of Central Administration of Emergency and Critical Care, the Egyptian ministry of health and population

## **Effective and safe patient flow-in the ambulatory healthcare center**

### **ACT.01 The ambulatory healthcare center grants patients access to its services according to pre-set eligibility criteria.**

*Patient-centeredness*

#### **Keywords:**

Granting access.

#### **Intent:**

Services available shall be relevant and effective for the served population to gain access to satisfactory health outcomes. The availability of services, and barriers to access, have to be considered in the context of the differing perspectives, health needs, and material and cultural settings of diverse groups in society. Pre-set criteria need to be available for those responsible for granting access to patients. In order to improve accessibility to the ambulatory healthcare center services, patients and families should be well informed about the available services.

The ambulatory healthcare center shall develop and implement a policy and procedures to guide the process of patient granting access. The policy addresses at least the following:

- a. The process of general, non-specific screening of patients that aims to determine that the ambulatory healthcare center scope of services can meet their healthcare needs.
- b. How to inform patients of the accessibility methods.
- c. Actions to be taken if the patient needs do not match the ambulatory healthcare center scope of service

#### **Survey process guide:**

- GAHAR surveyor may review the policy describing the patient granting access process.
- GAHAR surveyor may observe the process for informing patients about criteria of granting access at the point of the first contact in the ambulatory healthcare center (such as service desks, receptions, call centers, emergency rooms, and outpatient areas).

#### **Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy for granting access to patients that addresses all elements mentioned in the intent from a) through c).
2. The ambulatory healthcare center has a defined process for informing patients and families about services that are suitable for their needs.
3. Patients are referred and/or transferred to other healthcare organizations when healthcare needs are not matching with the ambulatory healthcare center scope of service.

#### **Related standards:**

PCC.02 Patient and family rights, ACT.03 Physical access and comfort, ACT.05 Patient's flow and uniform access, ACT.06 Coordination and continuity of care, ACT.10 Patient's transfer, referral and discharge, ICD.04 screening of healthcare needs, PCC.01 ambulatory healthcare center advertising.

**ACT.02 NSR.01 Accurate patient identification through at least two unique identifiers to identify the patient and all elements associated with his/her plan of care.**

*Safety*

**Keywords:**

Patient identification.

**Intent:**

Providing care or performing interventions on the wrong patient are significant errors, which may have grave consequences. Using two identifiers for each patient is the key driver in minimizing such preventable errors, which is especially important with the administration of high alert medications or performing high risk or invasive procedures.

The ambulatory healthcare center shall develop and implement a policy and procedures to guide the process of patient identification. The policy addresses at least the following:

- a. Two unique identifiers (personal).
- b. Occasions when verification of patient identification is required.
- c. Elements associated with care such as medications, clinical specimens, blood and blood products and others.
- d. Methods to document identifiers such as wristbands, ID cards, and others.
- e. The exclusion criteria for the patient identification such as the patient's bed number, patient's room number and others.
- f. Special situations when patient identification may not follow the same process, such as for unidentified patients, disasters and others.

**Survey process guide:**

- GAHAR surveyor may review patient identification policy to confirm that it includes all elements in the intent from (a) to (f).
- GAHAR surveyor may review a sample of medical records and check correct patient identification in each sheet as per center's policy.
- GAHAR surveyor may interview the healthcare professionals, to check their awareness.
- GAHAR surveyor may observe patient identification wristbands for the two identifiers and to observe the patient identification process before any planned procedures or care.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy and procedure for patient identification that addresses all elements mentioned in the intent from a) through f).
2. All healthcare professionals are aware of ambulatory healthcare center policy.
3. The patient's identifiers are recorded in each sheet of the patient's medical record.
4. The ambulatory healthcare center tracks, collects, analyzes, and reports data on the staff compliance with the patient's identification process.
5. Corrective actions are taken in accordance with the findings and results of patient identification compliance monitoring process.

**Related standards:**

DAS.04 Medical imaging pre-examination process, DAS.11 Laboratory pre-examination process, Minimum retesting, DAS.12 Specimen reception, tracking and storage, DAS.16 Laboratory -post examination process, Laboratory- turn-around time, STAT, DAS.24 Distribution and transfusion of blood and blood components, SAS.13 Time-out, MMS.05 Safe medication prescription\_ Medication reconciliation, IMT.05 Patient's medical record management

**ACT.03 The ambulatory healthcare center works in collaboration with other community stakeholders to provide comfortable and easy physical access.**

*Patient-centered*

**Keywords:**

Physical access and comfort

**Intent:**

Community members often encounter barriers to healthcare that limit their ability to obtain the care they need. In order to have sufficient access, necessary and appropriate healthcare services should be available and obtainable in a defined timeframe manner. Even when an adequate supply of healthcare services exists in the community, there are other factors to consider in terms of healthcare access. For instance, to have good healthcare access, a patient should also have the means to reach and use services, such as transportation to services that may be located at a distance. Ambulatory healthcare centers aiming at achieving accreditation may work with external community authorities or agencies to ensure availability of public transportation access, ramps and paths for wheelchairs and trollies.

**Survey process guide:**

- During GAHAR survey, the surveyor may observe the ambulatory healthcare center access, identifying potential blockages of access such as the absence of nearby public transportation, presence of a physical barrier like a canal or even absence of clear signs to direct patients in.

**Evidence of compliance:**

1. The ambulatory healthcare center has a defined process that guides safe physical access through multiple means of transportation, either private, public, or both.
2. The ambulatory healthcare center's services are accessible for patients with disabilities.
3. Measures as ramps, wheelchairs and trollies are available for served patients.
4. Barriers to access the ambulatory healthcare center services are identified and proper corrective actions are taken.

**Related standards:**

PCC.02 Patient and family rights, ACT.01 granting access, ACT.05 Patient's flow, EFS.01 Ambulatory healthcare center environment and facility safety structure.

## **Effective and safe patients flow within the ambulatory healthcare center.**

**ACT.04 Appropriate and clear wayfinding signage are used to help patients and families to easily reach their destination inside the ambulatory healthcare center.**

*safety*

### **Keywords:**

Wayfinding signage

### **Intent:**

Wayfinding systems aim to help ambulatory healthcare center to reduce their patients' stress by providing easy-to-follow signage and legible directions to their destinations. Wayfinding signage is important for the the prospective patients as they need to find their way and its design should be suitable for all types of patients, good lighting is very important. Signage needs to be readable in different lighting conditions and in different weathers (if the signage is used outdoors). In some settings, reliance on text-based signs is minimized, and systems rely heavily on non-text signs such as colors and symbols.

### **Survey process guide:**

- During the GAHAR survey, the surveyor may observe wayfinding signs readability, clarity, and acceptability. Wayfinding signs may include all those signs encountered by patients during their journey in the ambulatory healthcare center.

### **Evidence of compliance:**

1. Clear, readable, illuminated wayfinding signs are used in all relevant places and areas during working hours to reduce patient and family confusion.
2. When color-coded signage is used, clear instructions on what each color means should be available.
3. Staff is fully aware of wayfinding signage used.

### **Related standards:**

PCC.02 Patient and family rights, ACT.05 Patient's flow and uniform access.

EFS.01 Ambulatory healthcare center environment and facility safety structure.

**ACT.05 Patient flow in the ambulatory healthcare center is designed to provide efficient care and uniform access based on the needs of the patient.**

*Efficiency*

### **Keywords:**

Patient's flow and uniform access.

### **Intent:**

Patient flow is defined as the movement of patients between departments, staff groups, or ambulatory healthcare centers as part of a patient care pathway. Patient flow needs to be managed well for the ambulatory healthcare center to be efficient. For example, patients

with or without an appointment, patients who are ill and possibly infectious to other patients and staff, and patients with emergency needs that require stabilization and transfer all need to be managed efficiently. If reception/registration staff are to make decisions consistently and rapidly, they need to be supported with decision criteria and other tools to be effective. As reception/registration staff are often the first persons whom patients encounter, simple criteria are useful to identify patients who may need immediate assistance and when the medical staff should be notified. When there is a delay in care or treatment, or there are known long waiting periods for diagnostic and/or treatment services that require the patient to be placed on a waiting list, the patient is informed of the reasons for the delay or wait and informed of available alternatives

**Survey process guide:**

- The GAHAR surveyor may review the process for registering patients.
- The GAHAR surveyor may interview staff to ask about how to inform patients for reasons of the delay or wait.

**Evidence of compliance:**

1. There is a standardized process in place for registering patients based on the scope of services provided.
2. The registration process is managed to give priority to patients with urgent needs.
3. When there will be a delay in care and/or treatment, the patient is informed of the reasons for the delay or wait.
4. Patients are provided with information on available alternatives consistent with their clinical needs.

**Related standards:**

PCC.02 Patient and family rights, ACT.04 Wayfinding signage, ACT.03 Physical access and comfort, ACT.06 Coordination and continuity of care, ACT.09 Safe patient transportation, EFS.01 Ambulatory healthcare center environment and facility safety structure

**ACT.06 The ambulatory healthcare center designs and carries out processes to ensure continuity of patient care services.**

*Patient-centeredness*

**Keywords:**

Coordination and continuity of care.

**Intent:**

Throughout all phases of access to care and continuity of care, patient needs are matched with the required resources within the ambulatory center or outside when necessary. Continuity is enhanced when the healthcare professionals get the required information from patients about the current situation and past history that will help in patient diagnosis and decision-making. For patient care to appear seamless, the ambulatory center needs to design and



to implement processes for continuity and coordination of care, prioritize of patient clinical needs, setting criteria for patient end of care or transfer/referral process.

The responsible staff work together to design and to implement the processes of care coordination and continuity. These processes may be supported with the use of tools such as guidelines, clinical pathways, care plans, referral forms and checklists.

Ambulatory healthcare centers shall offer care to patients whose needs can be met within the capabilities of the centers' staff and scope of services. Appropriateness of care shall be based upon patient assessments, re-assessments, and desired outcomes. Provided care shall be uniformed for all ages regardless of national or ethnic origin, economic status, lifestyle, or beliefs.

The ambulatory healthcare centers shall develop a policy that addresses all the above-mentioned components of continuity of care, including patients' referral when their needs do not match the center's scope of services.

**Survey process guide:**

- The GAHAR surveyor may review coordination and continuity of care policy that describes the components of continuity of care, including patients' referral when their needs do not match the center's scope of services.
- The GAHAR surveyor may interview healthcare professionals to check their awareness of the approved policy.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that addresses all components of coordination and continuity of care.
2. Continuity and coordination of care are evidenced and documented throughout all phases of patient care.
3. The patient's medical record(s) is available and categorized to involve and document all phases of patient care.

**Related standards:**

PCC.02 Patient and family rights. ACT.01 granting access, ACT.05 Patient's flow and uniform access. ACT.07 Patient's care responsibility ,ACT.08 Handover communication, ACT.10 Patient's transfer, referral and discharge ,ICD.01 Uniform care provision, ICD.09 Consultation process



## **ACT.07 The ambulatory healthcare center ensures safe, effective and clear responsibilities for patient care.**

*Safety*

### **Keywords:**

Patient's care responsibility.

### **Intent:**

Patients often require concurrent care from more than one healthcare professional in ambulatory healthcare centers. Patients of large clinics or other healthcare facilities may also be cared for by more than one physician. The term most responsible physician (MRP) generally refers to the physician who has overall responsibility for directing and coordinating the care and management of an individual patient at a specific point in time. Misunderstandings about who among the healthcare team is responsible for a patient's care may compromise that care and may result in an adverse event and increased medico-legal risk. The ambulatory healthcare center shall identify the most responsible physician who shall properly manage handovers of care to reduce the possible medico-legal risks that arise and prevent potential breakdowns in the chain of communication between both patient and healthcare providers. The identity of who will act as MRP for a patient should be determined early and based on the particular circumstances of each case. It should be clear in the patient's medical record, which the physician is designated as the MRP. While typically the attending or admitting physician will be the MRP, this may not always be the case.

The ambulatory healthcare center shall develop and implement a policy and procedures to guide the process of assigning patient care responsibility. The policy addresses at least the following:

- a. Each patient is assigned to one Most Responsible Physician (MRP) as relevant to a patient's clinical condition.
- b. Conditions to request and grant transfer of care responsibility.
- c. How information about assessment and care plan, including pending steps, can be transferred from the first most responsible physician to the next one.(handover)
- d. The process to ensure clear identification of responsibility between transfer of responsibility parties.

### **Survey process guide:**

- The GAHAR surveyor may review the policy for assigning patient care responsibility.
- GAHAR surveyor may observe the process of transfer of care responsibility.
- The GAHAR surveyor may review a sample of medical records to verify that the process of assigning patient care responsibility is met center's policy.

### **Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy and procedure for assigning patient care responsibility that address all elements mentioned in the intent from a) through d).

2. The patient's medical record identifies the physician who has overall responsibility for directing and coordinating the patient care and management (MRP).
3. In cases of transfer of care responsibility, clear handover is signed by the most responsible physician and documented in patient medical record.

**Related standards:**

PCC.02 Patient and family rights, ACT.06 Coordination and continuity of care, ACT.08 Handover communication, ACT.10 Patient's transfer, referral and discharge, WFM.03 Job Description

**ACT.08 NSR.06 The ambulatory healthcare center ensures standardized accurate and complete hand over communication process.**

*Safety*

**Keywords:**

Handover communication

**Intent:**

The primary objective of a 'handover' is the direct transmission of accurate patient care information among staff members to ensure the continuity of care. Moreover, it provides a chance for clarifications, which subsequently decreases medical errors. Handovers of patient care within an ambulatory care organization occur in:

- i. Between healthcare professionals (for example, physician to physician, dentist to oral surgeon, and so forth);
- ii. Between different levels of care (for example, when transferring a patient from the ambulatory care center to a tertiary level of care);
- iii. From one department to another (for example, from the diagnostic imaging department to the interventional radiology department).

The ambulatory healthcare center shall develop and implement a policy and procedures to guide the process of handover communication. The policy addresses at least the following:

- a. Use of standardized methods, forms, or tools to facilitate consistent and complete handovers of patient care; such as SBAR, ISOBAR, I PASS the BATON, and others.
- b. Situations that require implementing handover process and tools
- c. Assign staff responsibilities.
- d. Recording of the process, such as handover logbook, endorsement form, electronic handover tool, and/or other methods as evidence of implementation.

Handover forms or tools are not required to be part of the medical record, and the detailed information communicated during the handover is not required to be documented.

**Survey process guide:**

- GAHAR surveyor may review the policy of handover communication and check the process implementation.
- GAHAR surveyor may review medical records, handover logbooks, endorsement form,

electronic handover tool, and/or other methods as evidence of implementation.

- GAHAR surveyor may interview staff to check their awareness of handover policy and procedures.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that addresses all elements mentioned in the intent from a) through d).
2. All healthcare providers are aware of how to apply the policy.
3. Handover communications records are available as per center's policy.
4. The ambulatory healthcare center tracks, collects, analyzes, and reports data on the staff compliance with the handover communication process.
5. The ambulatory healthcare center acts on the findings and results identified in the handover communication process.

**Related standards:**

ACT.06 Coordination and continuity of care, ICD.01 Uniform care provision, ICD.10 verbal and telephone orders, ICD.11 critical results

**ACT.09 The ambulatory health care center ensures that the transportation services provided comply with relevant laws and regulations and meet requirements for quality and safe transport.**

*Safety*

**Keywords:**

Safe patient transportation.

**Intent:**

Transportation in this standard refers to the act of lifting, maneuvering, positioning, and moving patients from one point to another point under the custody of ambulatory healthcare center staff members.

Evidence-based research has shown that safe patient handling interventions can significantly reduce overexertion injuries by replacing manual patient handling with safer methods. The ambulatory healthcare center should coordinate patient transportation between different departments and services. The ambulatory healthcare center should be able to meet patient needs within an approved timeframe, especially in critical conditions. Patient transportation should be facilitated and coordinated within the available services and resources. The ambulatory healthcare center shall develop and implement a policy and procedures for managing patient transportation. The policy addresses at least the following:

- a. Safe patient handling to and from examination bed, trolley, wheelchair, and other transportation means.
- b. Staff safety while lifting and handling patients.
- c. Coordination mechanism to ensure safe transportation within the approved timeframe, especially in critical conditions.

- d. Qualifications of responsible staff members for the transportation of patients. (The qualifications required depend on the type of the patient being transferred).

**Survey process guide:**

- The GAHAR surveyor may review the policy for patient transportation.
- GAHAR surveyor may observe the mechanisms of lifting, handling, and/or transporting patients during the survey.
- GAHAR surveyor may observe equipment used for lifting, handling, and/or transporting patients during ambulatory healthcare center tracers and tours.
- GAHAR surveyor may also interview healthcare providers to check their awareness of the policy.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that addresses all elements mentioned in the intent from a) through d).
2. All staff members involved in the transportation of patients are aware of the ambulatory healthcare center's policy.
3. Staff responsible for monitoring the patient during transportation are qualified according to the type of patient being transferred.
4. Requirements for transporting patients in critical conditions are identified, used, and timely recorded in the patient's medical record.

**Related standards:**

ACT.05 Patient's flow and uniform access, EFS.01 Ambulatory healthcare center environment and facility safety structure, ACT.10 Patient's transfer, referral and discharge.

**Effective and safe patients flow-out of the ambulatory healthcare center**

**ACT.10 Processes of patient transfer outside the ambulatory healthcare center, referral and discharge of patients are defined.**

*Safety*

**Keywords:**

Patient's transfer, referral and discharge.

**Intent:**

Discharge from the ambulatory healthcare center is the point at which the patient leaves the ambulatory healthcare center and returns home.

A referral is when the patient leaves the ambulatory healthcare center to seek additional medical care temporarily in another organization. A transfer is when the patient leaves the ambulatory healthcare center to another organization, such as a tertiary care organization, to a rehabilitation organization. Discharge, referral, and transfer involve the medical instructions that the patient will need to fully recover. For ambulatory healthcare centers, an effective patient referral system is an integral way of ensuring that patients receive

optimal care at the right time and at the appropriate level, as well as cementing professional relationships throughout the healthcare community. Recording and responding to referral feedback ensures continuity of care and completes the cycle of referral. The ambulatory healthcare center shall develop and implement a policy and procedures to guarantee the patient referral within an approved timeframe, which is based on the identified patient's needs that are guided by clinical guidelines/protocols.

Discharge summary is a communication tool that helps clinicians outside the center understand what happened to the patient during his patient care journey. An essential part of this process is the documentation of a discharge summary as it is considered a legal document, and it has the potential to jeopardize the patient's care if errors are made. A copy of the discharge summary shall be kept in the patient medical record. The ambulatory health care center shall identify conditions that require obtaining a discharge summary. The components of discharge summary shall be determined in the ambulatory health care center policy.

The discharge, referral, and/or transfer policy addresses at least the following:

- a. Planning for discharge, referral, and/or transfer out begins once diagnosis or assessment is settled and, when appropriate, includes the patient and family.
- b. The discharge, referral/transfer process documentation requirements include at least the following:
  - i. Reason for referral/transfer.
  - ii. Collected information through assessments and care.
  - iii. Medications and provided treatments.
  - iv. Transportation means and required monitoring.
  - v. Condition on discharge or referral/transfer.
  - vi. Destination on discharge or referral/transfer.
  - vii. Name and signature of the medical staff member who decided the patient discharge or referral/transfer.
  - viii. Any special discharge instructions for the patient.
  - ix. Patient details, discharge or referral/transfer' date and time.
- c. A qualified individual is responsible for ordering and executing the discharge, referral, and/or transfer out of patients.
- d. Defined criteria determine the appropriateness of referrals and transfers-out are based on the approved scope of service and patient's needs for continuing care.
- e. Coordination with transfer/ referral agencies, if applicable, other levels of health service and other organizations.

**Survey process guide:**

- GAHAR surveyor may review a policy that describes the ambulatory healthcare center processes for referrals, transfers, and discharges.
- GAHAR surveyor may interview staff especially the healthcare providers to check their awareness of the policy.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that addresses all elements mentioned in the intent from a) through e).
2. All staff members involved in discharge, referral, or transfer of patients are aware of how to apply the policy.
3. The discharge, referral, and/or transfer out is recorded in the patient's medical record using all the required elements from I) through IX).
4. The referral and/or transfer feedback is reviewed, signed, and recorded in the patient's medical record.

**Related standards:**

PCC.02 Patient and family rights, ACT.01 granting access, ACT.06 Coordination and continuity of care, ACT.07 Patient's care responsibility, ACT.09 Safe patient transportation.

## Integrated Care Delivery

### Chapter intent:

Screening is a strategy used in a population to identify the possible presence of an as-yet-undiagnosed disease in patients without signs or symptoms by performing a high-level evaluation of patients to determine whether a further deeper assessment is required. It is a crucial step to save resources and time.

Assessment is a structured deeper process when a patient checked holistically by listening to the patient's complaint, obtaining further information about illness history and performance of observation, inspection, palpation, percussion, and auscultation as techniques used to gather information. Clinical judgment should be used to decide on the extent of the assessment required. Ambulatory healthcare centers define the minimum contents of initial and subsequent assessments. This process starts with collecting enough relevant information to allow healthcare professionals to draw pertinent conclusions about the patient's strengths, deficits, risks, and problems. In addition to understanding the meaning of signs and symptoms, Healthcare professionals are distinguishing real problems from normal variations, identifying the need for additional analysis and intervention, distinguishing, and linking physical, functional, and psychosocial causes and consequences of illness and dysfunction and identifying a patient's values, goals, wishes, and prognosis. Taken together, this information enables pertinent, individualized care plans and interventions.

Individualized care plans developed by multiple disciplines after the collection of patient's needs. Literature shows that this concept helps to coordinate care, to improve healthcare service utilization, and to reduce costs at ambulatory healthcare centers. It also improves patient satisfaction and engagement.

The Egyptian government has announced a major initiative to transform the healthcare industry in Egypt, where payers and providers shall be separated, and a body of accreditation shall measure the quality of provided services. All this shall be under the umbrella of the Universal Health Insurance, where defined eligibility criteria are set for patients, and access and referral mechanisms shall be developed.

Ambulatory healthcare centers need to comply with a number of laws and regulations that maintain and organize the new healthcare initiative.

### Chapter purpose:

1. To emphasize, the uniformity of care through description of simple screening, assessment, and care provided to patient at the first point of contact with the ambulatory healthcare center.
2. To describe the basic screening, assessment, reassessment, and care processes.

3. To highlight the need for special forms of assessments and care processes based on the patient's needs or patient's risks.

**Implementation guiding documents:**

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

1. Egyptian Constitution
2. Drafted Egyptian law for Elderly care
3. Egyptian code of medical ethics 238/2003 (Medical Syndicate Publications)
4. Egyptian code of nursing ethics (Nursing Syndicate Publications)
5. Law 71/2009 on the care of psychiatric patients
6. Law 126/2008 on Egyptian Child
7. Law 10/2018 on the rights of handicapped
8. MOHP Ministerial decree 63/ 1996 for dialysis units
9. Regulation for the care of psychiatric patients 128/2010
10. Publications of Central Administration of Emergency and Critical Care, the Egyptian ministry of health and population
11. Emergency Department unified protocol, Egyptian ministry of health and population curative and critical sector
12. Prime Minister decree, 1063/2014 Management of Emergency cases
13. Requirements of inspection per MOHP law and regulation
14. National cancer treatment guidelines, High committee of cancer. The Egyptian ministry of health and population
15. Law 51/1981 for healthcare organizations
16. Managing victims of social abuse guidelines – ministry of health, UNFPA
17. Guidelines for the Provision of Intensive Care Services (GPICS) OCTOBER 2018 This is a joint project between the Faculty of Intensive Care Medicine (FICM) and the Intensive Care Society (ICS) [https://www.ficm.ac.uk/sites/default/files/gpics\\_v2-public-consultation-draft-october-2018\\_0.pdf](https://www.ficm.ac.uk/sites/default/files/gpics_v2-public-consultation-draft-october-2018_0.pdf)
18. Core Standards for Intensive Care Units [https://www.ficm.ac.uk/sites/default/files/Core%20Standards%20for%20ICUs%20Ed.1%20\(2013\).pdf](https://www.ficm.ac.uk/sites/default/files/Core%20Standards%20for%20ICUs%20Ed.1%20(2013).pdf)
19. SAFE INITIATION AND MANAGEMENT OF MECHANICAL VENTILATION A White Paper from the American Association for Respiratory Care (AARC) and University Health-System Consortium's (UHC) Respiratory Care Network



## **Sustaining uniform care**

### **ICD.01 The ambulatory healthcare center has a uniform process for care provision and treatment.**

*Equity*

#### **Keywords:**

Uniform care provision.

#### **Intent:**

Ambulatory healthcare centers treat similar patients in a similar way regardless of their different backgrounds (such as religion, economic class, literacy level, race, language, etc.) and regardless of the location or the time, the patients receive their care. Ambulatory healthcare centers are expected not to discriminate between patients and provide them a uniform medical care per their clinical requirement. Ambulatory healthcare centers are able to demonstrate a similar level of compliance across all departments and services.

The ambulatory healthcare centers shall demonstrate a uniform process when a service is provided in a department under the supervision of another department (such as comply with dialysis protocols even if dialysis services are provided outside dialysis units).

To carry out the principle of uniform care requires that the center's leaders plan and coordinate the provision of care and standardize care processes. To ensure this, ambulatory healthcare centers shall develop a policy that specifies what constitutes the uniform care and what practices can be followed to ensure that patients are not discriminated based on their background or category of their accommodation. Describing clear process for addressing and reporting the discrimination and/or harassment, if any.

#### **Survey process guide:**

- GAHAR surveyor may review the policy for uniform care provision.
- GAHAR surveyor may interview staff to check their awareness of the policy.
- GAHAR surveyor may review sample of pre-selected medical records.

#### **Evidence of compliance:**

1. Ambulatory healthcare center has a policy for the uniform care provision process.
2. When similar care is provided in more than one place in the organization or more than one site, care delivery is uniform.
3. There is a clear process that explains options for addressing discrimination and/or harassment and describes methods of investigations and reporting, if any.
4. All staff members involved in patient care are aware of the ambulatory healthcare center policy.

#### **Related standards:**

PCC.02 Patient and family rights, PCC.08 Complaints and suggestions, PCC.07 patient and family feedback, ICD.02 Clinical practice guidelines

**ICD.02 The ambulatory healthcare center ensures that the process of clinical practice guidelines' selection, development, and consistent use are strictly followed and implemented.**

*Effectiveness*

**Keywords:**

Clinical practice guidelines

**Intent:**

Clinical practice guidelines are statements that include recommendations intended to optimize patient care and reduce process variations. It serves as a framework for clinical decisions and support for best practices. Promoting uptake and use of clinical guidelines at the point of care delivery represents a final translation hurdle to move scientific findings into practice. Clinical practice guidelines are used to guide the assessment and treatment of applicable patients. The ambulatory healthcare centers shall select guidelines from among those applicable to the services and patients' population; it should formally approved or adopted from an authoritative source. Any mandatory national guidelines shall be included in this process, if present. The ambulatory healthcare center's leaders shall periodically measure the consistent use and effectiveness of the implemented guidelines. The ambulatory healthcare center shall develop a policy and procedure for clinical guidelines adaptation and adoption.

The policy addresses at least the following:

- a. Selection criteria of clinical practice guidelines.
- b. How clinical practice guidelines/protocols implementation are monitored and evaluated
- c. Staff training required to apply the selected guidelines, pathways, or protocols
- d. Periodic update of clinical practice guidelines based on changes in the evidence and evaluation of processes and outcomes.

**Survey process guide:**

- The GAHAR surveyor may review the ambulatory healthcare center policy followed by interviewing staff members to check their awareness of the policy.
- The GAHAR surveyor may review medical records to check implementation of clinical practice guidelines.
- The GAHAR surveyor may review a sample of staff file to check for the training records.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that guides all the elements mentioned in the intent from a) through d).
2. Related staff are trained on the implementation of the relevant approved clinical guidelines.
3. Compliance to clinical guidelines is linked to staff performance evaluation and appraisal processes.

**Related standards:**

ICD.01 Uniform care provision, WFM.07 staff performance evaluation, WFM.06 continuous education program, ICD.03 Clinical care standards, ICD.08 Plan of Care, ICD.14 Emergency Services, QPI.01 quality management program, QPI.02 Performance measures

**ICD.03 Clinical care standards are used when applicable to the patient's condition.**

*Effectiveness*

**Keywords:**

Clinical care standards.

**Intent:**

A clinical care standard is a small number of quality statements that describe how the care of patients should be offered by healthcare professionals for a specific clinical condition or defined clinical pathway in line with current best evidence. A systematic review of evidence and an assessment of the benefits and harms of alternative care options builds clinical care standards. Evidence-based clinical practice guidelines are a key aspect of clinical audits. The ambulatory healthcare center shall ensure that clinical care standards are used when indicated and identify list of the applicable clinical care standards, set certain criteria to monitor the implementation

This will require continuous awareness, education, and monitoring of clinical care standards requirements and standards of practice.

**Survey process guide:**

- GAHAR surveyors may review the center's scope of service to identify the list of applicable clinical care standards.
- GAHAR surveyor may review sample of medical records of cases with diagnoses related to applicable clinical care standards.
- GAHAR surveyors may review a sample of staff file to check the training records.

**Evidence of compliance:**

1. The approved list of clinical care standards is available, easily accessible when needed.
2. Relevant staff members are trained on the applicable clinical care standards pertinent to their jobs.
3. Compliance to clinical care standards is linked to staff performance evaluation and appraisal processes.

**Related standards:**

ICD.02 Clinical practice guidelines, ICD.08 Plan of Care, QPI.01 quality management program, QPI.02 Performance measures, WFM.07 staff performance evaluation, WFM.06 continuous education program

## **Effective screening, assessment, and care for ambulatory healthcare patients**

### **ICD.04 Patient's healthcare needs are identified through defined screening processes.**

*Effectiveness*

#### **Keywords:**

Screening of healthcare needs.

#### **Intent:**

Screening is a set of standardized rules or tests applied to patient groups on which to base a preliminary judgment that further evaluation or interventions are warranted, such as the need for a nutritional evaluation based on nutritional screening. Initial medical and/or nursing screening shall help to determine the need of further in-depth assessment or not and help to identify those patients in need of further nutritional, functional and special needs assessment. Qualified individual shall perform the screenings, and when the need for additional specialized assessments identified, patients shall be referred within the ambulatory care organization or to outside services in the community with a referral feedback for appropriate follow up. In addition, psychosocial screening may help to identify any behavioral issues and social determinants of health. Signs of abuse and neglect shall be included in the screening process, the ambulatory healthcare center shall develop a policy to guide the screening process; the policy addresses at least the following:

- a. Define screening criteria for assessing the patients' needs and determine who is responsible to perform the screenings and the related further assessments, when needed.
- b. Timeframe to complete and document the screening.
- c. Identifying the process when further assessment by specific specialty or sub-specialty is needed.
- d. Screening includes at least the following:
  - i. Nutritional status
  - ii. Functional status
  - iii. Psychosocial status
  - iv. Victims of abuse and neglect and other special needs population.

#### **Survey process guide:**

- GAHAR surveyor may review the ambulatory healthcare center policy that guide the screening process.
- GAHAR surveyor may review a patient's medical record to evaluate documents of screening.
- GAHAR surveyor may interview staff members to check their awareness of the screening policy.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy including elements in the intent from a) through d) to guide screening for patient's healthcare needs to define its content and timeframe based on center's policy.
2. All staff who perform the screening process are qualified and aware of how to apply it.
3. All screenings are completed and recorded within an approved timeframe as per center's policy.

**Related standards:**

ACT.01 granting access, ICD.05 Patient assessment process, ICD.06 Fall screening and prevention, ICD.07 Pain screening, assessment, and management.

**ICD.05 The ambulatory healthcare center ensures that a comprehensive, effective patient assessment process is implemented.**

*Effectiveness*

**Keywords:**

Patient assessment process.

**Intent:**

The initial assessment is considered the basis of all medical care decisions, it aids determination of severity of a condition, and it helps in prioritizing initial clinical interventions. Initial assessment should be standardized, comprehensive, detailed, and completed within a specific time span to achieve high-quality care that fulfills patient needs.

The ambulatory healthcare center shall develop a patient assessment policy and procedure, the patient assessment policy and procedure shall include at least the following:

- a. The scope and content of assessment required by different specialties and in different locations.
- b. The specific assessments when the initial screening labels the patient "at risk" for the screening elements, Identification of special-needs patient populations that visit the ambulatory healthcare center which should include at least the following:
  - i. Adolescents
  - ii. Elderly
  - iii. Disabled
  - iv. Immunocompromised
  - v. Patients with communicable diseases
  - vi. Patients with chronic pain
  - vii. Victims of abuse and neglect
- c. The timeframe for completion the initial assessment and situations when to consider the initial assessment not valid.
- d. The ambulatory healthcare center also defines whether ambulatory healthcare center verifies and/or accept the results of patient's assessments performed outside the

ambulatory healthcare center.

- e. Assessments are performed by each discipline within its scope of practice, licensure, certification and the applicable laws and regulations.

The ambulatory healthcare center shall ensure continuous monitoring of patients' clinical status and determine patient needs of re-assessment by defining who is permitted to perform clinical reassessments and the minimum frequency, content and validity of these reassessments. Re-assessments are performed by each discipline within its scope of practice, licensure, certification and the applicable laws and regulations.

**Survey process guide:**

- GAHAR surveyor may review the ambulatory healthcare center policy followed by interviewing staff members to check their awareness of the assessment and re-assessment policy.
- GAHAR surveyor may review a patient's medical record to check for evidence of patient assessment and re-assessment.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved assessment and re-assessment policy that contains at least from a) to e) in the intent
2. All staff, who is responsible of patient assessment process, is aware of the components of the policy.
3. Only qualified individuals conduct the patient' medical assessments and re-assessment.
4. Patient medical assessment is timely documented in the patient medical record according to the center's policy
5. The assessment process for special patient groups and populations is modified to reflect their needs.
6. Patient re-assessments are performed and timely documented in the patient's medical record according to the center's policy.

**Related standards:**

ICD.04 Screening of healthcare needs, ICD.08 Plan of Care, SAS.11 Assessment before surgery and invasive procedures, IMT.01 Documentation management system, SAS.08 Pre-sedation assessment, SAS.03 Pre-anesthesia assessment - Pre-induction assessment, ICD.07 Pain screening, assessment, , and management, ICD.06 Fall screening and prevention.

**ICD.06 NSR.05 Patient's risk of falling is screened, assessed, and managed safely.**

*Safety*

**Keywords:**

Fall screening and prevention.

**Intent:**

All patients are liable to fall; however, some are more prone to. Identifying the more prone is usually done through a screening process in order to offer tailored preventative measures against falling.

Screening tools are commonly used and include questions or items that are used to identify fall risk patients. For example, the questions may require a simple yes/no answer, or the tool may involve assigning a score to each item based on the patient's responses. When fall risk identified from the screening process, fall risk assessment shall be implemented to reduce fall risk for those patients identified to be at risk, preventive measures to minimize falling are those that are tailored to each patient and directed towards the risks being identified from risk assessment. The ambulatory healthcare center shall develop and implement a policy and procedures to guide the fall screening and prevention process. The policy addresses at least the following:

- a. Patient risk screening at first point of care.
- b. Timeframe to complete the fall screening.
- c. The need and frequency of fall re-assessment.
- d. General measures required to reduce risk of falling such as call systems, lighting, corridor bars, bathroom bars, bedside rails, wheelchairs, and trolleys with locks.

**Survey process guide:**

- The GAHAR surveyor may review the policy describing screening and prevention of patient fall.
- The GAHAR surveyor may review a sample of medical records to check the completeness of the patient fall screening/ assessment forms.
- The GAHAR surveyor may interview healthcare providers, to assess their knowledge about patient fall screening/ assessment process.
- The GAHAR surveyor may observe patient fall prevention' general measures.

**Evidence of compliance:**

1. The ambulatory care center has an approved policy and procedures for fall screening and prevention that addresses items a) and d) of the intent.
2. Staff is aware of the fall screening and prevention policy.
3. Patients at high risk of fall are identified and educated on fall prevention measures.
4. All fall risk screenings are completed and timely documented in the patient's medical record according to the center's policy.
5. Fall preventive general measures are recorded in the patient's medical record.

**Related standards:**

ICD.04 Screening of healthcare needs, ICD.05 Patient assessment process, IMT.01 Documentation management system, PCC.04 Patient and family education process

**Patient-tailored screening, assessment, and care processes**

**ICD.07 patients are screened for pain, assessed, and managed accordingly.**

*Patient-Centeredness*

**Keywords:**

Pain screening, assessment, and management.

**Intent:**

Each patient has the right to a pain-free life. Pain, when managed properly, leads to patient comfort, proper role function, and satisfaction. The ambulatory healthcare center shall develop and implement a policy and procedures for screening, assessment and management of pain processes. The policy addresses at least the following:

- a. Pain screening tool.
- b. Complete pain assessment elements that includes nature, site, and severity.
- c. The need and frequency of pain re-assessments.
- d. Pain management protocols.
- e. Assign responsibility for managing the pain.
- f. Process of recording pain management plan in the patient's medical record.

**Survey process guide:**

- GAHAR surveyor may review the policy for screening, assessment and management of pain, followed by interviewing relevant staff members to check their awareness of the policy.
- GAHAR surveyor may review a patient's medical record to check for evidence of pain assessment, re-assessment and management.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy to guide pain screening, assessment and management processes that addresses all elements mentioned in the intent from a) through f).
2. Relevant staff members are aware of how to apply the policy.
3. All patients are screened for pain using a valid, approved tool.
4. Pain assessment, re-assessment, and management plans are recorded in the patient's medical record.

**Related standards:**

ICD.04 Screening of healthcare needs, ICD.05 Patient assessment process, IMT.01 Documentation management system.



## **ICD.08 An individualized plan of care is developed for every patient.**

*Patient-centeredness*

### **Keywords:**

Plan of Care.

### **Intent:**

A plan of care provides direction on the type of healthcare the patient may need. The focus of a plan is to facilitate standardized, evidence-based, and holistic care. Recording a plan of care ensures medical staff members, nurses, and other healthcare professionals integrate their findings and work together with a common understanding of the best approach towards the patient's condition. The plan of care is:

- a. Developed by all relevant disciplines providing care under the supervision of the most responsible physician (MRP).
- b. Based on assessments of the patient performed by the various healthcare disciplines and healthcare professionals, (including the investigations' results, if any).
- c. Developed with the involvement of the patient and/or family through shared decision making, with discussion of benefits and risks that may involve decision aids.
- d. Includes identified needs, interventions, and desired outcomes with timeframes.
- e. Updated, as appropriate, based on the re-assessment of the patient.
- f. The progress of patient/service user in achieving the goals or desired results of treatment, care or service is monitored.

### **Survey process guide:**

- The GAHAR surveyor may review a patient's medical record to review the recorded plan of care.
- The GAHAR surveyor may interview healthcare professionals to check their awareness of the process.

### **Evidence of compliance:**

1. Patient' plan of care is performed by all relevant disciplines based on their assessments and addresses all the elements mentioned in the intent from a) through f).
2. Individualized plan of care is recorded in each patient's medical file.
3. Healthcare professionals are aware of the plan of care components.
4. Plan of care is revised/updated based on a re-assessment findings or any change of patient condition.

### **Related standards:**

ICD.02 Clinical practice guidelines, ICD.05 Patient assessment process, IMT.01 Documentation management system.

## **ICD.09 The consultation process is available, safe and effective.**

*Safety*

### **Keywords:**

Consultation process.

### **Intent:**

Consultation is the process of seeking an assessment by a medical staff member of a different discipline to suggest a diagnostic or treatment plan. Often, consultation leads to professional communication where clinicians share their opinions and knowledge with the aim of improving their ability to provide the best care to their patients. Such dialogue may be part of a clinician's overall efforts to maintain current scientific and professional knowledge or may arise in response to the needs of a particular patient. Although consultation usually is requested in an efficient manner that expedites patient care. The ambulatory healthcare center shall develop and implement a policy for safe and appropriate consultation process. The policy addresses at least the following:

- a. Defined criteria for patient consultation.
- b. Type and urgency of consultation.
- c. A clear process of communicating consultation requests to concerned medical staff member.
- d. Timeframe to respond to consultation requests.
- e. Consultation feedback' documentation process to ensure safe and appropriate care planning especially in case of urgency.

### **Survey process guide:**

- GAHAR surveyor may review the policy for the consultation.
- GAHAR surveyor may also interview medical staff members to check their awareness of the policy.

### **Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy of consultation that addresses all elements mentioned in the intent from a) through e).
2. Medical staff members who are involved in the consultation process are aware of how to apply the policy.
3. Consultations are performed and timely documented in the patient's medical record according to the center's policy.

### **Related standards:**

ACT.06 Coordination and continuity of care, ICD.05 Patient assessment process, IMT.01 Documentation management system.

**ICD.10 NSR.02 Verbal or telephone orders are communicated safely and effectively throughout the ambulatory healthcare center.**

*Safety*

**Keywords:**

Verbal and telephone orders.

**Intent:**

Miscommunication is the most common root cause for adverse events. Writing down and reading back the complete order, by the person receiving the information, minimizes miscommunication and reduces errors resulting from ambiguous speech, unfamiliar terminologies, or unclear pronunciation. This also provides an opportunity for verification. Limiting verbal communication to urgent situations in which immediate written or electronic communication is not feasible. For example, verbal orders can be disallowed when the prescriber is present. Verbal orders shall be restricted to situations in which it is difficult or impossible for hard copy or electronic order transmission, such as in operating theatre. The ambulatory healthcare center shall develop and implement a policy and procedures of verbal and telephone communication. The policy addresses at least the following:

- a. Process of recording verbal orders
- b. Process of recording telephone orders
- c. Read-back by the recipient
- d. Confirmation by individual giving the order

**Survey process guide:**

- The GAHAR surveyor may review the policy of verbal or telephone orders to check whether it clearly describes the process of recording, read-back by the recipient and confirmation by individual giving the order.
- The GAHAR surveyor may review documents of recording as dedicated registers and patient's medical record.
- The GAHAR surveyor may interview healthcare professionals to check their awareness of the policy.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy to guide verbal communications and to define its content that addresses at least all elements mentioned in the intent from a) through d).
2. Healthcare professionals are aware of how to apply the policy.
3. All verbal orders and telephone orders are recorded in the patient's medical record within a pre-defined timeframe.
4. The ambulatory healthcare center tracks, collects, analyzes, and reports data on compliance with the verbal and telephone order process.
5. The ambulatory healthcare center acts on the findings identified in verbal and telephone order process.

**Related standards:**

ICD.11 Critical results, IMT.05 Patient's medical record management, ACT.08 Handover communication

**Safe critical and special diagnostic and care procedures**

**ICD.11 NSR.07 Critical results are communicated timely, accurately and safely throughout the ambulatory healthcare center.**

Safety

**Keywords:**

Critical results.

**Intent:**

Patient safety and quality of care can be compromised when there are delays in completion of critical tests or in communicating the critical tests or critical results to the requestor. Miscommunication is the most common root cause for adverse events. Writing down and reading back the results, by the person receiving the information, minimizes miscommunication and reduces errors resulting from ambiguous speech, unfamiliar terminologies, or unclear pronunciation. This also provides an opportunity for verification. The process includes instructions for immediate notification of the authorized individual responsible for the patient with results that exceed the critical intervals. Any difficulties encountered in notifications shall be reported in the incident reporting system. The ambulatory healthcare center shall develop and implement a policy and procedures to guide the process of identifying and reporting critical results. The policy addresses at least the following:

- a. Lists of critical results and values.
- b. Critical test results reporting process including timeframe and read-back by the recipient.
- c. Process of recording.
  - i. Date and time of notification.
  - ii. Identification of the notifying responsible staff member.
  - iii. Identification of the notified person.
  - iv. Examination results conveyed.
  - v. Identification of what information needs to be documented in the patient medical record.
- d. Measures shall be taken in case of non-compliance with the critical results reporting process.

**Survey process guide:**

- The GAHAR surveyor may review the policy of critical results to check whether it clearly describes the process of recording, read-back by the recipient
- The GAHAR surveyor may review the recording in the dedicated registers and patient's

medical record.

- The GAHAR surveyor may interview healthcare professionals to check their awareness of the policy.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy to guide critical results communications and to define its content that addresses at least all elements mentioned in the intent from a) through d).
2. Healthcare professionals are aware of how to apply the policy.
3. All critical results are recorded in the patient's medical record within a pre-defined timeframe.
4. The ambulatory healthcare center tracks, collects, analyzes, and reports data on compliance with the critical results reporting process.
5. The ambulatory healthcare center acts on the findings identified in critical results reporting process.

**Related standards:**

ICD.10 Verbal and telephone orders, DAS.06 Medical imaging reports, ACT.08 Handover Communication, DAS.16 Laboratory -post examination process, Laboratory- turn-around Time, STAT, IMT.05 Patient's medical record management

**ICD.12 NSR.04 Systems are implemented to prevent catheter and tubing misconnections**

*Safety*

**Keywords:**

Catheter and tube misconnections

**Intent:**

Tubing and catheters are important steps of daily healthcare provision for the delivery of medications and fluids to patients. Patients, especially within critical and specialized care areas, are connected to many tubes and catheters, each with a special function (monitoring, access, drainage). During care, these tubes and catheters may be misconnected leading to the administration of wrong material via the wrong route resulting in grave consequences. The ambulatory healthcare center shall develop and implement a policy and procedures for catheter and tubing misconnections. The policy addresses at least the following:

- a. Responsibility of connection and disconnection of tubes should not be left to non-medical staff members, families, or visitors.
- b. Labeling of high-risk catheters (e.g. arterial, epidural, intrathecal).
- c. Avoidance of use of catheters with injection ports for these applications.
- d. Tracing of all lines from their origin to the connection port to verify attachments before making any connections or re-connections, or administering medications, solutions, or other products.

- e. Standardized line reconciliation, re-checking process, and catheter maps as part of handover communications.
- f. Acceptance testing and risk assessment (failure mode and effects analysis, etc.) to identify the potential for misconnections when purchasing new catheters and tubing.

**Survey process guide:**

- GAHAR surveyor may review the policy for catheter and tubing misconnections and may interview responsible staff to check their awareness.
- GAHAR surveyor may review patient's medical record to check recording of the used catheters and tubes.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy of catheter and tubing misconnections that addresses all the elements mentioned in the intent from a) through f).
2. All staff members using tubes and catheters are competent and aware of the ambulatory healthcare center policy.
3. Documents of tubes and catheters used as catheter map are recorded in the patient's medical record.

**Related standards:**

ACT.08 Handover communication, WFM.07 Staff Performance Evaluation, IMT.05 Patient's medical record management

**ICD.13 Response to medical emergencies and cardio-pulmonary arrests throughout the ambulatory healthcare center is managed safely for both adult and pediatric patients.**

*Safety*

**Keywords:**

Cardiopulmonary resuscitation and medical emergencies.

**Intent:**

Any patient receiving care within an ambulatory healthcare center is liable to suffer from a medical emergency requiring a rapid response. The medical emergency is simply defined as sudden onset of a medical condition with the manifestations of acute symptoms of sufficient severity (including severe pain), such that the absence of immediate medical attention could reasonably be expected to result in serious outcome. Skills are essential elements for an emergency service to ensure satisfactory outcomes. Therefore, trained staff members, at least on basic life support, should be available during working hours ready to respond to any emergency. All staff who provide patient care, including contracted physicians and independent healthcare practitioners, are trained to provide basic life support services. The ambulatory healthcare center shall develop and implement a policy and procedures to ensure safe management of medical emergencies and cardio-pulmonary arrests. The policy

addresses at least the following:

- a. Defined criteria of recognition of emergencies and cardio-pulmonary arrest including adults and pediatrics.
- b. Education and training of staff members on the defined criteria.(at least BLS)
- c. Identification of involved staff members to respond according to the appropriate training provided and age of population served.
- d. Mechanisms to call staff members; including code(s) that may be used for calling emergency.
- e. The time- frame for response.
- f. Recording of response and management process.

**Survey process guide:**

- GAHAR surveyor may review the policy for medical emergencies and cardio-pulmonary arrest and may interview healthcare professionals to check their awareness of the policy.
- GAHAR surveyor may check evidence of staff training on recognition and communication of medical emergencies or cardio-pulmonary arrest.
- GAHAR surveyor may observe the compliance with policies for medical emergencies and cardio-pulmonary arrest.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that addresses all the elements mentioned in the intent from a) through f).
2. All staff members involved in medical emergencies and cardiopulmonary resuscitation are aware of the ambulatory healthcare center policy.
3. All staff who provide patient care, including the independent healthcare practitioners, are trained to provide basic life support services.
4. Qualified individuals are responsible for the management of medical emergencies and cardio-pulmonary arrests.
5. Management of medical emergencies and cardio-pulmonary arrests are timely recorded in the patient's medical record.

**Related standards:**

ICD.01 Uniform care provision, WFM.06 Continuous Education Program

WFM.10 Clinical Privileges, WFM.07 Staff Performance Evaluation, IMT.05 Patient's medical record management, ICD.14 Emergency Services.

## **ICD.14 Urgent and emergency services are delivered according to applicable laws and regulations.**

*Effectiveness*

### **Keywords:**

Emergency Services.

### **Intent:**

To ensure consistency and coordination of services with higher levels of care, emergency services offered to the community should be provided within the capabilities of the ambulatory healthcare center as defined by law and regulations. The ambulatory healthcare center shall develop and implement a policy and procedures for triage and emergency services. The policy addresses at least the following:

- a. Qualified staff members are available during working hours.
- b. Defined criteria are developed to determine the priority of care according to a recognized triage process.
- c. Assessment, reassessment, and emergency care management follow approved clinical guidelines and protocols.
- d. Availability of medical equipment and medications required for resuscitation.

### **Survey process guide:**

- GAHAR surveyor may review the policy of triage and emergency services.
- GAHAR surveyor may review a patients' medical records to review the recorded emergency triage and plan of care.
- GAHAR surveyor may review emergency room records to check the registration process of emergency patients.

### **Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy for triage and emergency services as mentioned in the intent from a) to d).
2. Qualified staff members offer emergency services according to the policy of triage and emergency services.
3. Patients and families are informed of their priority level and expected time to wait before being assessed by a medical staff member.
4. Medical equipment and medications for resuscitation are standardized and available for use based on the needs of the population served.
5. Records of triage and emergency plan of care are recorded in the patient's medical record.

### **Related standards:**

ICD.02 Clinical practice guidelines, ICD.13 Cardiopulmonary resuscitation and medical emergencies, ICD.15 Emergency care uniform recording process., IMT.05 Patient's medical record management.



## **ICD.15 The ambulatory healthcare center has a uniform recording process for emergency care services.**

*Safety*

### **Keywords:**

Emergency care uniform recording process.

### **Intent:**

Due to the nature of emergency care areas, multiple staff members from emergency care area and from outside emergency care areas need to exchange information. This information has to be captured and recorded to ensure consistency and coordination of services with higher levels of care. When an ambulatory healthcare center provides emergency care, the emergency room registers usually include all the patients receiving care, their arrival and departure times, conclusions at the termination of treatment, patient's condition at disposition, patient's destination at disposition, and any follow-up care instructions. Reading and recording time might seem to be an easy process, yet, in some instances, emergency care staff members may rely on various sources to know the time. These sources might be their own watches, computer clocks, digital watches, or even mobile phones. If these sources are not calibrated, it might lead to a difference in reading and recording times. This process is especially important in healthcare and definitely in emergency care areas. Ambulatory healthcare centers have a uniform recording process for emergency care services. The record includes at least the following:

- a. Time of arrival and time of departure.
- b. Conclusions at the termination of treatment.
- c. Patient's condition at departure.
- d. Patient's disposition at departure.
- e. Follow-up care instructions.
- f. Departure order by the treating medical staff members.

### **Survey process guide:**

- GAHAR surveyor may review a patient's medical record to check the uniformity of emergency recording process.
- GAHAR surveyor may perform an audit on the time of patients' registration in emergency room and compare it to times from other sources (as medical records) to check compliance.

### **Evidence of compliance:**

1. The medical records of emergency patients include arrival and departure times.
2. The medical records of emergency patients include the patient's condition at time of discharge or transfer.
3. Departure order and follow up instructions are signed by the treating physician and recorded in time, in patient medical record.

4. Equipment and devices used for time recording as watches, clocks, digital clocks, and timers are functionally available in all emergency care areas.

**Related standards:**

ICD.13 Cardiopulmonary resuscitation and medical emergencies,

ICD.14 Emergency Services,   IMT.05 Patient's medical record management

## Diagnostic and Ancillary Services

### Chapter intent:

Patients seek medical help for the determination and treatment of various health problems. Sometimes a combination of the patient's history and a clinical examination by a physician are enough to decide whether medical treatment is needed, and what treatment should be given. However, often laboratory investigations or diagnostic imaging procedures are required to confirm a clinically suspected diagnosis or to obtain more accurate information. The scope of this chapter covers the following diagnostic and ancillary services;

- Diagnostic Imaging:
  - ▶ Radiological Imaging
  - ▶ Ultrasound
  - ▶ Mammography
  - ▶ Magnetic resonance imaging (MRI)
  - ▶ Computed tomography (CT)
  - ▶ Echocardiography
  - ▶ Bone densitometry
- Laboratory Medicine
  - ▶ Sample collection
  - ▶ Chemistry and Immunology
  - ▶ Microbiology
  - ▶ Hematology
  - ▶ Anatomic pathology and cytology
  - ▶ Molecular Biology
  - ▶ Point-of-care testing
- Blood Transfusion medicine
  - ▶ Collection and administration of blood\blood components
  - ▶ Handling, labelling and storage of blood\blood components
  - ▶ Disposal of the blood

There are generally three phases in the process of diagnostic investigation:

1. Before doing the investigation: comprises the time and all processes for the preparation of a patient for a diagnostic investigation to the moment when the investigation is performed.
2. During doing the investigation: comprises the time and all processes of a diagnostic investigation.
3. After doing the investigation: The post-analytical phase comprises the time and all processes for reporting the results of the diagnostic investigation to the person who then provides care to the patient.

Making errors during each phase influence the clinical relevance of a diagnostic report, and precautions should be taken to avoid results that are misleading or provide false information.

The diagnostic services familiarize the clinician with the value of the information obtained from an investigation, including its diagnostic specificity. This requires constant communication between clinicians and the diagnostic service' providers. Diagnostic reports are valuable only when the information can be used for patient management. It is, therefore, an obligation for the diagnostic service to provide the results to the clinician in a timely manner so that the results can be interpreted together with the clinical findings for the patient.

The chapter also covers blood transfusion services as one of the critical ancillary services. The quality and safety of blood and blood products should be assured and traced throughout the process starting from the selection of blood donors to the administration of blood to the patient or safe disposal of the blood/ blood component.

From the national perspective, laws, regulations, and guidelines are covering most of the critical processes and offering guidance to the healthcare professionals on the provision of appropriate safe care especially in the Medical Imaging and transfusion services, in the laboratory and other diagnostic services international guidelines are available to ensure effective analysis.

GAHAR surveyors may be focusing on the communication of the patient information to ensure correct and effective patient management plans. The accuracy and precision of the results reported to clinicians are one of the main targets of the survey together with the safety of the patients, staff, and facility since significant organization hazards are present in these areas, whether biological, chemical, and radiological or others.

### **Chapter purpose:**

The main objective is:

1. To ensure safe and effective medical imaging services.
2. To ensure safe and effective clinical laboratory and pathology services.
3. To ensure safe and effective blood transfusion services

### **Implementation guiding documents:**

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

1. National law for laboratories, 367/ 1954
2. Law 59/1960 regulation of Medical Imaging work
3. Law 178/1960 on organizing blood collection transport and storage
4. Law 104/1985 Blood banking services
5. MOHP Ministerial decree 385/1975 for management of blood banks
6. MOHP Ministerial decree 420/1994 for blood donor incentives
7. Law 192/2001 for Hazardous waste management

8. National Blood Transfusion Policy, MOHP, 2007
9. Anatomic pathology and Microbiology checklists, CAP accreditation program, 2014
10. ISO 15189, 2012
11. Requirements of blood bank staff, Egyptian MOHP
12. Requirements and equipment of blood bank, Egyptian MOHP
13. Requirements of a sub-blood bank, Egyptian MOHP
14. Tuberculosis Labs manual, Egyptian MOHP 2015
15. Laboratory biosafety manual, WHO, 2007
16. Good clinical diagnostic practice, WHO, 2005
17. Lab quality management system, WHO, 2011
18. Egyptian Swiss Radiology program, MOHP
19. List of essential in-vitro diagnostic tests, WHO, 2018
20. Law 51/1981 for healthcare organizations

## Medical Imaging

### Efficient planning and management of radiological services

**DAS.01 Medical Imaging services are planned, operated, and provided uniformly according to applicable laws, regulations.**

*Effectiveness*

**Keywords:**

Planning and provision the medical imaging services.

**Intent:**

Medical Imaging is a cornerstone for any ambulatory healthcare center. An efficient, high quality, medical imaging service increases patient satisfaction because of its ability to improve patient care. Over time, the service adds significant patient's volumes to the ambulatory healthcare center.

The location of medical imaging is important for easy access by emergency patients, ambulant patients and inpatients, different functional areas needs to be identified.

Special attention shall be given to the design of a medical imaging unit such as structural support for equipment, equipment positioning and safe patient movement, provision for cable support trays, ducts or conduits may be made in floors, walls, and ceilings, Equipment ventilation, required space and required special human expertise.

The ambulatory healthcare center should plan and design a system for providing medical imaging services required by its patient population, clinical services offered, and healthcare practitioner needs.

The ambulatory healthcare center can provide some or all of the services on-site or can refer to/ contract with other healthcare professionals for some or all of the services, to be performed according to quality expectations and professional standards.

When a medical imaging service is provided outside the designated radiology service area, it should follow the same protocols, guidelines, and safety procedures followed on the ambulatory healthcare center' main radiology service area.

The medical imaging services should meet national laws, regulations, and applicable guidelines.

**Survey process guide:**

- GAHAR surveyor may review the provision of medical imaging services, licenses and permits.
- GAHAR surveyors may observe the provided medical imaging services to check uniformity and standardization
- GAHAR surveyor may review contractual agreements and related reports.

**Evidence of compliance:**

1. Medical Imaging services are provided, either onsite or through outside source, meet laws, regulations, and applicable guidelines.
2. All related licenses, permits and guidelines are available.
3. List of medical Imaging services meets the scope of clinical services of the ambulatory healthcare center.
4. The ambulatory healthcare center demonstrates evidence of monitoring of the quality and safety of outsourced medical imaging services.
5. There is evidence of annual evaluation of the medical imaging services provided in a report discussed by the ambulatory healthcare center leaders and presented to the governing body.

**Related standards:**

APC.01 national regulation, licensures requirements, DAS.02 Medical imaging services healthcare professionals, DAS.03 Technical medical imaging standards (Practice Parameters), EFS.01 Ambulatory healthcare center environment and facility safety structure

**DAS.02 Medical imaging services are performed by licensed competent healthcare professionals and specific duties are assigned according to applicable laws and regulations and assessed competencies.**

*Efficiency*

**Keywords:**

Medical imaging services healthcare professionals.

**Intent:**

Medical imaging professionals are vital members in a multidisciplinary team that forms a core of highly trained healthcare professionals.

They also play a critical role in the delivery of health services as new modalities emerge and the need for medical imaging procedures increases within the laws and regulations.

Medical imaging professionals integrates scientific knowledge, technical competence, and patient interaction skills to provide safe and accurate procedures with the highest regard to all aspects of patient care.

Medical imaging professionals are sensitive to the needs of the patient through good communication, patient assessment, patient monitoring and patient care skills.

As members of the healthcare team, medical imaging professionals participate in quality improvement processes and continually assess their professional performance.

When Medical Imaging services are provided on-site at the ambulatory healthcare center they are managed by a healthcare professional who is qualified by education and training consistent with applicable laws and regulations.

The ambulatory healthcare center shall develop and implement a policy and procedures that addresses at least the following:

- a. Direct observation of routine work processes and procedures, including all applicable safety practices.
- b. Direct observation of equipment maintenance, function checks; and monitoring, recording and reporting of examination results
- c. Review of imaging professionals' human resources records;
- d. Training on special modalities, equipment, and studies.

Competence of medical imaging services staff can be assessed annually using any combinations, all of the approaches mentioned in the policy or following the guidelines according to the assigned job.

Privileges for performing each medical imaging service function is determined based on documented evidence of competency (experience- qualifications – certifications-skills) that is reviewed and renewed as needed.

#### **Survey process guide:**

- GAHAR surveyor may interview medical imaging services staff members to inquire about competence assessment methods, frequency and granting privileges.
- GAHAR surveyor may review medical imaging services staff members to verify competence assessment process.

#### **Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that addresses all the mentioned elements from a) through d) in the intent.
2. Privileges are granted for performing each medical imaging service function based on assessed competencies.
3. Competency assessment is performed annually and recorded in the staff file.
4. There is a mechanism to grant privileges temporarily in emergencies.

#### **Related standards:**

DAS.01 Planning and provision the medical imaging services, WFM.01 Workforce Laws and regulations, WFM.03 Job Description, WFM.04 Verifying credentials, WFM.10 Clinical Privileges, WFM.07 Staff Performance Evaluation.

### **DAS.03 Performance of medical imaging studies and procedures is standardized and effective.**

*Effectiveness*

#### **Keywords:**

Technical medical imaging standards (Practice Parameters).

#### **Intent:**

Medical imaging service encompasses different techniques, modalities, processes to analyze services, and therefore plays an important role in initiatives to improve public health for all population groups.



Furthermore, Medical imaging service is frequently justified in the follow-up of a disease already diagnosed and/or treated.

A procedure manual provides a foundation for the medical imaging service's quality assurance' program; its purpose is to ensure consistency while striving for quality.

The procedure manual may be used to document how studies are performed; train new staff members; remind staff members of how to perform infrequently ordered studies; troubleshoot technical problem; and measure acceptable performance when evaluating staff.

The medical imaging service develops technical procedures for all study types.

The technical medical imaging procedures should be written in a language commonly understood by the working staff and available in an appropriate location, it could be in a paper-based, electronic, or web-based format.

The ambulatory healthcare center shall develop and implement procedures for medical imaging to ensure safety and usability of modalities. For each modality, procedure manuals address at least the following:

- a. Scope and general overview
- b. Equipment description
- c. Maintenance procedures
- d. Quality control
- e. Safety procedures
- f. Critical findings

**Survey process guide:**

- GAHAR surveyor may review a sample of medical imaging procedure manuals and check for their availability. in the medical imaging department.
- GAHAR surveyors may interview staff to check their awareness about the procedure manual.

**Evidence of compliance:**

1. The medical imaging service has a written procedure for each study type.
2. Procedure manuals are readily available. Each procedure manual includes all the required elements from a) through f) in the intent.
3. Staff is trained and knowledgeable of the contents of procedure manuals.
4. Review the procedures manual are performed and reviewed on predefined intervals authorized staff members.

**Related standards:**

DAS.01 Planning and provision the medical imaging services, DAS.02 Medical imaging services healthcare professionals.

## Effective operational processes of medical imaging

### DAS.04 Medical imaging pre-examination process is effective.

*Effectiveness*

#### Keywords:

Medical imaging pre-examination process.

#### Intent:

Pre-examination processes in the path of workflow for medical imaging include all activities from the time the medical imaging services are ordered to the time that the patient be present in the medical imaging service area.

Medical imaging service should provide referrers and patients with information regarding the merits of the various diagnostic imaging techniques, so that referrers can make informed decisions about the diagnostic information and relative value of the range of studies provided as information about patient preparation requirements is important to ensure effectiveness. The ambulatory healthcare center shall develop and implement a pre-examination policy that can be in the form of medical imaging service manual and communicate it with all service users.

The policy includes at least the following:

- a. Proper completion of request form to include: patient identification (Full patient name, date of birth, gender, patient contact, and location), name of the ordering physician, studies requested, date and time of study, clinical information, special marking for urgent tests request.
- b. Patient preparations including specific risks.
- c. Description of study techniques.
- d. Pre-study review of requests to ensure that the requested examination is appropriate to the needs of the referrer and the patient.
- e. Actions to be taken when a request is incomplete, illegible, or not clinically relevant, or when the patient is not prepared.
- f. Recording informed approvals from patients and referrers when an additional or substituted examination is called for.

#### Survey process guide:

- GAHAR surveyor may review medical imaging pre-examination policy.
- GAHAR surveyor may trace a patient receiving a medical imaging service and review service request, patient preparation and service manual.
- GAHAR surveyor may interview responsible staff to check their awareness on preparation requirements.
- GAHAR surveyor may observe the implementation of medical imaging pre-examination process

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy to guide the medical imaging pre-examination process that includes elements from a) to f) in the intent.
2. Medical imaging service provides referrers and patients with information regarding the merits of the various diagnostic imaging techniques, manual is distributed to all users and available in all technical areas.
3. Medical imaging service' staff member review the patient requests and verify patient identity.
4. Medical imaging service' staff member ensures that the patient has complied with any preparation requirements (e.g. fasting) for the procedure that is being performed.
5. Actions are taken when a request is incomplete, illegible, or not clinically relevant, or when the patient is not prepared, to ensure patient safety.
6. When an additional or substituted examination is called for, medical imaging service staff member informs patients and referrers and records in the patient's medical record.

**Related standards:**

ACT.02 Patient identification, ICD.05 Patient assessment process.

**DAS.05 A medical imaging quality control program is developed.**

*Effectiveness*

**Keywords:**

Medical imaging quality control program.

**Intent:**

Management of the routine quality control (QC) of medical imaging equipment is a major responsibility of the medical imaging professionals.

Quality control measures are performed to monitor and ensure the reliability of study results produced by the medical imaging service.

Quality controls can identify performance problems not identified by quality control systems and help the medical imaging service to determine accuracy of images.

Management of routine quality control includes developing the QC protocols, implementation of the program, oversight of the program, and responsibility for determining the need for corrective action.

Quality control data is reviewed at regular intervals and recorded.

Outliers or trends in examination performance, that may indicate problems in the examination system, are analyzed and followed up, then preventive actions are taken and recorded before major problems arise.

The ambulatory health center shall develop and implement a procedure for quality control that includes at least the following:

- a. Elements of the internal quality control performed according to risk assessment for each study/modality.

- b. The frequency for quality control testing is determined by the ambulatory healthcare center according to the guidelines and the manufacturer instructions whichever is more stringent.
- c. Quality control methods to be used. It can be handled and tested in the same manner and by the same medical imaging staff member.
- d. Quality control performance expectations and acceptable results should be defined and readily available to staff so that they will recognize unacceptable results in order to respond appropriately.
- e. The quality control program is approved by the designee prior to implementation.
- f. Responsible authorized staff member reviews Quality Control data at a regular interval (at least monthly).
- g. Remedial actions taken for deficiencies are identified through quality control measures and corrective actions are taken accordingly.

**Survey process guide:**

- GAHAR surveyor may observe areas where medical imaging services provided to check the quality control procedures and records.
- GAHAR surveyor may interview medical imaging service staff members and other healthcare professionals to check their awareness on quality control performance.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved procedure describing the quality control process of all medical imaging tests addressing all elements in the intent from a) through g).
2. Medical imaging service staff members involved in quality control are competent in quality control performance.
3. All quality control processes are performed according to quality control procedure.
4. All quality control processes are recorded.
5. A responsible authorized staff member reviews quality control process and function and check data at least monthly.
6. Corrective action is taken whenever targets are unmet.

**Related standards:**

EFS.09 Medical Equipment management plan, QPI.02 Performance Measures

## **DAS.06 Medical Imaging investigations are reported within approved timeframe.**

*Timeliness*

### **Keywords:**

Medical imaging reports.

### **Intent:**

Reporting medical imaging investigations within the planned and targeted timeframe is crucial for proper decision making and is an essential function of the service, whenever emergency conditions occur.

Turnaround time (TAT) is the time interval from the time of submission of a process to the time of the completion of the process.

The process is initiated when a request is made. A medical imaging service' staff member identifies the patient and performs the study. Next stage is to record the study result and write a report for it and finally the result are sent back to the referring medical staff member.

The ambulatory healthcare center shall develop and implement a policy and procedures to guide the process of reporting medical imaging investigations that addresses at least the following:

- a. Timeframes for reporting various types of images to healthcare professional and to patients.
- b. Emergency and routine reports.
- c. Accountabilities on the medical Imaging services across the ambulatory healthcare center.
- d. Qualified licensed medical staff member is responsible for interpretation and reporting.

The written medical Imaging report is the most important means of communication between the radiologist and the referring medical staff member.

It is part of the patient's medical record, and interprets the investigation in the clinical context. Appropriate construction, clarity, and clinical focus of a radiological report are essential to high quality patient care that addresses at least the following:

- i. The ambulatory healthcare center name.
- ii. Patient identifiers on each page.
- iii. Type of the investigation.
- iv. Results of the investigations.
- v. Time of reporting.
- vi. Name and signature of the reporting medical staff member.

### **Survey process guide:**

- GAHAR surveyor may trace a patient receiving a medical imaging service and review service request, patient access to the service, study time and reporting time.
- GAHAR surveyor may perform patient's medical record review and assess completion of medical imaging service reports.

- GAHAR surveyor may interview responsible staff members to inquire about their experience regarding medical imaging service reporting time.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that addresses all elements mentioned in the intent from a) through d).
2. Staff members involved in interpreting and reporting results are competent to do so.
3. Results are reported within an approved timeframe.
4. The ambulatory healthcare center tracks, collects, analyzes, and reports data on its reporting times for medical imaging services.
5. The ambulatory healthcare center acts on improvement opportunities identified in its medical imaging service reporting times.
6. Completed medical imaging reports that include elements from (I) to (VI) are recorded in the patient's medical record.

**Related standards:**

QPI.02 Performance Measures, WFM.03 Job Description, WFM.07 Staff Performance Evaluation, IMT.05 patients medical record management, QPI.08 Performance improvement and patient safety plan.

**Safe medical imaging studies**

**DAS.07 NSR.20 Radiation safety program is developed and implemented.**

*Safety*

**Keywords:**

Radiation Safety Program.

**Intent:**

Radiation safety program provides information and training on the theory, hazards, biological effects, protective measures, monitoring and disposal of radioactive materials and radiological equipment; develops policies by which radiological equipment are used safely; ensures compliance with regulations; and provides emergency response assistance.

The ambulatory healthcare center environment, staff, patients, relatives and vendors should be safe from radiation hazards, as medical Imaging services are provided on-site, the ambulatory healthcare center has a radiation safety program that shall address all components of the ambulatory healthcare center medical Imaging services.

The ambulatory healthcare center shall develop and implement a program to guide the process of radiation safety program to ensure that the ambulatory healthcare center's environment, staff, patients, families, and vendors are safe from radiation hazards that addresses at least the following:

- a. Compliance to laws, regulations.
- b. All ionizing and non- ionizing radiation equipment are maintained and calibrated.

- c. Protocols to identify maximum dose of radiation for each type of examinations.
- d. Staff self-monitoring tools.
- e. Appropriate and safe waste disposal for radioactive materials.
- f. Staff suitable personal protective equipment.
- g. Patients' safety precautions.
- h. MRI safety plan.

**Survey process guide:**

- GAHAR surveyor may review the radiation safety program to check the approved level of exposure according to local laws and regulations, shielding methods and safety requirements for both staff members and patients.
- GAHAR surveyor may review environmental radiation measures, thermos-luminescent dosimeter (TLD) and/or badge films of the staff results, CBC results, and lead aprons inspection.
- GAHAR surveyor may interview staff to check their awareness.
- GAHAR surveyor may observe medical imaging services inside medical imaging area or outside it to check compliance with radiation safety precautions.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved radiation safety program for patients and staff that addresses potential safety risks and hazards encountered in the ambulatory healthcare center in addition to all elements mentioned in the intent from a) through h).
2. Identified radiation safety risks are mitigated through processes and safety protective devices, for both staff and patients.
3. Staff members involved in medical imaging are aware of radiation safety precautions and receive on-going education and training for new procedures and equipment.
4. Radiation doses for patients in all radiology areas are recorded in the patient's medical record.
5. The radiation safety program is part of the ambulatory healthcare center environment and facility safety program.

**Related standards:**

ICD.02 Clinical practice guidelines, EFS.01 Ambulatory healthcare center environment and facility safety structure, EFS.06 Safety Management Plan, EFS.09 Medical Equipment Plan

## Clinical Laboratory

### Appropriate planning and management

**DAS.08 Laboratory services are planned, provided, and operated according to applicable laws, regulations, and applicable guidelines.**

*Effectiveness*

**Keywords:**

Laboratory services planning and management

**Intent:**

Planned laboratory services are critical to ensuring that communities receive good clinical care. Despite recent major efforts to improve laboratory services, many laboratory systems are inadequate to meet priority needs.

There is a major need to develop effective laboratory plans, provision and operation to strengthen clinical care systems, as an integral part of strengthening overall ambulatory healthcare center systems.

The ambulatory healthcare center shall develop and implement a management and technical system for providing laboratory services required by its patient population, offered clinical services, and healthcare professional needs as well as ambulatory healthcare center mission. Laboratory scope of services is required to be enlisted and available for patients, ambulatory healthcare center staff, and healthcare professionals.

The designated area fulfilling the following:

- a. Is physically separate from other activities in the ambulatory healthcare center.
- b. Accommodate all laboratory activities.
- c. According to the governance's requirements.

**Survey process guide:**

GAHAR surveyor may visit the laboratory area(s) as part of a patient tracer or ambulatory healthcare center tour. During this visit, the surveyor may check laboratory scope of services and match it with related laws and regulations.

**Evidence of compliance:**

1. Laboratory services meet applicable national guidelines, standards of practice, laws and regulations.
2. Laboratory services are available to meet the needs related to the ambulatory healthcare center mission and patient population.
3. Scope of services defined and documented in the ambulatory healthcare center Laboratory.
4. The plan for services is periodically reviewed and modified as the requirements for services evolve and change.
5. The designated laboratory area is available and separate from any other activities
6. Presence of dedicated area for sample collection.



**Related standards:**

DAS.09 Laboratory Staff, EFS.01 Ambulatory healthcare center environment and facility safety structure

**DAS.09 Licensed, competent healthcare professionals are assigned to operate laboratory services and duties.**

*Effectiveness*

**Keywords:**

Laboratory Staff

**Intent:**

Laboratory competent staff have an influential role in the creation of a safe, healthy, productive working environment.

Staff competency assessment is an ongoing process for managers to evaluate employees' work performance, identify strengths and weaknesses, offer feedback, and set goals for future performance.

The laboratory shall develop and implement a policy and procedures describing the performance and documentation of personnel competency assessment that includes at least the following:

- a. Direct observation of routine work processes and procedures, including all applicable safety practices.
- b. Direct observation of equipment maintenance, function checks; and monitoring recording and reporting of examination results.
- c. Review of work records.
- d. Assessment of problem-solving skills.
- e. Examination of specially provided samples, such as previously examined samples, inter-laboratory comparison materials, or split samples.

Competence of laboratory staff can be assessed annually using any combinations, all of the approaches mentioned above or following the guidelines according to the assigned job.

Privileges for performing each laboratory function is determined based on documented evidence of competency (experience- qualifications – certifications-skills) that is reviewed and renewed as needed.

**Survey process guide:**

- GAHAR surveyor may review the policy that describe the performance and documentation of personnel competency assessment.
- GAHAR surveyor may interview laboratory services staff members to inquire about competence assessment methods, frequency and granting privileges.
- GAHAR surveyor may review laboratory services staff files to verify competence assessment process.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy and procedure that address all the mentioned elements from a) through e) in the intent.
2. Competency assessment is performed annually and recorded in the laboratory staff file.
3. Privileges are granted for performing each laboratory function based on assessed competencies.

**Related standards:**

DAS.08 Laboratory services planning and management, EFS.01 Ambulatory healthcare center environment and facility safety structure, WFM.01 Workforce Laws and regulations WFM.02 Staffing Plan, WFM.03 Job Description, WFM.04 Verifying credentials  
WFM.07 Staff Performance Evaluation

**DAS.10 Referral laboratory services are selected and monitored effectively.**

*Effectiveness*

**Keywords:**

Referral Laboratory services.

**Intent:**

A clinical Laboratory often requires the assistance of an outside laboratory or laboratories to perform unique or unusual services, as a backup service, or for routine services that the referring (primary) laboratory does not perform, as a result, primary laboratories refer selected tests to be sent to referral laboratories.

Laboratory remains responsible for the quality of testing even when it refers samples for testing to other laboratories (referral laboratories), so the performance of the referral laboratories should be monitored. The ambulatory healthcare center shall develop a policy describing the quality of performance. The referral laboratory services control shall include:

a. Selection

Selection should be based primarily on quality of performance.

Whenever possible, referral specimens are sent to a national or international accredited laboratory.

b. Evaluation:

The laboratory should implement an evaluation process either before starting contracting, during the contract, or upon renewal of the contract for the referral laboratory through monitoring the quality of performance, turnaround time, and result reporting.

c. Requirements:

A signed document specifying the expectations of the two parties involved should be readily available for quick referral. The document includes at least the following:

i. Scope of Service

- ii. Agreement conditions (including accreditation status).
- iii. Sample requirements
- iv. Turnaround Time (TAT)
- v. Result reporting
- vi. Release of information to the third party
- vii. Mean of solving disputes
- viii. The validity of the agreement and review schedule.

**Survey process guide:**

- GAHAR surveyor may review the ambulatory healthcare center's related policy.
- GAHAR surveyor may review send-out test records in the laboratory.
- GAHAR surveyor may review the evidence of referral laboratory accreditation status.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that addresses all elements mentioned in the intent from a) to c).
2. There is a written agreement between the two laboratories describing the expectations of the two parties fulfilling items in the intent from i) to viii).
3. Referral laboratory meets the selection criteria.
4. Referral laboratory is evaluated based on a predefined criteria and timeframe.
5. Records of send-out tests support compliance.

**Related standards:**

DAS.09 Laboratory Staff, OGM.09 Contracted services management.

**Effective operational processes in the laboratory**

**DAS.11 Laboratory pre-examination process is effective.**

*Effectiveness*

**Keywords:**

Laboratory pre-examination process, Minimum retesting interval.

**Intent:**

Pre-examination processes are the path of workflow for clinical laboratory including all activities from the time the laboratory tests are ordered through the time that the specimens are processed and delivered to the laboratory testing location.

Informing the client of what the laboratory provides is paramount to the quality of laboratory services.

Understanding pre-analytical variation and reducing errors in the pre-examination phase of the testing process are important for improved safety and quality of laboratory services delivered to patients.

The laboratory shall develop and implement a pre-examination policy that includes all needed information for the patient and laboratory staff including at least the following:

- a. Proper completion of request form to include: patient identification (Full patient name, date of birth, gender, patient contact, and location), name of the ordering physician, tests requested, date and time of specimen collection, identification of the person who collected the specimen, clinical information, type of specimen (source of specimens), special marking for urgent tests request.
- b. Patient preparations including instructions for dietary requirements (e.g., fasting and special diets).
- c. Description of specimen type collection techniques.
- d. Proper specimen labeling.
- e. Criteria for safe disposal of materials used in the collection.
- f. Proper handling and transportation of specimens.
- g. Turnaround time of tests
- h. Minimal Retesting Interval (defined as the minimum time before a test should be repeated, based on the properties of the test and the clinical situation in which it is used).

Informing the client of what the laboratory provides is paramount to the quality of laboratory services. Laboratory service manual (LSM) provides an overview for the laboratory service, containing information about the laboratory to the clients and explains all information they need regarding the pre-examination phase.

The laboratory service manual should be communicated to all service users to provide valuable information about the service offered by the laboratory for best patient care

**Survey process guide:**

- GAHAR surveyor may review laboratory pre-examination policy.
- GAHAR surveyor may trace a patient receiving a laboratory service and review service request, patient preparation and service manual.
- GAHAR surveyor may interview responsible staff to check their awareness on preparation requirements.
- GAHAR surveyor may observe the laboratory services area to check request review, patient identification process and communication with requestors and patients.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy to guide the pre-examination process that includes elements from a) to h) in the intent.
2. There is a laboratory service manual distributed to all users and available in all technical areas.
3. The ambulatory healthcare center has an approved policy to guide the process of minimal retesting interval.
4. All staff involved in requesting laboratory tests are aware of the pre-examination policy.
5. Preparation of specimen collection and labeling requirements are implemented.
6. Specimens are handled, transported and disposed safely.

**Related standards:**

ACT.02 Patient identification, ICD.05 Patient assessment process, DAS.12 Specimen reception, tracking and storage

**DAS.12 Specimen reception, tracking, and storage processes are effective.**

*Effectiveness*

**Keywords:**

Specimen reception, tracking and storage

**Intent:**

Specimen tracking is a process starting with specimen registration, collection, and labeling to specimen reception, analysis, and storage to significantly allow workers to identify the specimen location, history, and status.

The ambulatory healthcare center shall develop and implement a policy and procedures to describe securing patient samples and avoiding deterioration, loss, or damage during pre-examination activities and during handling, preparation, and storage.

The policy shall include at least the following:

- a. Setting criteria for acceptance or rejection of specimens.
- b. Evaluation of received specimens by an authorized staff member to ensure that they meet the acceptance criteria relevant for the requested examination(s).
  - i. Acceptable specimen: Specimen recording process in an accession book, worksheet, computer, or another comparable system, Recording includes the date and time of specimen's reception/registration and the identity of the person receiving the specimen.
  - ii. Unacceptable specimen: Records of rejection are maintained, including the cause of rejection, time and date, name of rejecting person, and name of the notified individual.
  - iii. Suboptimal specimen: Recording includes the date and time of specimen's reception/registration and the identity of the person, Indications of acceptance of suboptimal specimens and measures taken accordingly.
- c. Traceability of all portions of the primary specimen to the original primary sample.
- d. Process of recording all specimens referred to other laboratories for testing.
- e. Instructions for proper sample storage in the pre-examination phase.

**Survey process guide:**

- GAHAR surveyor may review the ambulatory healthcare center's policy followed by interviewing staff members to check their awareness of the policy.
- GAHAR surveyor may visit the laboratory to review records of received specimens and match reasons for rejection with approved criteria.
- GAHAR surveyor may also review laboratory specimen identification and traceability process.

**Evidence of compliance:**

1. The laboratory has an approved policy that addresses all elements in the intent from a) through e).
2. All staff involved in receiving specimens are aware of the policy requirements.
3. All received and accepted specimens are recorded including date and time of specimen's reception and the identity of the person receiving the sample.
4. Records for specimen rejection and specimens referred to other laboratories are maintained and include all data mentioned in the intent.
5. Evidence of traceability of all portions of the primary sample to the original primary sample.
6. Samples are stored in appropriate conditions during all pre-examination activities.

**Related standards:**

ACT.02 Patient identification, DAS.11 Laboratory pre-examination process, Minimum retesting.

**DAS.13 Verified/validated analytical test methods are selected and performed.**

*Effectiveness*

**Keywords:**

Verified / Validated test methods

**Intent:**

Analytical laboratory techniques and testing provide the data required to make critical decisions during clinical care, drive test improvement or meet regulatory compliance requirements.

In depth, knowledge of analytical laboratory technologies and how to apply them to a specific sample is critical to drive understanding about a test during analysis.

These technologies are often highly specialized analytical instruments, which can only be operated by competent professionals.

In order to ensure accurate and relevant test results, the laboratory uses accurate and reproducible analytical methods. This can be confirmed when the specified requirements for each examination procedure relate to the intended use of that examination.

The ambulatory healthcare center shall assign competent staff member for different activities of the selected methods.

The validated examination procedures, used without modification shall be subject to verification by the laboratory before being in routine use.

The laboratory shall develop a policy for verification of examination procedure following reliable guidelines.

Once the manufacturer claim is confirmed, the laboratory documents the procedures used for verification and records the results obtained and the staff with the appropriate authority.

Verification of performance characteristics of the process shall include at least the following:

- a. Measurement of trueness.
- b. Measurement of precision.
- c. Measurement of linearity (detection and quantification limits).

The laboratory shall validate the examination procedures when:

- i. Using a non-standard method.
- ii. The standard method used outside its intended scope.
- iii. The validated method with modification.

The laboratory shall follow verification/validation methods endorsed by reliable and updated guidelines. When changes are made to a verified/ validated examination procedure, a new verification/validation shall be carried out and documented.

**Survey process guide:**

- GAHAR surveyor may review ambulatory healthcare center policy to check the followed by interviewing staff members to check their awareness of the policy, their competence and knowledge of the introduced or changed tests.
- GAHAR surveyor may visit the laboratory to review verification/ validation and revalidation records.

**Evidence of compliance:**

1. The laboratory has an approved policy to guide the selection of the examination methods for all tests provided by the laboratory.
2. The laboratory follows verification/validation methods endorsed by reliable and updated guidelines.
3. The responsible authorized staff member demonstrates competence and in-depth knowledge of the introduced or changed test.
4. Records of verification and /or validation results fulfilling acceptable criteria based on predetermined guidelines.
5. There is recorded evidence of reverification/revalidation whenever indicated.

**Related standards:**

DAS.14 Laboratory examination procedures instructions, DAS.15 Laboratory Internal quality control -External quality control- proficiency test

**DAS.14 Instructions for performing test methods and procedures are consistently and effectively followed.**

*Effectiveness*

**Keywords:**

Laboratory examination procedures instructions.

**Intent:**

Laboratory service encompasses different techniques, processes to analyze services, and therefore plays an important role in initiatives to improve public health for all population groups.

Furthermore, laboratory service is frequently justified in the follow-up of a disease already diagnosed and/or treated.

A procedure manual provides a foundation for the laboratory's quality assurance program. The laboratory shall provide carefully documented instructions—in the form of procedures—for all activities that support the performance of analytic testing. These instructions provide essential information for both new and experienced employees on how to perform all examination procedures.

Its purpose is to ensure consistency while striving for quality.

The laboratory shall develop technical procedures for all analytical test methods.

The technical laboratory procedures should be written in a language commonly understood by the working staff and available in an appropriate location.

It could be in a paper-based, electronic, or web-based format.

The Laboratory technical procedures are consistently followed and regularly reviewed. They include at least the following:

- a. Principle and clinical significance of the test.
- b. Requirements for patient preparation and specimen type, collection, and storage.
- c. Criteria for acceptability and rejection of the sample.
- d. Reagents and equipment used.
- e. Verification/validation of examination procedures.
- f. The test procedure, including test calculations and interpretation of results.
- g. Calibration and control procedures and corrective actions to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
- h. Verified/Validated biological reference intervals/clinical decision values.
  - i. Critical test results.
- j. Analytical measurement range and instructions for determining results when it is not within the measurement interval.
- k. Limitations in methodologies including interfering substances.
- l. References.



**Survey process guide:**

- GAHAR surveyor may review laboratory procedures.
- GAHAR surveyor may trace and observe a patient undergoing a laboratory service and review preparation processes.
- GAHAR surveyor may interview laboratory staff members to check their awareness of the analytic procedures.
- GAHAR surveyor may visit laboratory service areas to observe medical calibration, reagent use, ranges and results.

**Evidence of compliance:**

1. The laboratory has a written procedure for each analytical test method.
2. The technical laboratory procedures are readily available when needed.
3. Each procedure includes all the required elements from a) through l) in the intent.
4. Staff are trained and knowledgeable of the contents of procedure manuals.
5. The procedures are consistently followed.
6. Authorized staff member reviews the procedures on predefined intervals.

**Related standards:**

DAS.13 Verified / Validated test methods, DAS.15 Laboratory Internal quality control -External quality control- proficiency test

**DAS.15 Quality control programs are developed and implemented for all tests.**

*Effectiveness*

**Keywords:**

Laboratory Internal quality control -External quality control- proficiency test.

**Intent:**

Quality control programs include the internal and external quality control or its alternatives. Internal quality control testing is performed within a laboratory to monitor and ensure the reliability of test results produced by the laboratory. Control materials are used to monitor the test system and verify that quality patient test results have been attained.

A control is a stabilized sample with a predetermined range of result values that simulates a patient sample. Quality control data shall be reviewed at regular intervals (at least monthly) and shall be recorded.

Outliers or trends in examination performance, that may indicate problems in the examination system, shall be analyzed, followed up and preventive actions shall be taken and recorded before major problems arise.

The laboratory shall develop and implement a procedure for internal quality control which shall include at least the following:

- a. The frequency for quality control testing is determined by the ambulatory healthcare center according to guidelines and manufacturer instructions whichever is more stringent.

- b. Quality control materials to be used. They shall be handled and tested in the same manner and by the same laboratory staff member testing patient samples.
- c. Quality control performance expectations and acceptable ranges should be defined and readily available to staff so that they will recognize unacceptable results and trends in order to respond appropriately.
- d. Acceptance-rejection rules for internal quality control results.
- e. The IQCP is approved by the designee prior to implementation.
- f. Quality Control data is reviewed at a regular interval (at least monthly) by responsible authorized staff member.
- g. Remedial actions taken for deficiencies identified through quality control measures and corrective actions taken accordingly.

External quality control program is a system designed to objectively assess the quality of results obtained by laboratories, by means of an external body.

The laboratory shall participate in an external quality assessment program that covers the maximum number and complexity of tests performed by the laboratory.

The laboratory shall subscribe to proficiency testing according to the laboratory scope.

When there is no proficiency testing available, the laboratory performs inter-laboratory comparison or proficiency test alternatives according to guidelines. This system is used, and its results are recorded at least semiannually.

**Survey process guide:**

- GAHAR surveyor may visit laboratory to check internal and external quality control procedures and records.
- GAHAR surveyor may interview laboratory staff members to check their awareness of the internal and external quality control performance.

**Evidence of compliance:**

1. The laboratory has an approved procedure describing the internal quality control process of all laboratory tests addressing all elements in the intent from a) through g).
2. Laboratory staff members involved in internal quality control are competent and responsible authorized staff member reviews quality control data at least monthly.
3. All internal quality control processes are performed and recorded according to the internal quality control procedure and the Corrective actions are taken when indicated.
4. The laboratory subscribes to an external proficiency-testing program that covers the whole number of analysts performed by the laboratory and available from the provider, as well as the complexity of the testing processes used by the laboratory.
5. Records of all processes of external quality control including testing, reporting, review, conclusions, and actions, are present and retained for at least one year.
6. Evidence of proficiency testing alternative procedures used according to guidelines whenever no proficiency testing is available.

**Related standards:**

DAS.13 Verified / Validated test methods, DAS.14 Laboratory examination procedures instructions

**DAS.16 Laboratory post-examination process is developed and implemented effectively to ensure accurate, Timely reporting and release of verified laboratory tests.**

*Effectiveness*

**Keywords:**

Laboratory -post examination process, Laboratory- turn-around time, STAT

**Intent:**

Laboratory post-examination key processes in the path of workflow include activities related to reporting results and archiving results and specimen material.

The overall purpose of all post-examination activities is to ensure that the results of examinations are presented accurately, timely and clearly.

Turnaround time (TAT) is a period of time required for completing a particular process.

TAT is commonly measured in the clinical analyses in the lab, but nowadays, TAT includes all the phases from request of the samples until the reporting of test results.

STAT testing is defined as laboratory testing urgently needed for diagnosis or treatment of a patient when any delay can be life threatening. The laboratory shall develop a policy defining the total turnaround time for each laboratory test. The laboratory shall define the tests that can be ordered on a STAT basis and the interval of time between sample collection, reception, and reporting results.

The ambulatory healthcare center shall develop and implement a policy and procedures for post examination process. The post examination process includes at least the following:

- a. Final report data fulfillment including at least: identity of the laboratory, patient identification, tests performed, ordering clinician, date and time of specimen collection and the source of specimen, reporting date and time, test results and reference interval, identification of the verifying individual (Approved), interpretation of results, appropriate, advisory, or explanatory comment when needed.
- b. Reviewing, verifying, and reporting of results by an authorized staff member
- c. All laboratory tests (TAT) shall be defined by the laboratory.
- d. The laboratory shall define the tests that can be ordered on STAT base.
- e. Criteria for specimen storage.
- f. The defined retention time of laboratory results
- g. The defined retention time of patient samples

**Survey process guide:**

- GAHAR surveyor may visit laboratory area to check specimen storage and retention times.
- GAHAR surveyor may perform patient's medical record review and assess laboratory results reporting time and authorization.

- GAHAR surveyor may interview laboratory healthcare professionals to check their awareness of laboratory retention time.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy to guide the post-examination process that include all elements mentioned in the intent from a) through g).
2. The laboratory defines the authorized staff member who review and release the patient's results.
3. The laboratory has a STAT List of tests; acceptable STAT reporting time for each laboratory test is defined.
4. Delays in turnaround time are notified to requestors, investigated and proper actions are taken according
5. The retention process of a final laboratory report is implemented with easy retrieval.
6. Required specimens are easily retrieved.

**Related standards:**

ACT.02 Patient identification, ICD.11 Critical results

**Safe laboratory services**

**DAS.17 NSR.21 A comprehensive laboratory safety program is implemented.**

*Safety*

**Keywords:**

Laboratory Safety Program

**Intent:**

The laboratory environment can be a hazardous place to work.

Laboratory staff member are exposed to numerous potential hazards including chemical, biological, physical and radioactive hazards, as well as musculoskeletal stresses.

Laboratory safety is governed by numerous regulations and best practices. Over the years, multiple guides published to make laboratories increasingly safe for staff members.

Laboratory management should design a safety program that maintains a safe environment for all laboratory staff, patients, and families.

The laboratory should have a documented program that describes the safety measures for laboratory facilities according to the national requirements.

This program should be properly implemented and communicated to all staff. The program shall include at least the following:

- a. Safety measures for Healthcare professionals.
- b. Safety measures for the specimen.
- c. Safety measures for the environment and equipment.
- d. Incidents handling and corrective action are taken when needed.
- e. Proper Disposal of Laboratory Waste.

- f. Material Safety Data Sheets (MSDS) Requirements.
- g. Handling Chemical Spills/Spill Clean Up.
- h. Instructions for the use of personal protective equipment.
- i. Risk management process.

**Survey process guide:**

- GAHAR surveyor may review laboratory safety program that should include at least: list of chemicals and hazardous materials, dealing with spills, safety requirements, suitable PPE, maintenance and calibration of medical equipment, and staff orientation, and proper waste disposal.
- GAHAR surveyor may review laboratory safety reports, lab equipment safety, storage of chemicals, labeling and waste disposal process.

**Evidence of compliance:**

1. A written program that describes safety measures for laboratory services and facilities is documented and includes the items in the intent from a) to i).
2. Laboratory staff are trained on the safety program.
3. Laboratory risk assessment is performed and safety reports are issued at least semi-annually to the ambulatory healthcare center environment and facility safety committee.
4. Spill kits, safety showers and eye washes are available, functioning and tested.
5. Safety precautions are implemented.
6. The ambulatory healthcare center tracks, collects, analyzes and reports data on laboratory safety program and it acts on identified improvement opportunities.

**Related standards:**

EFS.01 Ambulatory healthcare center environment and facility safety structure, EFS.05 Hazardous materials safety, EFS.06 Safety Management Plan, EFS.09 Medical Equipment management plan, IPC.04 infection risk and assessment

**Effective Point of care testing**

**DAS.18 Point-of-care testing is monitored for providing accurate and reliable results.**

*Effectiveness*

**Keywords:**

Point of care testing.

**Intent:**

Point-of-care testing (POCT) is defined by the College of American Pathologists as “tests designed to be used at or near the site where the patient is located, that do not require permanent, dedicated space, and that are performed outside the physical facilities of the clinical laboratories.”

The laboratory shall assign a responsible staff member to ensure the quality of these devices and that the reagents and other laboratory supplies are consistently available for it. The

laboratory shall have a clearly defined approach to POCT to ensure that it is performed safely and correctly and that the results generated are accurate and reliable.

The ambulatory healthcare center shall identify all POCT sites and the testing performed, prepare an audit form, perform inspection to determine if any deficiencies currently exist, implement corrective actions for any deficiencies identified in the inspection.

**Survey process guide:**

- GAHAR surveyor may review procedure manual in each point of care testing area, patient results and reporting process, quality control, maintenance, and function checks, evidence of testing staff member training and competency records.

**Evidence of compliance:**

1. The laboratory assigns a competent responsible staff member for supervising the point of care testing services.
2. Staff members who are responsible for performing point of care testing are competent to do so.
3. There is a defined process for performing and reporting point of care testing (POCT).
4. Quality control procedures for POCT are recorded and implemented.

**Related standards:**

DAS.11 Laboratory pre-examination process, Minimum retesting, DAS.15 Laboratory Internal quality control -External quality control- proficiency test, DAS.16 Laboratory -post examination process, Laboratory- turn-around time, STAT, WFM.07 Staff Performance Evaluation

**Blood Transfusion Services**

**Efficient planning and management of blood bank**

**DAS.19 Blood transfusion services are planned, operated and provided uniformly according to applicable laws, regulations and clinical guideline /protocol.**

*Efficiency*

**Keywords:**

Uniform Blood Transfusion services and planning.

**Intent:**

With the growing population and the advancement in medical science, the demand for blood has increased. Lack of communication between the blood donors and the blood recipients lead to a situation where most of the patients in need of blood do not get blood on time.

Improper management of blood may lead to wastage of the available blood inventory.

These problems can be dealt with by developing a robust management system for blood transfusion services to bridge the gap between the donors and the recipients and to ensure safety and efficiency.

The blood bank should function under the direction of a certified physician who is trained

and experienced on blood bank activities

Blood bank should have its own policies and procedures manual.

The manual addresses at least the following:

- a. Organization and Management.
- b. Resources, Equipment and Supplies
- c. Customer needs
- d. Process control
- e. Documents and records
- f. Deviations, nonconformance and complications
- g. Donor Assessments
- h. Blood screening
- i. Process improvements
- j. Facilities and safety

Suitable and safe space, environment and equipment should be available

All blood bags, tubes, connections, reagents and supplies used for storage, preservation or testing of blood and blood components should meet professional requirements

**Survey process guide:**

- GAHAR surveyor may observe areas where blood banking and transfusion occur and observe the space and design to ensure safe blood transfusion process.
- GAHAR surveyor may interview blood transfusion services staff members to inquire about competence assessment methods, frequency and granting privileges for requestors
- GAHAR surveyor may review blood transfusion services staff members' files to verify competence assessment process.

**Evidence of compliance:**

1. There is an approved quality manual that addresses all elements mentioned in the intent from a) through j).
2. All blood transfusion staff members are aware of the quality manual.
3. Blood transfusion services have suitable space, environment, equipment and supplies.
4. Blood transfusion services are monitored by a licensed qualified medical staff member.

**Related standards:**

DAS.20 Safe blood donation, EFS.01 Ambulatory healthcare center environment and facility safety structure, WFM.03 Job Description, WFM.04 Verifying credentials



## Effective operational processes of blood transfusion service

**DAS.20 Blood donation is accepted only from voluntary, non-remunerated, low risk, safe and healthy donors.**

Safety

### Keywords:

Safe blood donation

### Intent:

Millions of people need blood transfusions each year. Some may need blood during surgery. Others depend on it after an accident or because they have a disease that requires blood components. Blood donation makes all of this possible.

There is no substance yet that can act as a 100% substitute for human blood functions. Blood donation remains the main source of human blood

The ambulatory healthcare center shall develop and implement a policy and procedures for donors' selection. The policy shall include at least the following:

- a. Screening based on:
  - i. Donor's history of surgeries, vaccination, receiving blood and donation interval
  - ii. Donor's physical examination including general appearance, height and weight and vital signs
  - iii. Blood bag laboratory testing, including specified communicable diseases, Blood grouping and RH typing
- b. Mechanisms to ensure voluntary non-remunerated blood donation.
- c. Pre-donation counselling by trained staff that include risk behaviors and self-exclusion for patient safety, tests carried out on donated blood and potential side effects. (Questionnaires may be used)
- d. Donor safety and privacy

### Survey process guide:

- GAHAR surveyor may review blood donation selection policy.
- GAHAR surveyor may interview staff to check their awareness of the policy.
- GAHAR surveyor may interview a person donating blood unit to inquire about assessment and counseling.
- GAHAR surveyor may review blood donation records.
- GAHAR surveyor may observe areas where blood donation occurs to check compliance with requirements.

### Evidence of compliance:

1. The ambulatory healthcare center has an approved policy that describes all elements mentioned in the intent from a) through d).
2. Blood bank staff are aware of the ambulatory healthcare center policy.
3. Blood donors are selected safely



4. Blood donors receive pre-donation counselling.
5. Blood donor selection and counselling is recorded.

**Related standards:**

DAS.19 Uniform Blood Transfusion services and planning, DAS.21 Blood Procurement and storage.

**DAS.21 Processes of collection, handling, testing, labelling and storage of blood, and blood components are performed safely and effectively according to regulations and national requirements.**

*Safety*

**Keywords:**

Blood Procurement and storage

**Intent:**

Each step in the process of blood procurement (collection, handling and testing) affects the specimen quality, thus it is important for preventing specimen laboratory error, subsequent patient injury or even death.

The ambulatory healthcare center shall develop and implement a policy for management of blood and blood components.

The policy addresses at least the following:

- a. Collection:
  - i. Donation of blood: Donor area cleanliness and convenience, Donor Reaction and Outdoor blood donation campaigns.
  - ii. Infection control precautions.
- b. Handling:
  - i. Identification of blood/blood components bags and tubes.
  - ii. Temperature controls.
  - iii. Transportation of blood.
- c. Testing:
  - i. Determination of ABO group
  - ii. Determination of Rh(d) type previous records
  - iii. Laboratory tests for infectious diseases
  - iv. Quarantine storage
- d. Preparation:
  - i. Sterility
  - ii. Seal
  - iii. Blood components preparation instructions and protocols
- e. Labelling :

A numeric or alphanumeric system should be used, that will track any unit of blood or component from source to final destination and to recheck records applying to the specific

unit. Labels should include at least the following:

- i. Traceable number
- ii. Name of blood bank
- iii. Product type and volume
- iv. Blood group and Rh group
- v. Sero-negative
- vi. Used anticoagulant, when applicable
- vii. Required storage conditions
- viii. Date of collection
- ix. Date of expiry

f. Storage :

- i. Storage conditions should limit deterioration and prevent damage to materials in process and final products. Storage should be access-controlled.
- ii. Refrigerators, freezers and platelets incubators in which blood and blood components are stored should be used for storage of blood, blood components and blood samples only and not for any other items and should have monitored temperature as per approved guidelines
- iii. Expiry dates should be monitored and actions are taken for expired blood or blood components as per approved guidelines
- iv. Blood bank should have physical separation between screened and unscreened blood bags
- v. Method of disposal of blood bags should comply with requirements of waste management rules, regulations, and approved ambulatory healthcare center process.

#### **Survey process guide:**

- GAHAR surveyor may review blood transfusion services policy.
- GAHAR surveyor may perform a tracer session on a person donating blood or on the donation process to review assessment, collection, handling, testing and preparation steps
- GAHAR surveyor may interview blood transfusion services healthcare professionals to check their awareness of requirements.
- During the GAHAR survey, the surveyor may observe at the blood storage and preparation areas to assess storage conditions and labeling.
- During the GAHAR survey, the surveyor may observe areas such as perioperative and procedural settings to check handling conditions of blood bags before their use.

#### **Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that describes all elements mentioned in the intent from a) through d) and based on national guidelines.
2. Blood and/or blood components are collected and handled as elements from a) through

- b) and based on national guidelines
- 3. Blood and/or blood components are tested and prepared as elements from c) through d) and based on national guidelines
- 4. Blood and /or blood components are labelled and stored as elements from e) through f) and based on national guideline
- 5. An alarm system and a provision for alternate power supply is available.
- 6. Expired blood or blood components are managed effectively.

**Related standards:**

DAS.19 Uniform Blood Transfusion services and planning, DAS.20 Safe blood donation

**DAS.22 obtaining blood from a blood bank outside the ambulatory healthcare center has a safe and effective process.**

*Safety*

**Keywords:**

Contracted blood banks

**Intent:**

Due to regulations organizing blood transfusion services and the pressure to provide quality services while operating cost-effectively, providing all required blood and blood components types in-house becomes unfeasible.

As a result, ambulatory healthcare center blood bank may obtain blood units from an outside blood bank.

Blood bank should take all necessary measures to ensure quality of blood or blood components; this means that the performance of the outside blood bank should be evaluated to assure the quality of performance.

Proper control of outside blood bank services includes:

a. Selection

Selection should be based primarily on quality of performance

Whenever possible, blood and blood components are obtained from an accredited blood bank .

b. Evaluation:

The blood bank should implement an evaluation process before starting relationship by assessing blood bank accreditation status, inspection reports, performing an on-site visit to the blood bank, or by other means of evaluation

The blood bank should implement an evaluation process during the relationship with the outside blood bank by monitoring and evaluating certain quality measures

c. Requirements:

A signed document specifying the expectations of the two parties involved should be readily available for quick referral. The document includes at least the following:

i. Scope of Service.

- ii. Agreement conditions (including accreditation status).
- iii. Agreement on safe storage and transportation conditions.
- iv. Role of the involved parties in look back and transfusion transmitted diseases investigation.
- v. Predefined acceptance criteria for each blood component received.
- vi. Release of blood, blood components or information to the third party.
- vii. Mean of solving disputes.
- viii. Validity of the agreement and review schedule.
- d. Inspection:
  - ix. Checking for meeting predefined acceptance criteria for each blood component received.
  - x. Evaluation and verification of units' identification information including unit numbers, ABO/Rh-D and Expiration dates.
  - xi. Conformation of ABO/Rh-D for RBC components.
  - xii. Actions taken for unsatisfactory blood or blood component units.
  - xiii. Evaluation and verification of the transportation condition of each blood component.

**Survey process guide:**

- GAHAR surveyor may review ambulatory healthcare center policy and review contracted blood bank agreement and results.
- GAHAR surveyor may review records in the blood bank or observe the receiving process.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that addresses all elements mentioned in the intent from a) to d).
2. There is a written agreement between the two blood banks describing the expectations of the two parties fulfilling items in the intent from i) to xiii).
3. Contracted blood bank meets the selection criteria.
4. Contracted blood bank is evaluated based on predefined criteria.
5. Blood bank staff members involved in receiving blood or blood components from contracted blood banks are aware of the predefined acceptance criteria.
6. Records of inspecting received blood and blood components support compliance.

**Related standards:**

DAS.21 Blood Procurement and storage, OGM.09 Contracted services management.

## Safe transfusion services

### **DAS.23 Requesting blood and/or blood component services occurs in a safe and effective way.**

*Safety*

#### **Keywords:**

Ordering of blood and blood component.

#### **Intent:**

Access to sufficient supplies of safe blood and blood products provided within a blood transfusion service is a vital component in achieving equitable health outcomes. To ensure timely and equitable access to safe blood transfusion, the providers of blood for transfusion need to know how much blood is required for their patients and where and when it is needed so that blood is neither under- or over-supplied.

A realistic assessment of blood requirements is fundamental to effective planning for the rational, fair, and effective distribution of blood and blood components within a blood transfusion service.

Usually, a physician's order is required for blood components and products. In some cases; such as elective surgeries, over ordering of blood is a common practice.

The ambulatory healthcare center shall develop and implement a policy and procedure to address safe blood transfusion service. The policy shall include at least the following:

- a. Assessment of patient's clinical need for blood.
- b. Education of patient and family about proposed transfusion and recording in the patient's medical record.
- c. Selecting blood product and quantity required and completing the request form accurately and legibly.
- d. Recording the reason for transfusion, so that the blood bank can check that the product ordered is suitable for diagnosis.
- e. Clearly communicate whether the blood is urgently or routinely needed.
- f. Sending the blood request form with blood sample to the blood bank.
- g. When recipient's blood sample is received, a qualified member of the staff should confirm, if the information on the label and on the transfusion request form are identical. In case of any discrepancy or doubt, a new sample should be obtained.

#### **Survey process guide:**

- GAHAR surveyor may review the ambulatory healthcare center policy followed by interviewing medical staff members, nurses and other healthcare professionals to check their awareness of the order process.
- GAHAR surveyor may observe patient's medical records to assess the completion, legibility and clarity of blood transfusion orders.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that describes all elements mentioned in the intent from a) through g).
2. Blood bank staff members are aware of the ambulatory healthcare center policy.
3. Indication for transfusion is recorded in the patient's medical record.
4. Blood bank staff members receive information about indication of transfusion, clinical information of the patient and whether the request is needed on emergency or routine basis.
5. Blood sample label and blood transfusion request are completed with all required data and cross-checked before issuing blood or blood components

**Related standards:**

ICD.02 Clinical practice guidelines, ICD.05 Patient assessment process

DAS.24 Distribution and transfusion of blood and blood components

**DAS.24 Blood and/or blood components are distributed from the blood bank and transfused safely.**

*Safety*

**Keywords:**

Distribution and transfusion of blood and blood components

**Intent:**

Distribution of blood and/or blood components is a big line of defense to prevent tragic mistakes that could cost a patient his/her life.

By following the steps of safe distribution process and using a few good techniques to reduce the risk of error. The ambulatory healthcare center shall develop and implement a policy and procedures for safe distribution of blood and blood components

The policy addresses at least the following:

- a. Blood compatibility testing of all whole blood and red cells transfused.
- b. The cross-matching report form should have patient's first name with surname, age, sex, identification number, ABO and Rh (D) type.
- c. The form should have donor's unit identification number, segment number, ABO and Rh (D) type and expiry date of the blood.
- d. Interpretation of cross matching report and the name of the person performing the test and issuing the blood should be recorded.
- e. Each unit of blood should be visually inspected before distribution. It should not be distributed if there is any evidence of leakage, hemolysis or suspicion of microbial contamination such as unusual turbidity, or change of color.

In addition, the policy shall include special situations such as;

- f. Conditions for reissuance of blood: when blood and/or blood components are returned to blood bank to be reused/reordered.

- g. Urgent requirement of blood.
- h. Actions to be taken when the required blood type is not available.

Errors in transfusion of blood and/or blood components lead to significant risks for patients. Wrong blood administration incidents are mainly due to human error leading to misidentification of the patient and can lead to life-threatening hemolytic transfusion reactions and other significant morbidities.

The ambulatory healthcare center shall develop and implement a policy and procedures for transfusion of blood and/or blood components

The policy addresses at least the following:

- i. Visually checking the bag for integrity.
- ii. Blood transfusion in emergencies
- iii. Conditions when the bag shall be discarded.
- iv. The rate for blood transfusion.
- v. Recording the transfusion.
- vi. Monitoring and reporting any adverse event.
- vii. Special considerations for use of blood components.
- viii. Management of transfusion complications.

**Survey process guide:**

- GAHAR surveyor may review the policy and procedures of safe distribution of blood and blood components.
- GAHAR surveyor may interview responsible staff to check their awareness of the policy.
- GAHAR surveyor may observe the process of blood transfusion.
- GAHAR surveyor may review patients' medical records to check the records of blood transfusion.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy regarding distribution that describes all elements mentioned in the intent from a) through h).
2. The ambulatory healthcare center has an approved policy regarding blood transfusion that describes all elements mentioned in the intent from I) through VIII).
3. Blood bank staff members are aware of the ambulatory healthcare center policy.
4. Cross matching reports show recipient and donor data.
5. Blood or blood component bags are checked before transfusion.
6. Monitoring of patient condition during transfusion is recorded in patient's medical record.

**Related standards:**

ACT.02 Patient identification, DAS.23 Ordering of blood and blood component.

## **Surgery, Anesthesia, and Sedation**

### **Chapter intent:**

Generally, surgery and invasive procedure refer to any procedure involving puncture or incision of the skin or insertion of an instrument or foreign material into the body. This definition includes those procedures that investigate and/or treat diseases.

The scope of this chapter covers any surgical or invasive procedure that require informed consent and performed in any of the following services/places:

1. Operation Rooms (OR).
2. Endoscopy unit.
3. Catheterization laboratory.
4. Emergency rooms.
5. Outpatient rooms.
6. Any other unit in the ambulatory healthcare center either with or without anesthesia or sedation, including local anesthesia.

Surgical and invasive procedures include an approach to the human body that maybe through:

1. Skin or mucous membrane whether through an open cut, percutaneous, percutaneous endoscopic.
2. An orifice as in, opening endoscopic, opening with percutaneous endoscopic assistance.

**Procedural sedation** is defined as the technique of administering sedatives or dissociative agents with or without analgesics to induce an altered state of consciousness that allows the patient to tolerate painful or unpleasant procedures while preserving cardiorespiratory function.

GAHAR surveyors shall survey all areas where surgery, invasive procedures, anesthesia, or sedation are taking place; to ensure patient safety, staff competency, and effective utilization of these areas.

### **Chapter purpose:**

1. To ensure that organizations provide/maintain safe, timeliness, patient-centeredness, and effective surgical, procedural, anesthesia care, and sedation services.
2. To describe processes before, during, and after the surgical or invasive procedure.
3. To define anesthesia leadership, followed by pre-anesthesia, during anesthesia, and post-anesthesia required processes.
4. To describe sedation care including pre-sedation, during sedation, and post-sedation care.

This chapter does not address the use of sedation for the purposes of anxiolysis.



**Implementation guiding documents:**

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

1. Egyptian Constitution
2. Law 51/1981 for healthcare organizations
3. MOHP Ministerial Decree 216 for operation procedures
4. Prime Minister decree, 1063/2014 Management of Emergency cases
5. MOHP Ministerial decree 236/2004 on anaesthesia service requirements
6. MOHP Ministerial Decree 153/2004 on minimum requirements for anaesthesia services
7. MOHP Ministerial decree 244/2001 on competencies of surgeons
8. MOHP Ministerial decree 34/2001 on surgery and anaesthesia services
9. Patient Safety during operation procedure committee recommendations, 2003
10. Egyptian code of medical ethics 238/2003 ( Medical Syndicate Publications)
11. MOHP Ministerial decree 284/1985 on requirements for OR
12. Egyptian code of nursing ethics (Nursing Syndicate Publications)
13. Emergency Department unified protocol, Egyptian ministry of health and population curative and critical sector
14. Requirements of inspection per MOHP law and regulation
15. ICD-10-PCS
16. WHO Surgical Safety checklist

## Safe and effective anesthesia care

### **SAS.01 Anesthesia, sedation services is provided according to applicable laws and regulations and clinical guideline/protocol.**

*Safety*

#### **Keywords:**

Provision of anesthesia, Sedation services.

#### **Intent:**

The provision of anesthesia and sedation is a complex process and problem-prone service; Laws, regulations, and guidelines set governing framework to control these services.

Sedation and anesthesia require complete patient assessment, continued patient monitoring, and identified recovery criteria. The ambulatory healthcare center shall define sedation and anesthesia services required to provide according to its patient population, clinical services offered, and health care practitioners' needs.

Management of anesthesia emergencies and complications is the most critical part of providing anesthesia care. Written protocols for management of complications ensures professional management of these conditions if occurred. To unify the provision of anesthesia services, clinical protocols shall be developed for the approved anesthesia techniques based on approved guidelines.

For the safe provision of anesthesia and sedation, a minimum setup shall be available, which includes equipment, medications, medical supplies, and medical gases.

Anesthesia and sedation services are provided based on the applicable professional practice standards for providing anesthesia and sedation care and meet all applicable national laws and regulations.

#### **Survey process guide:**

- GAHAR surveyor may review clinical guidelines and protocols for anesthesia.
- GAHAR surveyor may interview staff to check their awareness of the standardized techniques for anesthesia.
- GAHAR surveyor may observe the structure of the place, available equipment, medications, and medical supplies followed by observing the process.

#### **Evidence of compliance:**

1. The provision of sedation and anesthesia service meets the applicable professional practice guidelines, national laws and regulations.
2. Sedation and anesthesia services are available to meet patient needs.
3. Anesthesia services are standardized and uniformly implemented throughout the ambulatory healthcare center.
4. Ambulatory healthcare center has an approved protocol for the management of any potential anesthesia emergencies or complications.

**Related standards:**

ICD.02 Clinical practice guidelines, SAS.02 Qualified Anesthesiologist, APC.01 National regulations and licensure requirements.

**SAS.02 Anesthesia and sedation services are provided under the direction of a qualified anesthesiologist.**

*Effectiveness*

**Keywords:**

Qualified Anesthesiologist.

**Intent:**

Safe provision of anesthesia and sedation services requires appointment of experienced and qualified individual(s) (anesthesiologist) to perform and supervise the services provided. The job description shall clearly determine his responsibility that include at least the following:

- a. Determine the resources required including staffing, equipment, medications and medical supplies.
- b. Develop all required policies, procedures, applicable guidelines and protocols
- c. Supervise all activities related to anesthesia and sedation services
- d. Evaluate the outcome of anesthesia and sedation services
- e. Perform anesthesia staff ongoing performance evaluation.

The ambulatory healthcare center shall determine the required qualifications, training, expertise, and experience of anesthesiologist that all are consistent with the applicable laws and regulations.

**Survey process guide:**

- GAHAR surveyor may review the staff file for the anesthesia and sedation leader to check the availability of all requirements in his job description.
- GAHAR surveyor may interview the anesthesia leader to check his awareness of the assigned responsibilities.

**Evidence of compliance:**

1. Clear, specific job description for the anesthesia and sedation leader is available in the leader's staff file, that include items from a) to e) in the intent.
2. Sedation and anesthesia services are under the direction of one or more qualified individuals.
3. The qualified individual (anesthesiologist) fully understands and is aware of his responsibilities mentioned in the job description.

**Related standards:**

SAS.01 Provision of anesthesia, Sedation services, WFM.03 Job Description WFM.04 Verifying credentials, WFM.10 Clinical Privileges, WFM.07 Staff Performance Evaluation

### **SAS.03 A qualified anesthesiologist performs a pre-anesthesia assessment and pre-induction assessment**

*Safety*

#### **Keywords:**

Pre- anesthesia assessment\_ Pre- induction assessment.

#### **Intent:**

Anesthesia services usually start with a pre-anesthesia assessment that performed by a qualified anesthesiologist. Pre-anesthesia assessment determines patient's condition, risk scoring for receiving anesthesia, and required interventions/care before, during, and after receiving anesthesia. The ambulatory healthcare center shall develop a policy for pre-anesthesia and pre-induction assessment that clearly identify when and how those assessments are performed.

The pre-anesthesia assessment shall be completed prior to the surgical procedure or shortly before the surgical procedure.

The pre-induction assessment is separate from the pre-anesthesia assessment, as it determines the physiological stability and readiness of the patient for anesthesia and occurs immediately prior to the induction of anesthesia.

In case of emergency, the pre-anesthesia assessment and pre-induction assessment shall be performed immediately, simultaneously, but are documented independently.

#### **Survey process guide:**

- GAHAR surveyor may review the ambulatory healthcare center policy for pre-anesthesia assessment.
- GAHAR surveyor may observe patient who received anesthesia to evaluate the process of pre-anesthesia assessment.

#### **Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy of pre-anesthesia and pre-induction assessment that clearly identify when and how those assessments are performed.
2. Pre-anesthesia assessment is performed for each patient to evaluate risk scoring for receiving anesthesia.
3. The pre-anesthesia assessment and pre- induction assessment are recorded separately in the patient's medical record.
4. Pre- induction assessment is performed for each patient immediately before induction of anesthesia.
5. Relevant staff is educated and fully aware of how to apply the policy.

#### **Related standards:**

PCC.05 Informed consent, SAS.04 Anesthesia plan, IMT.05 Patient's medical record management, WFM.03 Job Description, WFM.04 Verifying credentials.

**SAS.04 The ambulatory healthcare center ensures performing anesthesia plan for each patients.**

*Effectiveness*

**Keywords:**

Anesthesia plan.

**Intent:**

Anesthesia care shall be planned and documented in the medical record. The plan includes at least the following:

- a. Information from the complete patient assessments and identifies the appropriate anesthesia to be used,
- b. The method of administration,
- c. Other medications and fluids needed,
- d. Monitoring procedures,
- e. Anticipated post anesthesia outcome.
- f. The anesthesia agent, and anesthetic technique
- g. Signature and full name of the participating anesthesia team shall be documented in the medical file.

**Survey process guide:**

- GAHAR surveyor may review samples of patients' medical records to check for anesthesia care plan' complete documentation.
- GAHAR surveyor may interview the relevant staff to check their awareness of the anesthesia care plan.

**Evidence of compliance:**

1. Each patient' anesthesia care plan is performed and documented in the patient's medical record.
2. The anesthesia care plan includes all items from a) to g) in the intent.
3. The anesthesiologist, anesthesia assistants and all participated team are identified in the patient's medical record.

**Related standards:**

PCC.05 Informed consent, SAS.03 Pre- anesthesia assessment, pre-induction assessment, IMT.05 Patient's medical record management

## **SAS.05 A qualified anesthesiologist performs continuous monitoring of the patient's physiological status during anesthesia.**

*Safety*

### **Keywords:**

Continuous monitoring during anesthesia.

### **Intent:**

Administering anesthesia and performing surgeries and invasive procedures are associated with changes in the patient physiologic status that could be very rapid. Accordingly, the patient physiologic status is required to be continuously monitored starting before receiving the anesthesia to determine the baseline of patient condition, which is used in determining the patient criteria of discharge from the post-anesthesia care unit. Continuous monitoring allows the anesthesiologist for on-time intervention for any changes in the patient's condition. The type and frequency of anesthesia monitoring is determined according to, at least the following:

- a. Patient's condition and age,
- b. Pre-anesthesia assessment
- c. Anesthesia plan
- d. Type of anesthesia,
- e. Type and duration of surgery or invasive procedure performed
- f. The applicable, approved clinical practice guidelines.

### **Survey process guide:**

- GAHAR surveyor may observe a patient while receiving the anesthesia service to evaluate the process of patient monitoring and the staff involved in this process.
- GAHAR surveyor may review samples of patients' medical records to check for anesthesia monitoring documentation.

### **Evidence of compliance:**

1. The frequency and type of monitoring during anesthesia and surgery is determined according to item a) through item f) from the intent.
2. Monitoring of the patient's physiological status is consistent with the ambulatory healthcare center clinical practice guidelines.
3. The results of monitoring are documented in the patient's medical record.
4. A qualified anesthesiologist performs the anesthesia monitoring.

### **Related standards:**

SAS.02 Qualified Anesthesiologist, SAS.03 Pre- anesthesia assessment\_ Pre- induction assessment.

SAS.04 Anesthesia plan, IMT.05 Patient's medical record management, EFS.10 Critical alarms.

## **SAS.06 Post anesthesia care, monitoring, and discharge is done by competent individual.**

*Safety*

### **Keywords:**

Post- anesthesia care.

### **Intent:**

Post-anesthesia care includes monitoring of the patient physiologic status that allows anesthesiologist to do an on-time intervention for any changes in patient's condition and determine patient's criteria of discharge from the post-anesthesia care unit.

Administration of any medications, IV fluids, blood, or blood products ordered and administered should be recorded in the patient's medical record.

The ambulatory healthcare center is required to record any special or unusual events occurred inside the post-anesthesia care unit with the management provided, the time of receiving the patient, and the time of transfer from post-anesthesia unit. If the patient is transferred directly from the operating theatre to a receiving unit, monitoring and documentation are the same as would be required in the recovery room. The ambulatory healthcare center shall develop and implement policy of post anesthesia care and monitoring that describe the process of post-anesthesia care, assign responsibility and describe the documentation requirements.

The patient is discharged, by a fully qualified anesthesiologist or other individual authorized by the individual(s) responsible for managing the anesthesia services. A qualified individual records at least the following:

- a. The patient's physiologic status
- b. Time of receiving the patient
- c. Used type of anesthesia.
- d. Administered medications with dose, route, and time of administration.
- e. Fluid management includes intake and output.
- f. Administered blood or blood products.
- g. The occurrence of any unusual event.
- h. The patient condition before leaving according to defined criteria
- i. Patient disposition
- j. Time of transfer from the post-anesthesia care unit
- k. Signature of the physician who order patient discharge or disposition.

### **Survey process guide:**

- GAHAR surveyor may review the post- anesthesia care and monitoring policy.
- GAHAR surveyor may observe the process of post-anesthesia care and monitoring process
- GAHAR surveyor may review a sample of patients' medical records to check for post-anesthesia care plan documentation
- GAHAR surveyor may interview the relevant staff to check their awareness of the policy and process.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy of post anesthesia care and monitoring that clearly describe the process of post-anesthesia care, assign responsibility and describe the documentation requirements.
2. Post-anesthesia care plan documented in the patient's medical record including items from a) to k) in the intent.
3. The time of patient arrival at and discharge from the recovery area are documented in the patient's medical record.
4. The ambulatory healthcare center has a clear process of monitoring, when the patient is transferred directly from the operating theatre to a receiving unit.

**Related standards:**

SAS.03 Pre- anesthesia assessment\_ Pre- induction assessment.

SAS.04 Anesthesia plan, IMT.05 Patient's medical record management

**Safe and patient-centered sedation services**

**SAS.07 Sedation administration is standardized throughout the ambulatory healthcare center, monitoring and management of complications is guided by evidence based guidelines.**

*Effectiveness*

**Keywords:**

Sedation administration and monitoring\_ Sedation complications.

**Intent:**

Procedural sedation, which includes moderate and deep sedation, involves any sedation administered intravenously for a procedure. Procedural sedation may also include the use of oral medications (for example, the use of chloral hydrate in children). To ensure uniformity of sedation services, sedation techniques shall be based on approved guidelines. Sedation techniques are provided according to the scope of service of the ambulatory healthcare center and type of surgeries and invasive procedures.

All individuals privileged to perform sedation are trained to include at least the following items:

- a. Proper use and administration of sedation techniques and methods.
- b. Management of complications that could occur by providing sedation and the process followed, if any.
- c. Monitoring requirements

Procedural sedation is provided by a qualified individual trained in advanced life support (appropriate for the age of patient) and use of emergency medical equipment and supplies. Uninterrupted monitoring of the patient's physiological parameters and assistance in supportive or resuscitation measures shall be documented in patients' medical records. Patients continue to require monitoring until they have reached near their baseline level of



consciousness and hemodynamic parameters. Identified criteria help identify patients who are recovered and/or ready for discharge. All required training records shall be documented in the staff personnel file.

**Survey process guide:**

- GAHAR surveyor may review the standardized sedation records, relevant staff file for the required training records.
- GAHAR surveyor may review the list of individuals privileged to perform sedation.
- GAHAR surveyor may observe process of discharging sedated patients after surgery or invasive procedures.

**Evidence of compliance:**

1. The administration of procedural sedation is standardized throughout the ambulatory care center.
2. Procedural sedation is performed by a qualified individual with advanced life support training (appropriate for the age of the patient).
3. All individuals privileged to perform sedation are trained for items from a) to c) in the intent.
4. The ambulatory healthcare center has a defined process for the management of sedation complications. (If any).
5. The equipment, medications, and medical supplies needed during the sedation are readily available in the ambulatory healthcare center.
6. Established criteria are identified and documented for the recovery and discharge from procedural sedation.

**Related standards:**

ICD.02 Clinical practice guidelines, ICD.13 Cardiopulmonary resuscitation and medical emergencies, SAS.08 Pre- sedation assessment, WFM.10 Clinical Privileges, EFS.09 Medical Equipment management plan.

**SAS.08 The pre-sedation assessment is performed by a qualified individual.**

*Safety*

**Keywords:**

Pre- sedation assessment.

**Intent:**

Sedation services start with performing a pre-sedation assessment. The pre- sedation assessment determines patient's condition, risk scoring for receiving sedation, and required interventions/care before, during, and after receiving sedation.

Sedation services shall be performed by a qualified individual who is trained on providing sedation service and have advanced competency in resuscitative services.

The ambulatory healthcare center is required to perform pre- sedation assessment for

all patients before transfer to perform the surgeries or procedures. The outcome of the assessment includes the risk scoring of receiving sedation and the sedation plan.

A pre-sedation assessment of the patient shall be done to

- a. Identify any airway problems.
- b. Evaluate at-risk patients
- c. Plan the type of sedation and the level of sedation the patient will need based on the procedure being performed;
- d. Safely administer sedation;
- e. Interpret findings from patient monitoring during procedural sedation and recovery.

**Survey process guide:**

GAHAR surveyor may observe the process of pre-sedation assessment

GAHAR surveyor may review sample of patients' medical records to check for pre-sedation assessment, sedation care plan' documentation.

**Evidence of compliance:**

1. There is a pre-sedation assessment performed and documented that includes at least a) through e) in the intent.
2. Pre-sedation assessment is performed and documented by a qualified individual.
3. Sedation care plan is performed safely based on the outcome of pre-sedation assessment.
4. A copy of sedation records is kept in the patient's medical record.

**Related standards:**

SAS.07 Sedation administration and monitoring\_ Sedation complications., SAS.09 Post sedation care unit, IMT.05 Patient's medical record management.

**SAS.09 The post- sedation care› unit is safely designed and appropriately equipped to meet patients' needs.**

*Effectiveness*

**Keywords:**

Post- sedation care unit.

**Intent:**

Sedation risks may occur even during post-sedation period, so, patient should be regularly monitored. The ambulatory healthcare center shall be requested to ensure the availability of the emergency and resuscitative equipment while the patient is present.

A trained, competent healthcare provider is responsible of the post-sedation care monitoring. Accordingly, there shall be a post-sedation care unit equipped by at least a monitoring equipment, crash cart with a defibrillator, source of oxygen supply, recommended medications, and medical supplies, and all other equipment as required by national laws and regulations.

**Survey process guide:**

- GAHAR surveyor may observe the units where sedation is permitted in the ambulatory healthcare center, the equipment and other resources available in the unit.
- GAHAR surveyor may interview relevant staff to check their awareness of the post-sedation care plan and monitoring.

**Evidence of compliance:**

1. The post-sedation care unit is equipped with the required resources and equipment.
2. A competent, trained healthcare provider is responsible of the post-sedation care.
3. Staff involved in post- sedation care and plan is aware of how to perform the post-sedation monitoring.

**Related standards:**

SAS.08 Pre- sedation assessment, EFS.09 Medical Equipment Plan, WFM.07 Staff Performance Evaluation, WFM.06 Continuous Education Program,

**Safe and effective surgical and invasive procedures care**

**SAS.10 The ambulatory healthcare center ensures that provision of surgeries and invasive procedures is effective, safe and appropriate to patient's needs.**

*Safety*

**Keywords:**

Provision of surgeries and invasive procedures.

**Intent:**

The ambulatory healthcare center is required to provide the surgery and invasive procedure services all over the ambulatory healthcare center safely by providing the required resources as obliged by the national laws and regulations. All units providing surgery and invasive procedure services have appropriate spacing, ventilation, infrastructure including medical gases, appropriate equipment, medical supplies, and medication.

Applying the process of booking in the ambulatory healthcare center decreases the waiting time for surgeries and invasive procedures and allowing the ambulatory healthcare center to plan efficiently in providing the surgery and invasive procedure services.

The ambulatory healthcare center shall develop and implement a policy and procedures for surgery and invasive procedures safe provision that addresses at least the following:

- a. Scheduling process for surgeries and invasive procedures.
- b. Granting clinical privileges to staff to perform those types of surgeries and invasive procedures.
- c. Recording of surgeries and invasive procedures, whether they are scheduled, performed, or canceled.
- d. Patients' identification verification methods.
- e. A clear and safe mechanism to call patients for surgeries or invasive procedures.

- f. The recorded timing of all patient flow steps inside the unit and the analysis of this punctuality.
- g. Analysis of the postponed and canceled surgeries and invasive procedures to support the ambulatory healthcare center with reliable data for better management.
- h. Process to verify availability of all required resources.

**Survey process guide:**

- GAHAR surveyor may review the policy for surgery and invasive procedures safe provision
- GAHAR surveyor may review qualifications and privilege of staff who permitted to perform surgeries and invasive procedures.
- GAHAR surveyors may review evidence of postponed and canceled procedures analysis.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy to guide the surgery and invasive procedures safe provision that addresses all elements mentioned in the intent from a) through h).
2. Analysis of postponed and canceled procedures is continuously monitored, reported and acted upon.
3. Punctuality of the procedural unit is maintained and recorded starting by patient call until room cleaning after the procedure.
4. Staff who permitted to perform surgery and invasive procedure services are qualified and privileged in the ambulatory healthcare center to perform those types of surgeries and invasive procedures.

**Related standards:**

ICD.02 Clinical practice guidelines, SAS.11 Assessment before surgery and invasive procedures, WFM.10 Clinical Privileges, QPI.04 incident reporting system, SAS.12 pre-operative verification process

**SAS.11 Patient assessment is performed by the responsible physician before surgery or invasive procedure.**

*Safety*

**Keywords:**

Assessment before surgery and invasive procedures

**Intent:**

Complete patient assessment before surgery with requesting the needed investigations either for ensuring the diagnosis, revealing risk factors, assessing patient medical condition, or determining baseline patient condition followed by proper management of all identified diagnoses and risk factors. This assessment shall be done by the responsible physician, (preferred the patient's surgeon).

Accordingly, assessment of the patient's condition is needed for all surgeries to determine

the precautions needed and informing the patient and family about the expected outcome of the surgery.

Patient assessment should be reviewed and repeated if a surgery/invasive procedure is postponed or canceled to maintain the validity of the patient assessment. The pre- surgical assessment and care plan for each patient is documented in the patient's medical record, including a preoperative diagnosis.

The ambulatory healthcare center is required to perform a complete patient assessment before any elective surgery supported by the results of required investigations. The ambulatory healthcare center is required to document the patient assessment in the patient's medical record for the medico legal issues and for proper communication between staff followed by developing the patient's plan of surgical care that includes at least the following:

- a. Patient needs and condition.
- b. Pre-operative diagnosis.
- c. Plan for surgery (and invasive procedure).

**Survey process guide:**

GAHAR surveyor may review sample of patients' medical records to check for documentation of Pre-surgical assessment, Pre-operative diagnosis, Plan for surgery and actions taken for the management of any risk factors.

**Evidence of compliance:**

1. A complete pre- surgical assessment is performed and documented for all patients planned for surgery or invasive procedure, with documentation of any identified risks for the patient's conditions.
2. Pre-operative diagnosis and actions taken for the management of any risk factors are documented in the patient medical record before surgery or invasive procedure.
3. Patient's plan of surgical care is performed and timely documented in the medical record.
4. In life-threatening emergencies, a brief assessment and surgical care planning is performed and timely documented in the patient's medical record.

**Related standards:**

PCC.05 Informed consent, SAS.10 Provision of surgeries and invasive procedures, SAS.12 Pre-Operative verification process, ICD.05 Patient assessment process.

**SAS.12    NSR.10 The ambulatory healthcare center has a pre-operative verification process to ensure patient safety, availability and appropriateness of care before calling for the patient for surgery.**

*Safety*

**Keywords:**

Pre-operative verification process.

**Intent:**

Ensuring the availability of all needed items as blood booking, results of the requested investigation or special prosthesis should be done as a pre-operative verification process to ensure patient safety and appropriateness of care.

Ensuring the availability and functioning of needed equipment minimizes the risk of errors by preventing the use of malfunctioning equipment or cancellation of surgery and invasive procedure after the patient went to the operating rooms or invasive procedure unit.

The ambulatory healthcare center is required to ensure the availability and functioning of equipment needed for the surgery and invasive procedure before calling for the patient. This equipment and tools could be differed according to the type of surgery and invasive procedure or the use of anesthesia and sedation.

In addition, the ambulatory healthcare center is required to develop a process for pre-operative verification of the availability of all needed or requested documents and other items before the patient going for the surgery or invasive procedure.

**Survey process guide:**

- GAHAR surveyor may review the policy of pre-operative verification and check the availability of all needed documents and equipment.
- GAHAR surveyor may interview responsible staff to check their awareness of the pre-operative verification process.

**Evidence of compliance:**

1. The ambulatory healthcare center has a defined process for pre-operative verification including all needed documents and equipment.
2. Pre-operative verification of all needed documents and equipment is documented before each surgery and invasive procedure.
3. Responsible staff is aware of the pre-operative verification process.

**Related standards:**

ACT.02 Patient identification, SAS.11 Assessment before surgery and invasive procedures  
SAS.13 Time-out, SAS.14 Site marking and identification.

**SAS.13 NSR.11 Time-out is performed pre-operatively, just before starting a surgical or invasive procedure.**

*Safety*

**Keywords:**

Time-out.

**Intent:**

Time out aims for verification of the correct patient, correct procedure, and correct site and side of surgery or invasive procedure. Time- out is a single process that has been proved to reduce wrong-site surgery. The time-out shall conducted in the location at which the procedure will be done and involves the active participation of the entire team. Patient participation is not obligatory. Completion of the time-out is documented and includes the date and time that the time-out was completed. The ambulatory healthcare center shall develop and implement a policy of time- out that describe the process.

If surgery is performed in settings other than the operating theatre, the ambulatory healthcare center shall implement a uniform processes (as in operating theatre) to ensure the correct site, correct procedure, and correct patient.

**Survey process guide:**

- GAHAR surveyor may review the policy for time –out and interview the relevant staff to check their awareness of the policy.
- GAHAR surveyor may review the document used to record time-out process
- GAHAR surveyor may observe the time-out process.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy for time-out to ensure the correct patient, procedure, site and side.
2. When surgery or invasive procedure is performed outside the operating theatre, Time-out process implemented.
3. Time- out is implemented immediately before the start of surgery or invasive procedure.
4. The surgery or invasive procedure team is involved in the time out process
5. Relevant staff is fully aware and trained for time-out process.

**Related standards:**

ACT.02 Patient identification, SAS.12 Pre-Operative verification process SAS.14 Site marking and identification.

**SAS.14 The ambulatory healthcare center uses an easily noticeable mark for surgical/invasive procedure site identification that is consistent throughout the center.**

*Safety*

**Keywords:**

Site marking and identification.

**Intent:**

Visible and clear site marking is an error reduction strategy that should be performed by the responsible physician who will perform the surgery and invasive procedure (patient's surgeon) with the involvement of the patient if the patient is an adult and fully conscious or patient's family in other situations. The site marking in each organization should be unified, detectable, and placed on the nearest site to the surgical site.

When performing a surgery or invasive procedure, healthcare professionals should verify the right patient, the right type of surgery, right site, right side. The site is marked in all cases including laterality, multiple structures (fingers, toes). Alternative methods for dental site marking include using images of the patient's teeth or paper diagrams of teeth to mark the site.

**Survey process guide:**

- GAHAR surveyor may interview staff to check their awareness of the site marking procedure

**Evidence of compliance:**

1. Surgical/invasive procedure site marking is done by the person performing the procedure.
2. The patient is actively involved in the site marking process with exception in some circumstances.
3. The mark is visible after the patient is prepped, draped, prepared for surgery or procedure.

**Related standards:**

SAS.12 Pre-Operative verification process, SAS.13 Time-out

**SAS.15 Details and information about surgery or procedures are recorded in the operative report immediately after the procedure.**

*Safety*

**Keywords:**

Operative report.

**Intent:**

Immediate reporting of the procedure has a significant role in the continuity of care. Planning for postoperative care depends on findings and special events that occurred during the procedure, as failure to report these events markedly compromises patient care.

The ambulatory healthcare center is requested to immediately report the procedure details



before the patient leaving the procedural unit.

Recording the names of all staff involved in the procedure has a medico legal aspect and communication aspect and any similarity or discrepancy in the patient diagnoses before and after the procedure should be documented and clarified. Details of the procedure should be clearly stated, including the incision site, if applicable, step by step of the surgical technique, and ended by how the skin closure or ending the procedure is done. Use of any prosthesis or implantable devices should be stated in the report, including any special precautions when dealing with or to remove it.

Occurrence of complications during the procedure should be recorded with the action taken to manage. Any specimen removed from the body should also be stated clearly in the procedure report. That addresses at least the following:

- a. Time of start and time of the end of the procedure.
- b. Name of all staff involved in the procedure, including anesthesia.
- c. Pre-procedure and post-procedure diagnoses.
- d. The procedure performed with details.
- e. The details of any used implantable device or prosthesis including the batch number
- f. The occurrence of complications or not.
- g. Any removed specimen or not.
- h. Signature of the performing physician.

**Survey process guide:**

- GAHAR surveyor may review sample of patients' medical records to check the completeness of all components needed in the operative/procedure report.

**Evidence of compliance:**

1. The operative/procedure report is readily available for all patients who underwent a procedure before leaving the procedural unit.
2. The operative/procedure report includes at least items from a) through h) in the intent.
3. The report is kept in the patient's medical record.

**Related standards:**

SAS.11 Assessment before surgery and invasive procedures, IMT.05 Patient's medical record management

**SAS.16 NSR.12 Accurate counting of sponges, needles, and instruments pre and post-procedure is verified.**

*Safety*

**Keywords:**

Pre and post procedure count verification process.

**Intent:**

Missing sponges, needles, towels, or instruments inside the patient body act as a foreign body and causes serious morbidity in the form of pain, organ injury and sepsis, which necessitate re-opening the patient and could reach up to mortality.

The ambulatory healthcare center is required to spend every effort by the surgical team to prevent missing any foreign body during surgery/invasive procedure by meticulous counting of any used item before, during the closure of each body space, and after the closure of the skin.

**Survey process guide:**

- GAHAR surveyor may review the record for the preoperative, intraoperative and postoperative count of sponges, needles, towels, or instruments.
- GAHAR surveyor may interview relevant staff to check their awareness of the process.

**Evidence of compliance:**

1. Counting of sponges, needles, towels, or instruments is done pre, intra and post-operative by two independent staff.
2. There is a record for the preoperative, intraoperative and postoperative count of sponges, needles, towels, or instruments.
3. The performing physician confirmed the process and signed the count sheet.

**Related standards:**

SAS.12 Pre-Operative verification process

**SAS.17 Surgically removed tissue is sent to the ambulatory healthcare center laboratory services for pathological examination unless present in the list of exempted tissues from the pathological examination.**

*Effectiveness*

**Keywords:**

Pathological examination of surgically removed tissue.

**Intent:**

Surgically removed tissue from the human body shall be sent for pathological, histopathological, or immune histochemical examination for continuity of care as it is essential to confirm or prove a diagnosis. Operative care also may depend on findings in the examination of the frozen section. For some surgically removed tissues, there is no need to have a pathological examination of these tissues.

The ambulatory healthcare center has to identify those tissues clearly to be exempted from pathological examination in routine cases unless requested by the physician.

The ambulatory healthcare center is required to design a pathway for tissues removed from the human body to the laboratory to obtain a sample for examination, then sent to the appropriate disposition according to the type of tissue.

**Survey process guide:**

- GAHAR surveyor may trace the pathway of a surgically removed body part until its disposition. This tracing includes staff interviews and document review in the operating room and laboratory.
- GAHAR surveyor may review sample of medical record to check the availability of pathology results with the time -frame of the results.

**Evidence of compliance:**

1. There is a clear process and pathway of any surgically removed tissue.
2. There is a list of exempted tissue from pathological examination.
3. Surgically removed tissues are sent for pathological examination, and the results of the examination are available in the patient's medical record within the defined time- frame.

**Related standards:**

ACT.02 Patient identification, DAS.12 Specimen reception, tracking and storage.

**SAS.18 The ambulatory healthcare center requires special considerations for surgeries involving implantable devices or lenses.**

*Safety*

**Keywords:**

Implantable Devices

**Intent:**

The implantable device is a medical device that is permanently placed into the body to continuously assist, restore, or replace a function or structure of the body throughout the useful life of the device.

Examples include intra-ocular lens, Intra-uterine devices, dental implants and infusion pumps.

There are many considerations while using implantable devices, which include the special instructions for use, sterility, manufactural consideration, and malfunction.

The ambulatory healthcare center is required to track the implantable device from its primary source to discover any unstable, contaminated, defective, or imitation product.

Every patient who has an implantable device should be easily identified, easily reachable within a defined time- frame to be ready for any device recall.

**Survey process guide:**

- GAHAR surveyor may review the list of implantable devices and may inquire about the process for the retrospective tracing of any implantable device.
- GAHAR surveyor may review a process for the recall of a patient who has an implantable device in a defined time- frame after receiving the notification of a recall.

**Evidence of compliance:**

1. There is a list of implantable devices used in the ambulatory healthcare center.
2. There is a process for the retrospective tracing of any implantable device.
3. There is a process for the recall of a patient who has an implantable device in a defined time- frame after receiving the notification of a recall.

**Related standards:**

ACT.02 Patient identification, SAS.11 Assessment before surgery and invasive procedures, SAS.12 Preoperative verification process, SAS.12 Time-out.

**SAS.19 Post-operative care plan is performed and recorded before transfer of patient to the next level of care.**

*Effectiveness*

**Keywords:**

Post-operative plan of care.

**Intent:**

Post-operative care is a main factor in determining procedure outcome. Creating the postoperative care plan should start immediately after the procedure and before the patient leaving the procedural room to prevent any delay, wrong, unnecessary, or missing care.

Postoperative plan of care is developed by the physician who performed the procedure and the anesthesiologist (when applicable) and includes

- a. Recent level of care,
- b. Patient position,
- c. Patient activity,
- d. Required further monitoring,
- e. Diet,
- f. Medications, intravenous fluids,
- g. Required investigations
- h. Follow up instructions.

**Survey process guide:**

GAHAR surveyor may review sample of medical records to check for the postoperative plan of care followed by observing the implementation of the physician orders related to the postoperative plan of care

**Evidence of compliance:**

1. There is a postoperative care plan for all patients performing the surgery/procedure that includes items from a) to h) in the intent.
2. The postoperative care plan is documented in the medical record before patient leaving the procedure room.
3. Postoperative plan of care is performed by the physician who performed the procedure and the anesthesiologist (when applicable)

**Related standards:**

SAS.11 Assessment before surgery and invasive procedures, SAS.15 Operative Report, IMT.05 Patient's medical record management, ICD.08 Plan of Care.

## Medication Management and Safety

### Chapter intent

Getting the most from medications for both patients and society is becoming increasingly important as more people are taking more medications. Medications are offered by health services throughout the world. Medications prevent, treat, or manage many illnesses or conditions and are the most common interventions in healthcare.

Medication is defined as any prescription medications including narcotics; herbal remedies; vitamins; nutraceuticals, over-the-counter medications; vaccines; biological, diagnostic and contrast agent used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications; respiratory therapy treatments; parenteral nutrition; blood products; medication containing products, and intravenous solutions with electrolytes and/or medications. The definition of medication does not include enteral nutrition solutions (which are considered food products), oxygen, and other medical gases unless explicitly stated.

Medication management is one of the major responsibilities in any healthcare organization. It is a complex process that involves different phases, including planning, procurement, storage, prescribing, transcribing, ordering, dispensing, administration, monitoring of the medications, and evaluation of the program. Evidence suggests that, at each phase of the cycle, errors do occur adversely influencing patients' safety, which is a priority in today's practice. However, with substantial and increasing medication use comes a growing risk of harm. This is compounded by the need to prescribe for a special population, including pediatrics, pregnancy, and the aging population with increasingly complex medical needs and the introduction of many new medications. These issues are particularly relevant in ambulatory healthcare centers.

Additionally, medication errors are one of the most commonly occurring errors in healthcare organizations, and they can occur in any step along the pathway of medication management. It is further stated that morbidity from medication errors results in high financial costs for healthcare institutions and adversely affects the patient's quality of life. Preventing medication errors is a major priority in the health system, and many international organizations such as the World Health Organization (WHO) have launched medication safety as part of its global patient safety initiatives.

### Chapter purpose

1. To highlight the principle for medication management and use in ambulatory healthcare centers promoting safe, quality use of medications, and medication management.
2. To provide a framework for an effective and safe medication management and use program.

3. To evaluate the continuity of medication management processes from planning to monitoring and evaluation with a special focus on the identification of risk points to improve patients' outcomes and safety.
4. To advocate a partnership and systems approach to achieve safe and quality use of medications and medication management in ambulatory healthcare centers.

### **Implementation guiding documents:**

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

1. The decision of the Minister of Health and Population number 496- the year 2012
2. The decision of the Minister of Health and Population number 368- the year 2012 for developing a pharmacovigilance center
3. The decision of the Minister of Health and Population number 475- the year 2019
4. Institute for Safe Medication Practices. ISMP Medication Safety Tools and Resources. Accessed Dec 6, 2017. <https://www.ismp.org/tools/>.
5. Law No. 127/1955 on practicing the profession of pharmacy.
6. Law No. 182/1960 on narcotics
7. Law No. 151/2019 on establishment of Egyptian Drug Authority
8. Prime Minister's Decree 777/2020 about the EDA executive bylaws.
9. Rational Drug Use Publication No: 4, year 2017 of Antimicrobial Stewardship
10. Rational Drug Use Publication No: 1, year 2019 of The Egyptian Crash cart and emergency drug list
11. The Egyptian Guidelines of Medication Management Standards first edition (2018)
12. The Egyptian Drug Authority Decree No. 271, year 2021 on the regulation of Drug storage requirements for pharmaceutical institutions.
13. The Egyptian Drug Authority Decree No. 340, year 2021 on the re-regulation of handling of the pharmaceutical substances and products affecting the mental state
14. The Minister of Finance Decree No. 89, year 1998 on the regulation of tenders and auctions law promulgated, and its implementing regulations.
15. The Minister of Health and Population decree number 104, year 2003 on the regulation of expiry drugs.
16. The Minister of Finance Decree No. 182, year 2018 on the regulation of tenders and auctions law promulgated, and its implementing regulations
17. The Minister of Health and Population Decree No. 380, year 2009 on the re-regulation of the health requirements for pharmaceutical institutions.
18. The Minister of Health and Population Decree Number 172, year 2011 on the re-regulation of handling of the pharmaceutical substances and products affecting the mental state.
19. The Minister of Health and Population Decree No. 475, year 2019 on the re-regulation of handling of the pharmaceutical substances and products affecting the mental state.

## Medication Use, Selection, and Procurement

### **MMS.01 Medications available for use are managed, selected, listed, and procured based on approved criteria.**

*Effectiveness*

#### **Keywords:**

Medication management.

#### **Intent:**

Medication management remains a primary concern in any healthcare setting, and is often an important component in the palliative, symptomatic, and curative treatment of many diseases and conditions. The unsafe use of medication is not the only safety problem in any healthcare system, but it is certainly one of the most significant issue. Ensuring a safer medication management program at an organizational level, is a major challenge.

All medication management processes (Selections, procurement, prescribing, preparation, administration and monitoring) in ambulatory healthcare centers are conducted and implemented according to the Egyptian laws and regulations (The Egyptian Drug Authority (EDA), and the Egyptian Ministry of Health (MOH)). Ambulatory healthcare center is equipped with updated and appropriate medication-related information source(s) electronic or paper based formats to staff members involved in medication use.

The ambulatory care center shall develop an inventory medication list of all the medications it stocks. The medications shall be selected from the EDA and other national authorizing bodies legally approved medications based on community needs. The list shall include (but not limited to):

- a. Name(s) of medication(s)
- b. Strength(s)/concentration(s) of medication(s)
- c. Dosage form(s) of the medication(s)
- d. Indication
- e. Expiration date

The procurement and distribution system covers the processes: to select the most cost-effective essential medications to treat commonly encountered diseases; to quantify the needs; to pre-select potential suppliers; to manage procurement and delivery; to ensure good product quality; and to monitor and evaluate the performance of suppliers and the procurement system.

The process for evaluating new suppliers can include checking the licensure, providing formal visit(s), reference checks with past clients and agencies, test purchases in small quantities and informal local information gathering.

The ambulatory healthcare center shall have a process to investigate if the medications are contaminated, defective, or counterfeit and to trace them back to determine the cause of the problem, and to notify the manufacturer and/or distributor when something discovered



while checking the supply on receiving step. In addition, the ambulatory care center shall define a procedure to inform healthcare providers and physicians about non-available medications and products and respective substitutes.

Due to repeated antimicrobial prescription for dubious indications and for longer than necessary, antimicrobial resistance is acquired, which can have a negative impact on the patient's outcomes and poses a major threat to patient safety.

Implementation of antimicrobial stewardship activities will reduce the development and spread of resistant bacteria and deliver better patient outcomes.

In October 2017, the Egyptian Drug Authority (EDA), Ministry of Health, Egypt, mandated in response to the global initiatives, the rational use of antibiotics, and the implementation of the antimicrobial stewardship program. In 2018, the national action plan for combating antimicrobial resistance was approved by the Egyptian Ministry of Health. One of the main pillars of this action plan is the implementation of the national antimicrobial stewardship program.

Antimicrobial stewardship is the effort to promote the optimal use of antimicrobial agents, reducing the transmission of infections and educate healthcare professionals, patients and the public. The primary goal of antimicrobial stewardship is to optimize outcomes while minimizing the unintended consequences.

The ambulatory healthcare center is expected to effectively implement at least one antimicrobial stewardship activity that meets a need within the centers, using a stepwise implementation approach that helps to familiarize staff with the new policies and procedures. Interventions may include the development and implementation of clinical guidelines based on either local, national, or international data (management of urinary tract infections, respiratory tract infection, and prophylactic use of antibiotics in surgery). Interventions may also include the restriction of the use of certain antimicrobial agents based on the spectrum of activity, or cost, the development of clinical criteria and guidelines for switching from parenteral to oral agents, and detection and prevention of antibiotic-related drug-drug interactions. The decision to select which intervention should be based on staffing, patient population, as well as the clinical resources.

Evaluating the effectiveness of the selected activities is important to assess, monitor and improve the stewardship interventions; examples include using measures such as inappropriate use of antimicrobials, adherence to antibiotic prescribing policies and antibiotic use, antimicrobial consumption, and cost.

### **Survey process guide**

- GAHAR surveyors may review the medication management program and the credential(s) and job description(s) of the healthcare professional(s) responsible for the program.
- GAHAR surveyors may review the updated list of medications available in the center.
- GAHAR surveyors may interview staff about the accessibility to the drug information

source(s).

- GAHAR surveyor may review evidence of the antimicrobial stewardship activities implementation and evaluation.

**Evidence of Compliance:**

1. The ambulatory healthcare center has an updating program that clearly describes the medication use and management which is under the direct supervision of qualified healthcare professional(s).
2. Updated and appropriate medication-related information sources are available in written and/or electronic formats to those involved in medication use.
3. The ambulatory healthcare center has an approved policy and procedures addressing the criteria of appropriate selection and procurement of medications in accordance to the organization's mission, patient needs and safety.
4. The ambulatory healthcare center has an approved and updated list of the medications, which covers at least items from a) to e) in the intent.
5. The ambulatory healthcare center implements and evaluates at least one antimicrobial stewardship activity in place using organization-approved interdisciplinary protocols and acts accordingly.

**Related standards:**

MMS.02 Medication storage and labelling, IPC.17 Multi-Drug Resistant Organisms, WFM.07 Staff Performance Evaluation, OGM.07 Supply Chain Management.

**MMS.02 NSR.08 Medications are safely and securely stored in a manner to maintain its quality.**

Safety

**Keywords:**

Medication storage and labelling.

**Intent:**

Well-designed and appropriate storage of medications can reduce waste, and incorrect medication dispensing, and handling. The ambulatory healthcare center maintains proper medications storage conditions (temperature, light, and humidity) in medication storage areas to protect their stability 24 hours a day, and 7 days a week according to the manufacturer/marketing authorization requirements. The stability and effectiveness of the medications depend on storing them at the correct temperature, for example, those medications requiring refrigeration and multi-dose containers.

There should be clear evidence that ambulatory healthcare center ensures the storage of medications in a manner to maintain its quality and integrity. Also, the ambulatory healthcare center limits access to medication storage areas with the level of security required to protect it against loss or theft depending on the types of medications stored like the storage

requirements for narcotics and psychotropic medications.

When patient emergencies occur, quick access to appropriate emergency medications is critical and may be lifesaving. The ambulatory healthcare center shall develop a policy and procedures that ensure the availability and the location of emergency medications and the medications to be supplied in these locations. For example, agents to reverse anesthesia are found in the operating theatres.

Medications or other solutions in unlabeled containers are unidentifiable. Errors, sometimes tragic, have resulted from medications and other solutions removed from their original containers and placed into unlabeled containers. This unsafe practice neglects the basic principles of safe medication management. The ambulatory healthcare center shall ensure that the labeling of all medications, medication containers, and other solutions is a risk-reduction activity consistent with safe medication management. This practice addresses a recognized risk point in the administration of medications. The following data are clearly shown on the labels (If not apparent on the original packages or boxes):

- a. The name,
- b. concentration/strength,
- c. expiration date,
- d. batch number, and
- e. any applicable warnings

#### **Survey process guide**

- GAHAR surveyor may review policy of handling emergency medications.
- GAHAR surveyor may observe that all medications are stored as manufacturer/marketing authorization requirements and all are clearly labeled
- GAHAR surveyor may observe narcotic and psychotropic medications' storage conditions and their security.
- GAHAR surveyor may interview the staff to check their awareness of the action(s) taken when there is an electric outage

#### **Evidence of Compliance:**

1. Medications are safely and securely stored under manufacturer/marketing authorization holder recommendations, are kept clean, and organized all the time.
2. The ambulatory healthcare center has well-implemented policy and procedures to ensure that emergency medications including anesthesia reversing agents and antidotes are accessible, securely stored and protected from loss or theft in all storage areas and are uniformly stored and clearly arranged and managed.
3. Psychotropic, and narcotic medications are stored in accordance to the applicable laws and regulations.
4. The ambulatory healthcare center has a process for the handling of multi-dose medications to ensure its stability and safety.

5. The ambulatory healthcare center has a clearly implemented process to deal with an electric power outage to ensure the integrity of any affected medications before use.
6. Medications, medication containers, and the components used in their preparation are clearly labeled (if not apparent on the original packages or boxes) with elements from a) to e) in the intent.

**Related standards:**

MMS.01 Medication management. MMS.03 High- alert medications, Look alike Sound alike medications, EFS.11 Utilities Management plan.

**MMS.03 NSR.09 High alert medications and look alike sound alike medications, are managed in a way assures that risk is minimized.**

*Safety*

**Keywords:**

High- alert medications, Look-alike Sound alike medications.

**Intent:**

High- alert medications are those bearing a heightened risk of causing significant patient harm when they are used incorrectly. Examples of high- alert medications include (but not limited to): anesthesia medications, inotropic agents, adrenergic agonists, concentrated electrolytes, and look-alike/sound alike medications.

The ambulatory healthcare center needs to develop its own list of high alert medications based on its own data and both national and international recognized organizations (e.g., Institute of Safe Medication Practice (ISMP) and the World Health Organization (WHO)). In addition, ambulatory healthcare center has strategies in place to prevent the inadvertent use and administration of these medications.

Look-alike/sound alike (LASA) medications are those visually similar in physical appearance or packaging and names of medications that have spelling similarities and/or similar phonetics. Any confusion between these medications may lead to harmful errors. The Institute for Safe Medication Practices (ISMP) maintains an ongoing list of LASA medication names to highlight medications that may require special safeguards or strategies to help prevent healthcare providers from accidentally mistaking one medication for another. Another strategy that the ISMP recommends for reducing LASA medication name errors is to include both the brand name and nonproprietary name, dosage form, strength, directions, and the indication for use, which can be helpful in differentiating LASA medication names. Other recommendations aimed at minimizing name confusion include conducting a periodic analysis of new product names; physically separating and segregating these medications in medication storage areas prevents confusion and promotes safety.

Ambulatory healthcare center needs to establish risk management strategies to minimize adverse events with LASA medications, enhance patient safety and protect against inadvertent administration.

**Survey process guide:**

- GAHAR surveyor may review the updated lists of high alert medications and LASA medications.
- GAHAR surveyor may observe the different strategies implemented to ensure safe management of high alert medications and LASA medications.
- GAHAR surveyor may interview staff to check their awareness of management of high alert medications and LASA medications.

**Evidence of Compliance:**

1. The ambulatory healthcare center has an annually updated list(s) of high alert medications, and concentrated electrolytes (if available)
2. The ambulatory healthcare center has an annually updated list of look-alike sound alike medications.
3. The ambulatory healthcare center has uniform process for the safe storage and administration of high alert medications and concentrated electrolytes (if available), including separation, and labeling.
4. The ambulatory healthcare center has a defined process for the safe handling of look-alike sound alike medications including separation, labeling and administration.
5. Responsible staff members are aware of the strategies implemented when managing high alert medications, concentrated electrolytes (if available) and look alike sound alike medications

**Related standards:**

MMS.02 Medication storage and labelling. MMS.06 Medication preparation and administration.

**MMS.04 The ambulatory healthcare center has a drug recall system in place.**

*Effectiveness*

**Keywords:**

Drug recall system.

**Intent:**

A drug recall is required when safety issues arise, and defective products are required to be returned to the manufacturer/distributor. This includes expired, outdated, damaged, dispensed but not used, and/or contaminated medications.

Drug recalls can be extremely costly and can damage consumer confidence in the product or company, so naturally all companies try their best to avoid such scenarios.

The ambulatory healthcare center shall have a system in place for the proper identification and retrieval of medications recalled by the Egyptian Drug Authority (EDA), the manufacturer/marketing authorization holder, or other well-recognized bodies. Recalled medications are clearly labeled and separated from regular stock pending removal by the manufacturer/marketing authorization holder, or destruction.

The recall system includes:

- a. Process to retrieve recalled medications
- b. Labelling
- c. Separation
- d. Disposal or removal
- e. Patient notification (when applicable)

The ambulatory healthcare center shall develop and implement a policy and procedures to ensure that medications meet the required standards for product integrity, and that expired medications cannot be inadvertently used or administered. Regular monitoring of disposal of unused, unwanted, or expired medications assists in identifying the potential for, and actual unauthorized, diversion of medications.

It is the responsibility of the ambulatory healthcare center to ensure that all staff members dealing with medications are aware of the drug recall system and the procedures of handling expired, damaged, outdated or contaminated medications.

#### **Survey process guide**

- GAHAR surveyor may observe the drug recall system for removal, storing, and disposing of expired, damaged, or contaminated medications.
- GAHAR surveyor may interview staff members to check their awareness of the drug recall policy.
- GAHAR surveyor may trace a recalled drug from the reception of drug recall notice till disposal or removal.

#### **Evidence of compliance:**

1. The ambulatory healthcare center has a drug recall system that includes elements from a) to e) in the intent.
2. The ambulatory healthcare center has an approved policy and procedures in place for removal, storing, and disposing of expired, damaged, or contaminated medications.
3. Recalled medications are clearly labeled and separated according to the manufacturer/ marketing recommendations.
4. Staff members involved in drug recall process are aware of the drug recall system and the process of handling of expired medications.

#### **Related standards:**

MMS.01 Medication management.MMS.02 Medication storage and labelling

## **MMS.05 Medications are safely ordered and prescribed after proper medication reconciliation.**

*Safety*

### **Keywords:**

Safe medication prescription\_ Medication reconciliation.

### **Intent:**

Treating a patient by medication(s) requires specific knowledge and experience. When prescribed and used effectively, medications have the potential to significantly improve the quality of lives and improve the patients' safety and outcomes. However, the challenges associated with prescribing the right medications, and supporting patients to use them effectively should not be underestimated.

Patients often receive new medications or have changes made to their existing medications at times of transitions of care (ambulatory healthcare center admission, or discharge from the ambulatory healthcare center). As a result, the new medication regimen prescribed at the time of discharge may inadvertently omit needed medications, unnecessarily duplicate existing therapies, or contain incorrect dosages. These discrepancies place patients at risk of adverse drug events (ADEs).

The ambulatory healthcare center shall develop and implement a structured process to guide the medication reconciliation process addresses on admission to and discharge from the ambulatory healthcare center. Reconciliation process address at least the following:

- i. Situations when medication reconciliation is required:
  - I. On admission (matching the current medication orders with the best possible medication history (BPMH),
  - II. On discharge (checking that medications ordered on the discharge prescription match those on the discharge plan and the medications list and confirming that changes have been documented).
- ii. Identify responsibility to perform medication reconciliation.
- iii. Patients and families involvement.
- iv. Steps of medication reconciliation process such as collecting the list of medications, vitamins, nutritional supplements, over-the-counter drugs, and vaccines used by patients, clarification whether these medications and their dosages are appropriate, matching with new list of medication and recording changes.

Each organization is responsible for identifying those individuals by experience and who are permitted by licensure, certification, laws, or regulations to prescribe or to order medications. The ambulatory healthcare center has policy and procedures to guide the processes of ordering, prescribing, and transcribing of medications including narcotics and psychotropic agents. The policy defines the elements of the complete prescription and the types of orders that are acceptable for use to minimize the potential for errors when orders are recorded. The complete prescription includes at least the following:



- a. Patient's identifications
- b. Patient's demographics
- c. Medication name
- d. Dosage form
- e. Strength or concentration
- f. Dosage, frequency, and duration of medication
- g. Route of administration
- h. Rates of administration (when intravenous infusions are ordered)
- i. Indications for use and the maximum frequency and maximum daily dose (for PRN orders)
- j. Date and time of the order
- k. Prescriber identification

Abbreviations avoidance prevents misunderstanding, miscommunications and administration of incorrect prescriptions. The ambulatory healthcare center shall ensure the standardized use of approved symbols and abbreviations across the organization.

**Survey Process Guide:**

- GAHAR surveyor may review a number of patient's medical records to assess recording of current medications upon admission.
- GAHAR surveyor may review the ordering, prescribing policy, and the review number of patient's records to assess compliance with prescribing policy, including the completion, legibility and clarity of the medication orders/prescriptions.

**Evidence of Compliance:**

1. The ambulatory healthcare center is responsible for identifying those individuals permitted by law and regulation, qualification, training, experience, and job description to order/prescribe medications.
2. The ambulatory healthcare center has an approved policy and procedures for the safe and complete medication ordering, and prescribing which covers elements from a) to k) in the intent.
3. Psychotropic, and narcotic medications are safely prescribed in accordance to the applicable laws and regulations
4. Medication prescribers compare the list of current medications with the list of medications to be prescribed and make clinical decisions based on the comparison.
5. The ambulatory healthcare center has an implemented structured process to ensure that accurate medication reconciliation is performed for all patients on admission to and before discharge from the ambulatory healthcare center.

**Related standards:**

MMS.01 Medication management. MMS.06 Medication preparation and administration, WFM.10 Clinical Privileges



## **MMS.06 All medications are safely and accurately prepared and administered.**

*Safety*

### **Keywords:**

Medication preparation and administration.

### **Intent:**

All medication orders must be reviewed before administration. Each prescription shall be reviewed for the completion, accuracy and appropriateness of the medication for the right patient and for the right clinical needs. Each prescription/order is reviewed by a qualified healthcare professional for completion, accuracy and appropriateness prior to administration.

Appropriateness review covers at least the following

- a. Suitability of the medication to the patient's characteristics and condition
- b. Therapeutic duplication,
- c. Real or potential allergies,
- d. Major drug interactions, and
- e. Potential organ toxicity.

Actions must be taken when medication prescriptions are incomplete, illegible, unclear or inappropriate for the patient.

A safe, clean, and organized working environment provides the basis for good medication preparation practice. This includes qualified/trained staff, appropriate physical surroundings, adequate shelving and storage areas, proper work surfaces, suitable equipment, and necessary packaging materials.

The ambulatory healthcare center identifies the standards of practice for a safe medication preparation and administration environment. Healthcare professionals who prepare medications are requested to use techniques to ensure accuracy (e.g., double-checking calculations), and avoid contamination, including using clean or aseptic technique as appropriate; maintaining clean, and uncluttered areas for product preparation. In addition, healthcare professionals preparing compounded sterile products or preparing medications using multi-dose vials or hazardous medications are trained on the principles of medication preparation and aseptic technique. Similarly, laminar airflow hoods are available and used when indicated by professional practices (e.g., preparation of cytotoxic medications).

Prepared medications are labeled in a standardized manner. This requirement applies to any medication that is prepared but not administered immediately (this requirement does not apply to a medication prepared and administered immediately in the emergencies). At a minimum, labels (if not apparent from the container) must include the following:

- f. Patient identifications (2 unique identifiers)
- g. Medication name
- h. Strength/concentration
- i. Amount

- j. Expiration date
- k. Beyond use date
- l. Directions for use
- m. Any special/cautionary instructions
- n. Date and time of preparation and the diluent for all compounded intravenous (IV) admixtures, and parenteral solutions (if available).

In addition, medications preparation and administration within the ambulatory healthcare center follow standardized processes to ensure appropriateness, effectiveness and safety of medication based on medication prescription or order. Medication preparation and administration to manage a patient requires specific knowledge and experience. The safe administration of medications includes ensuring the following:

- o. Right patient
- p. Right medication
- q. Right time and frequency of administration
- r. Right dosage amount and regimen
- s. Right route of administration
- t. Right reasons/indication of medication therapy.
- u. Review if the patient allergic to any medication in the prescription or order.
- v. Provision of information about the medications that they are going to be given and the patients are given the chance to ask questions.

In addition, there is a clear process for preparation and administration psychotropic, and narcotic medications in accordance to the applicable laws and regulations.

The ambulatory healthcare center educates patients and/or their families about the safe and effective use of medication(s) prescribed and to be administered including (if needed) any potential significant adverse reactions, or other concerns about administering a medication.

#### **Survey Process Guide:**

- GAHAR surveyor may interview responsible staff to check their awareness of the appropriateness process.
- GAHAR surveyor may observe the process of preparing/compounding medication order and observe the labeling of the prepared products.
- GAHAR surveyor may review the medication administration process including the narcotics and psychotropic medications.

#### **Evidence of Compliance:**

1. The ambulatory healthcare center identifies those individuals, by law and regulation, qualification, training, experience, and job description, authorized to prepare and/or administer medications and admixtures, with or without supervision.
2. Each prescription/order is reviewed by a trained healthcare professional for completion, accuracy and appropriateness prior to administration and covers at least elements from

- a) to e) in the intent.
3. The ambulatory healthcare center has a process to guide the preparation and compounding of sterile and non-sterile preparations including preparation of cytotoxic medications (if available).
  4. All medications prepared in the ambulatory healthcare center are correctly labeled in a standardized manner with at least the elements from f) to n) in the intent.
  5. The ambulatory healthcare center has a process that covers elements from o) to v) in the intent to ensure safe medication administration.
  6. Psychotropic, and narcotic medications are prepared and administered in accordance to the applicable laws and regulations.

**Related standards:**

ACT.02 Patient identification MMS.03 High- alert medications, Look alike Sound alike medications, MMS.05 Safe medication prescription\_ Medication IPC.06 Standard precautions measures

**MMS.07 The ambulatory health care center has a process for both monitoring the medication effects on patients, and detecting, acting on and reporting of adverse drug events, medication errors, and near misses.**

*Effectiveness*

**Keywords:**

Medication errors, adverse drug events and near misses.

**Intent:**

Medications are monitored for clinical effectiveness, and adverse medication effects. The purpose of monitoring is to evaluate the therapeutic response of the medication(s), including safety and effectiveness in order to adjust the dosage or type of medication when required, evaluate for any medication interaction, and evaluate the patient for adverse effects or allergic reactions.

Monitoring medication effects includes observing and documenting any adverse effects. This is done using a standardized format (The Egyptian National Forms). Reporting to the authorized institutions is done in a timely manner as per national regulations.

Medication errors and near misses are particularly important given the large and growing global volume of medication use. This is especially critical in the healthcare settings where a significant proportion of prescribing occurs.

It is important that, the ambulatory healthcare center has process to identify and report on medication errors and near misses. The process includes defining a medication error and near miss, and educating staff on the process and importance of reporting.

**Survey Process Guide:**

- GAHAR surveyor may interview responsible staff to check their awareness of monitoring the effect of medications process.
- GAHAR surveyor may review the process of detecting, and reporting adverse drug reactions/events.
- GAHAR surveyor may review the process of defining, acting upon and reporting of medication errors, near misses.

**Evidence of Compliance:**

1. Effect(s) of medication(s) including actual or potential medication adverse effects on patients is/are monitored and documented in the patients' records including the action(s) to be taken in response.
2. Adverse drug events (ADEs) are reported in a manner consistent with the national guidelines using standardized national format.
3. The ambulatory healthcare center has clear definitions for medication error(s), and near miss(es) and implements a process for acting upon and reporting of medication errors, and near misses in a manner consistent with the national guidelines.

**Related standards:**

MMS.05 Safe medication prescription, MMS.06 Medication preparation and administration.  
QPI.04 Incident Reporting System QPI.07 Sentinel events



## SECTION 3

### ORGANIZATION-CENTERED STANDARDS



## Section 3: Organization-Centered Standards

While in the previous section, Patient centered care and safety was the focus. Yet, Patients are not the only customers of healthcare systems. Healthcare professionals face risks, as well. Although debate continues regarding whether workers' wellbeing should be considered as part of the patient safety initiatives, many organizations think about it that way, including major players in the healthcare industry worldwide. Three major aspects may affect workers' wellbeing; Safety, Stress, and Ambulatory healthcare center Structure.

Regarding Safety, according to the United States Department of Labor, Occupational Safety and Health Administration (OSHA), an ambulatory healthcare center is one of the most hazardous places to work. Healthcare professionals experience some of the highest rates of non-fatal illness and injury surpassing both the construction and manufacturing industries. In fact, healthcare accounts for nearly as many serious violent injuries as all other industries combined. Many more assaults or threats go unreported. Workplace violence comes at a high cost; however, it can be prevented.

On the other hand, being exposed to stress for too long may lower a person's efficiency and could trigger negative consequences on one's health or family and social life. Nevertheless, not every manifestation of stress is always a workplace stress. Workplace stress may be caused by various factors. Some professions are inherently more stressful than others. Some studies showed that healthcare professions are among the first six most stressful ones. Not all health professionals develop the same level of stress, and not all of them develop signs of professional burnout either.

Ambulatory healthcare center structure provides guidance to all staff by laying out the official reporting relationships that govern the workflow of the company. A formal outline of an ambulatory healthcare center structure makes it easier to add new positions in the ambulatory healthcare center, as well, providing a flexible and ready means for growth. Organization management needs to be according to a clear ethical framework that is responsive to community needs. Organizations have an obligation to act for the benefit of the community at large. Workers, as community members, need to be engaged in assessing community needs and responding to them, in addition, to being protected from safety and stress hazards while working in the ambulatory healthcare center.

Nevertheless, both the ambulatory healthcare center and the staff bear the responsibility to keep themselves safe. For example, while management provides personal protective equipment (PPE), such as safety glasses to keep debris and chemical splashes away from the eyes, it is the staff's responsibility to wear the PPE when performing work that management has identified as requiring it.

One of the tools used to design this section is called Health-WISE, which is an action tool

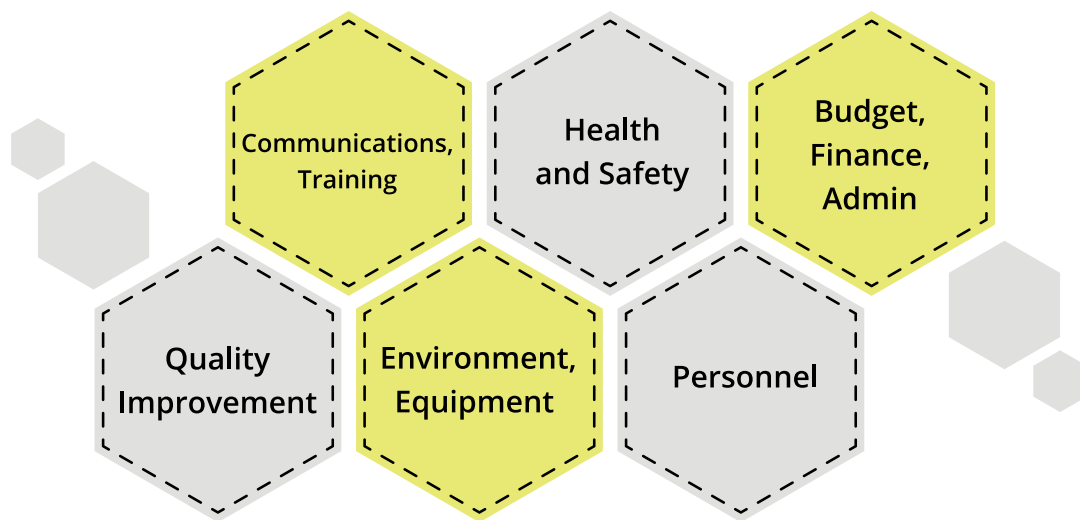


developed by the International Labor Organization (ILO) in collaboration with the WHO. This tool emerged from traditional thinking about patient safety and improvement more generally. It describes a process and structure that may lead to improved safety in a variety of healthcare settings.

The aim of HealthWISE is to provide healthcare institutions with a cost-effective tool to improve work conditions, performance, occupational health and safety for health workers, and the quality of health services provided.

HealthWISE puts the health workforce in focus and addresses topics that are key to delivering high quality of care.

As organization, management is responsible for providing an efficient ambulatory healthcare center structure. Leaders are identified and responsive to the ambulatory healthcare center needs, Leaders work collaboratively to run the ambulatory healthcare center towards preset approved strategic directions. An established structure includes defining capacity and roles of the ambulatory healthcare center workforce, providing sufficient orientation and education, and continuous monitoring and evaluation. Hence, strong information management and technology are needed to record data and information, in addition to a strong quality management program that can capture and interpret data and information.



## Elements For Safe Healthcare

## Environmental and Facility Safety

### Chapter intent:

Environmental and Facility Safety (EFS) in ambulatory healthcare centers aims at minimizing potential risks for patients, visitors, staff, and buildings through compliance with local laws, regulations, fire, and building codes for providing a safe and secure work environment.

From an environmental standpoint, it involves creating a systematic approach to compliance with environmental regulations, such as managing waste and maintaining a safe environmental condition. From a safety standpoint, it involves creating organized efforts and procedures for identifying workplace hazards and reducing accidents and exposure to harmful situations and substances. It also includes training of staff members in accident prevention, accident response, emergency preparedness, and use of protective clothing and equipment.

Globally, Healthcare design standards are developed to maintain proper ambulatory healthcare center structure that maintains safety and efficiency for all users. Facility Guideline Institute issues periodical research-based standards for healthcare facility designs. OSHA, CDC, WHO and other international healthcare entities set certain standards for various aspects of healthcare design. Locally, Regulatory requirements play an important role in EFS. The ambulatory healthcare center shall identify and understand all relevant EFS regulations to implement the required measures.

National initiatives include but not limited to; organization building codes, licensure requirements for the whole organization and the individual functions/machine/equipment/units inside the ambulatory healthcare center, Civil defense laws, Green ambulatory healthcare center initiative, Environmental laws.

GAHAR surveyor is going to meet the concerned staff in EFS and discuss the different standards of this chapter, review the documents, trace the activities and functions, and measure their facility safety awareness. Facility tour is an important tool used by surveyors to measure environmental safety risks in an ambulatory healthcare center.

### Chapter purpose:

The main objective is to ensure that organization is able to identify the safety issues and provide safe and effective program to handle and maintain environment safety. The chapter discusses the following:

- **Fire safety:**  
Prevention, early detection, response, and safe evacuation in case of fire.
- **Hazardous materials:**  
Safe handling, storage, transportation, and use of hazardous materials, and waste disposal.

- **Safety:**

Providing a safe work environment for all occupants, ensuring that the ambulatory healthcare center buildings, construction areas, and equipment do not pose a hazard or risk to patients, staff, and visitors.

- **Security:**

Protection of all occupants' properties from loss, theft, destruction, tampering, or unauthorized access or use.

- **Medical equipment:**

Selection, inspection, testing, maintenance, and safe use of medical equipment.

- **Utility systems:**

Ensuring efficiency and effectiveness of all utilities through regular inspection, maintenance, testing, and repair of essential utilities to minimize the risks of operating failures.

- **Disaster preparedness:**

Responding to the disasters and emergencies that have the potential of occurring within the geographical area of the ambulatory healthcare center with an evaluation of the structural integrity of the patient care environment.

**Implementation guiding documents:**

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

1. Egyptian building codes for healthcare organizations.
2. Egyptian civil defense laws
3. MOHP regulation in NICU, 2007
4. MOHP requirements in the website [www.mohp.org.eg](http://www.mohp.org.eg)
5. MOHP Ministerial decree 34/2001 on surgery and anesthesia services
6. Law 192/2001 for Hazardous waste management
7. Presidential decree number 3185/2016
8. MOHP Ministerial decree 284/1985 on requirements for OR
9. MOHP Ministerial decree 306/2002 on medication storage spaces
10. Egyptian Food safety guidelines
11. Egyptian Guideline for Medical Device Vigilance System
12. Guideline ambulatory healthcare center disaster planning
13. National strategy in disasters management
14. National Law for Environment
15. Atomic Energy Commission rules
16. The Green Pyramid Rating System (GPRS)
17. WHO Early Warning Alert And Response Network in emergencies
18. WHO International Health Regulation
19. Guidance in environmental safety book
20. Core Medical equipment -WHO

## Effective leadership and planning of environment and facility safety

### **EFS.01 Ambulatory healthcare center facilities comply with laws, regulations, fire, and national building codes.**

*Safety*

#### **Keywords:**

Ambulatory healthcare center environment and facility safety structure

#### **Intent:**

While ambulatory healthcare centers are meant to provide healing and comfort, they also include certain dangers.

Ambulatory healthcare centers that contain hazardous chemicals, chemotherapeutic drugs, radioactive materials, and infectious matter, among other threatening items.

For this reason, governmental authorities enforce laws and regulations to ensure protection against these exposures.

In addition, there are also dangers from fire and smoke that can be particularly perilous for the vulnerable ambulatory healthcare center's patients.

Building Codes established to provide guidance on safety measures while designing ambulatory healthcare center settings.

The ambulatory healthcare center should comply with relevant laws, regulations, and codes like civil defense, fire and building codes to ensure the safety of patients, staff, visitors, vendors, and the environment.

The ambulatory healthcare center shall develop and maintain basic infrastructure for environmental and facility safety program:

- a. If an external authority, such as civil defense, reported an observation during its inspection, the ambulatory healthcare center leadership is responsible for providing a corrective action plan and for following up of any non-compliance within the required timeframe.
- b. Clinical and diagnostic services with adequate spaces according to applicable laws, regulations, and approved ambulatory healthcare center scope of service.
- c. Permits, licenses and ambulatory healthcare center design drawings are available, valid, and current.
- d. Budget is planned for upgrading and/or replacement of instruments or systems to keep environmental safety and/or to expand services provided within the ambulatory healthcare center.
- e. Qualified environmental safety staff are available and match requirements of ambulatory healthcare center scope of services, laws and regulations.

The ambulatory healthcare center shall build an environmental safety oversight structure:

- f. The ambulatory healthcare center should have a committee overseeing environmental safety activities and trainings through regular meetings, the committee could be held urgently if needed.

- g. The committee role should include review of aggregated essential data, incident reports, drill reports, and safety plans measures, recommended actions, and following up to ensure compliance with all safety requirements.
- h. The committee should report to the ambulatory healthcare center's leadership quarterly and a feedback from ambulatory healthcare center leadership should be received.

**Survey process guide:**

- GAHAR surveyor may review documents demonstrating ambulatory healthcare center drawings, budget, safety staff qualifications, external authorities' reports, action plans and recorded committee meeting notes and agenda.
- During ambulatory healthcare center tours and tracers, GAHAR surveyor may observe compliance with laws and regulations and matching of allocated spaces to departmental functions.

**Evidence of compliance:**

1. The ambulatory healthcare center leadership complies with environmental safety laws, regulations, and national building codes.
2. The ambulatory healthcare center maintains basic requirement for development of environment and facility safety program.
3. The ambulatory healthcare center has a committee overseeing environmental safety with approved terms of references.
4. Environment and facility safety committee meets regularly (at least quarterly) and meeting minutes including actions taken are recorded.
5. The ambulatory healthcare center's leadership ensures compliance with external inspection reports and correction of observations within the required timeframe.

**Related standards:**

APC.01 National regulations and licensure requirements, DAS.01 Planning and provision the medical imaging services, DAS.07 Radiation Safety Program, DAS.08 Laboratory services planning and management, OGM.02 Ambulatory healthcare center director.

**Safe fire planning**

**EFS.02 NSR.13 Fire and smoke safety plan addresses prevention, early detection, response, and safe evacuation in case of fire and/or other internal emergencies.**

Safety

**Keywords:**

Fire and smoke safety.

**Intent:**

One of the critical considerations in the safety design for ambulatory healthcare centers is the prevention of fire, particularly with respect to the combustibility of construction and furnishing materials and the spread of fire and smoke.

In the event of either accidental or malicious fires, suppression equipment needs to be readily accessible to combat these fires.

Staff members of the ambulatory healthcare center need to have working knowledge of how to use the equipment and to avoid panic.

The last option, failing the ability to completely suppress the fire, is to evacuate the ambulatory healthcare center.

Moving all patients, visitors, and staff out of dangerous and/or damaged facilities as safely as possible is always the goal of an evacuation.

It is important to recognize that people's attention towards details and processes will not be optimal in an evacuation scenario. To that end, understanding key principles will help staff members make good decisions during a chaotic event.

The ambulatory healthcare center develops a fire and smoke safety plan that addresses at least the following:

- a. An ongoing risk assessment that will have the following features:
  - I. Assesses compliance with Civil Defence regulations.
  - II. Assesses compliance with fire and building codes.
  - III. Includes fire and smoke separation, areas under construction and other high-risk areas for example stores, fuel tanks, kitchens including hoods, generators, laundry, oxygen supply, medical gases rooms, electrical control panels, medical records room, garbage room, etc.
  - IV. Addresses the safety of all occupants including patients, families, full time staff, part time staff, visitors, suppliers, contractors and others.
  - V. Addresses evacuation for fire and non-fire emergencies, for example, dangerous gas leakage.
  - VI. A special risk assessment is performed during renovation and construction.
- b. Early detection of fire and smoke system, including the central control panel connected to all areas in ambulatory healthcare centers according to its functionality, and ensure continuous monitoring 24/7.
- c. Fire suppression system such as water system, automated or manual fire extinguisher.
- d. Listing of firefighting and alarm systems includes maintenance testing, inspection schedule.
- e. Availability of safe, unobstructed fire exits, with clear signage to assembly areas and emergency light, in addition to other related signage like how to activate the fire alarm using a fire extinguisher and hose reel.
- f. Inspection of all firefighting and alarm systems should be in place, and results are recorded with needed corrective actions.
- g. Safe storage and handling of highly flammable materials.

- h. The ambulatory healthcare center should perform proper annual training and orientation to all staff in a practical manner to make sure that everyone in the ambulatory healthcare center can:
  - i. Demonstrate RACE and PASS.
  - ii. Define who is responsible for medical gas valves shut off, with alternative oxygen sources in case of fire.
  - iii. Safely evacuate all occupants.
  - iv. Provide specific training for the evacuation of high-risk patients like (Operating theatres, Dialysis units).
  - v. Ambulatory healthcare center evacuation' pathway, gathering areas, and assembly points.
- i. Documentation of all results in a proper way and repetition according to the training plan.
- j. The plan is evaluated annually and, if needed, according to related performance measures results or major incidents.

**Survey process guide:**

- GAHAR surveyor may review the fire safety plan, facility fire safety inspections, and fire system maintenance.
- GAHAR surveyor may check that fire alarm; firefighting and smoke containment systems are working effectively and complying with civil defense requirements.
- GAHAR surveyor may review plan of testing (drills) and staff training (all staff should be trained on fire safety).

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved fire and smoke safety plan that includes all elements from a) through j) in the intent.
2. The ambulatory healthcare center fire alarm, firefighting and smoke containment system are available, functioning and comply with civil defence requirements.
3. Inspection, testing and maintenance of fire alarm, firefighting and smoke containment systems are performed and recorded.
4. The ambulatory healthcare center provides education for fire response and evacuation to all staff at least once annually.
5. The ambulatory healthcare center guarantees safe evacuation processes for all occupants in case of fire and/or other internal emergencies.
6. The fire and smoke safety plan is evaluated annually and, whenever indicated, with aggregation and analysis of necessary data.

**Related standards:**

EFS.01 Ambulatory healthcare center environment and facility safety structure EFS.03 Smoking-Free Environment, EFS.04 Fire drills, EFS.06 Safety Management Plan, QPI.03 Risk Management Program



### **EFS.03 The ambulatory healthcare center clinical and non-clinical areas are smoking-free.**

*Safety*

#### **Keywords:**

Smoking-Free Environment

#### **Intent:**

According to Center for Disease Control (CDC), Smoking causes about 90% (or 9 out of 10) of all lung cancer deaths. More women die from lung cancer each year than from breast cancer. Smoking causes about 80% (or 8 out of 10) of all deaths from chronic obstructive pulmonary disease (COPD). Cigarette smoking increases risk for death from all causes in men and women.

Literature shows that although ambulatory healthcare centers restrict smoking inside, many people continue to smoke outside, creating problems of second-hand smoke, litter, fire risks, and negative role modeling.

Smoke-free policies are an important component of an ecological and social-cognitive approach to reducing tobacco use and tobacco-related disease.

The ambulatory healthcare center ensures a smoking-free environment for patients and environmental safety through the availability of smoking-free environment policy and procedure, proper signage according to laws and regulations.

The policy should include any exceptions, penalties, and the designated smoking area outside the building.

All staff should be oriented about the smoking-free environment policy.

#### **Survey process guide:**

- GAHAR surveyor may review the smoking-free policy followed by interviewing staff and/or patients to check their awareness of ambulatory healthcare center policy, smoking areas location and consequences of not complying with the policy.
- During the GAHAR survey, surveyors may observe evidences of not complying with the policy such as cigarette remnants and cigarette packs specially in remote areas.

#### **Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy for a smoking-free environment.
2. Staff, patients and visitors are aware of the ambulatory healthcare center policy.
3. Occupants, according to laws and regulations, do not smoke in all areas except designated areas.
4. The ambulatory healthcare center monitors compliance to smoking-free policy.

#### **Related standards:**

EFS.01 Ambulatory healthcare center environment and facility safety structure

EFS.02 Fire and smoke safety EFS.06 Safety Management Plan QPI.03 Risk Management Program



**EFS.04 NSR.14 Fire drills are performed in different clinical and non-clinical areas, including at least one unannounced drill annually.**

*Safety*

**Keywords:**

Fire drills.

**Intent:**

Fire drills are designed to ensure through regular training and simulations, that staff members will: have knowledge and understanding of the fire safety plan so that they can act swiftly, safely, and in an orderly manner and to increase the self-confidence and power to fulfill their responsibilities in the event of a fire.

The ambulatory healthcare center staff should be well trained on firefighting and safe evacuation through practical simulations and regular drills to ensure staff readiness in case of fire and/or other internal emergencies.

The ambulatory healthcare center records fire drills details including, but are not limited to, the following:

- a. Dates and timings.
- b. Staff who participated in the drill.
- c. Involved areas.
- d. Shifts.
- e. Drill evaluation and corrective action plan.

**Survey process guide:**

- GAHAR surveyor may review the records of fire and evacuation drills with dates, timings, staff who participated, the involved areas in the ambulatory healthcare center and corrective action plan based on the drill evaluation.
- GAHAR surveyor may Interview staff to check their awareness of fire safety plan and basic procedures in such cases like (Rescue, Alarm, Confine, Extinguish/Evacuate and Pull, Aim, Squeeze, Sweep).

**Evidence of compliance:**

1. Fire drills are performed based on a predefined time interval.
2. Staff members participate in fire drills at least once annually.
3. Fire drill results are recorded from a) through e) in the intent.
4. Fire drill results evaluation is performed after performing each drill.
5. The ambulatory healthcare center plans a corrective action, whenever indicated.

**Related standards:**

EFS.02 Fire and smoke safety, EFS.13 Disaster Plan WFM.06 Continuous Education Program

## Safe hazardous materials and waste management plan

### **EFS.05 NSR.15 The ambulatory healthcare center plans safe handling, storage, usage and transportation of hazardous materials and waste disposal.**

*Safety*

#### **Keywords:**

Hazardous materials safety.

#### **Intent:**

Hazardous materials are chemical substances, which, if released or misused, can pose a threat to the environment, life or health. Industry, agriculture, medicine, research, and consumer goods use these chemicals.

Hazardous materials come in the form of explosives, flammable and combustible substances, poisons, and radioactive materials. These substances are most often released because of transportation accidents or chemical accidents in ambulatory healthcare centers.

Because the effects of hazardous materials can be devastating and far-reaching, it is important that ambulatory healthcare centers plan for their safe use and establish a safe working environment.

Ambulatory healthcare center's waste is any waste, which is generated in the diagnosis, treatment or immunization of human beings or in research in an ambulatory healthcare center.

Healthcare waste includes infectious, chemical, expired pharmaceutical and radioactive items and sharps. These items can be pathogenic and environmentally adverse. Other waste items generated through healthcare but not hazardous include medication boxes, the packaging of medical items and food, remains of food, and waste from offices.

Ambulatory healthcare center Waste Management means the management of waste produced by ambulatory healthcare centers using such techniques that will help to check the spread of diseases.

The ambulatory healthcare center should identify and control hazardous material and waste all over the ambulatory healthcare center to ensure that staff, patients, relatives, vendors, and the environment are safe. Hazardous material and waste are categorized into the following categories according to the WHO classification:

- i. Infectious
- ii. Pathological and anatomical
- iii. Pharmaceutical
- iv. Chemical
- v. Heavy metals
- vi. Pressurized containers
- vii. Sharps

- viii. Genotoxic/cytotoxic
- ix. Radioactive

Hazardous materials and waste management plan includes, but is not limited to, the following:

- a. A current and updated inventory of hazardous materials used in the ambulatory healthcare center, the inventory should include the material name, hazard type, location, usage, consumption rate, and responsibility.
- b. Material safety data sheet (MSDS) should be available and includes information such as physical data, hazardous material type (flammable, cytotoxic, corrosive, carcinogenic, etc.), safe storage, handling, spill management and exposures, first aid, and disposal.
- c. Appropriate labeling of hazardous materials.
- d. Procedure for safe usage, handling, storage, and spillage of hazardous materials.
- e. Appropriate segregation, labeling, handling, storage, transportation, and disposal of all categories of hazardous waste.
- f. Availability of required protective equipment and spill kits.
- g. Investigation and documentation of different incidents such as spill and exposure.
- h. Compliance with local laws and regulations, availability of required licenses, and/or permits.
- i. Staff training and orientation.
- j. The plan is evaluated and updated annually and/or when required.

**Survey process guide:**

- GAHAR surveyor may review the hazardous materials and waste management plan to make sure that it covers all safety requirements of hazardous materials, safe storage, handling, spills, required protective equipment and waste disposal according to local laws and regulations.
- GAHAR surveyor may observe the hazardous materials, and waste inventories, as well as the Material Safety Data Sheet (MSDS).
- GAHAR surveyor may observe the hazardous materials labeling and storage in addition to waste collection segregation storage and final disposal.

**Evidence of compliance:**

1. The ambulatory healthcare center develops hazardous materials and waste management plan that addresses all elements from a) through j) in the intent.
2. The ambulatory healthcare center ensures staff safety when handling hazardous materials/or waste.
3. Waste disposal occurs according to laws and regulations.
4. The ambulatory healthcare center ensures safe usage, handling, storage, and labeling of hazardous materials.
5. The ambulatory healthcare center has an approved document for spill management, Investigation, and recording of different incidents related to hazardous materials.
6. The plan is evaluated and updated annually with aggregation and analysis of necessary data.

**Related standards:**

DAS.17 Laboratory Safety Program IPC.13 Disinfection, sterilization, IPC.15 Laundry service, textile management, WFM.06 Continuous Education Program

**Safety and security planning**

**EFS.06 NSR.16 A safe work environment plan addresses high-risk areas, procedures, risk mitigation requirements, tools, and responsibilities.**

Safety

**Keywords:**

Safety Management Plan.

**Intent:**

Health services are committed to providing a safe environment for patients, staff, and visitors. Ambulatory healthcare center safety arrangements keep patients, staff, and visitors safe from inappropriate risks such as electricity and from inappropriate behavior such as violence and aggression.

The ambulatory healthcare center must have a safety plan that covers the building, property, medical equipment, and systems to ensure a safe physical environment for patients, families, staff, visitors, and vendors.

The safety plan includes at least the following:

- a. Proactive risk assessment.
- b. Effective planning to prevent accidents and injuries and minimize potential risks, to maintain safe conditions for all occupants to reduce and control risks.
- c. Processes for pest and rodent control.
- d. The ambulatory healthcare center identifies potential risks because of system failure and/or staff behavior, for example: wet floor; water leakage from the ceiling beside electrical compartments; improper handling of sharps; non-compliance to personal protective equipment in case of working at heights, cutting, and welding, dealing with high voltage; and unsafe storage.
- e. Regular inspection with documentation of results, performing corrective actions, and appropriate follow up.
- f. Improvements for long-term upgrading or replacement.
- g. Safety training depending on job hazard analysis.

**Survey process guide:**

- GAHAR surveyor may review safety plan/s to make sure that they include suitable risk assessment surveillance.
- GAHAR surveyor may review surveillance rounds plan. Checklist, different observations, and proper corrective actions when applicable.
- GAHAR surveyor may observe workers in different areas to check their usage of suitable personal protective equipment (PPE).

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved plan to ensure a safe work environment that includes all elements from a) through g) in the intent.
2. Staff is aware of safety measures pertinent to their job.
3. Safety measures are implemented in all areas.
4. Safety instructions are posted in all high-risk areas.
5. Safety management plan is evaluated and updated annually with aggregation and analysis of necessary data.

**Related standards:**

DAS.07 Radiation Safety Program, DAS.17 Laboratory Safety Program, EFS.02 Fire and smoke safety, EFS.03 Smoking-Free Environment, EFS.05 Hazardous materials safety, EFS.11 Utilities Management plan.

IPC.08 Safe injection practices, WFM.05 Orientation Program, QPI.03 Risk Management Program, QPI.02 Performance measures.

**EFS.07 The ambulatory healthcare center performs a pre-construction risk assessment when planning for construction or renovation.**

*Safety*

**Keywords:**

Pre-Construction and renovation risk assessment.

**Intent:**

New construction or renovation in an ambulatory healthcare center has an impact on all occupants, who could suffer from changing air quality by dust or odors, noise, vibration, and wreckage.

Upon new construction or renovation in the ambulatory healthcare center, a pre-construction risk assessment (PCRA) should be performed and evaluated in order to develop a plan that will minimize associated risks.

The ambulatory healthcare center ensures involvement of all departments affected by construction or renovation, including project management, infection control, safety, security, housekeeping, information technology, engineering, clinical departments, and external constructors.

The pre-construction risk assessment includes, but is not limited to, the following:

- a. Noise level
- b. Vibration
- c. Infection control
- d. Air quality
- e. Fire risk
- f. Utilities affected (electricity, water, gases, etc.)
- g. Hazardous materials

- h. Waste and wreckage
- i. Any other hazards related to construction/renovation

The ambulatory healthcare center ensures monitoring, documentation of all activities, and all risks related to construction and renovation.

**Survey process guide:**

- GAHAR surveyor may review pre-construction risk assessment documents and check implementation of risk assessment recommendations.
- GAHAR surveyor may interview staff, patients, or contractors in the construction area to check their awareness of the required precautions.

**Evidence of compliance:**

1. The ambulatory healthcare center performs a pre-construction risk assessment before any construction or renovation.
2. All affected departments are involved in the risk assessment.
3. The ambulatory healthcare center plans corrective actions whenever indicated.
4. If a contractor is used, contractors' compliance is monitored and evaluated by the ambulatory healthcare center.

**Related standards:**

EFS.02 Fire and smoke safety, EFS.05 Hazardous materials safety, EFS.11 Utilities Management plan, IPC.04, Infection risk assessment, QPI.03 Risk Management Program

**EFS.08 Security plan addresses security of all occupants and properties including restricted and isolated areas with risk mitigation, control measures, tools, and responsibilities.**

*Safety*

**Keywords:**

Security Plan.

**Intent:**

Security issues such as violence, aggression, thefts, harassment, suicide, bomb threat, terrorism, gunshot, and child abduction are common in ambulatory healthcare centers. Usually, ambulatory healthcare centers enforce a code of behaviour that does not tolerate physical or verbal aggression, or abuse towards staff, patients, family members or visitors. To keep staff, patients and visitors safe, ambulatory healthcare centers may use a range of security measures, including the use of (closed-circuit television) CCTV cameras, duress alarms for staff members and electronic access control systems for doorways. Some ambulatory healthcare centers also employ security staff. The ambulatory healthcare center ensures protection of all occupants from violence, aggression, thefts, harassment, suicide, bomb threat, terrorism, gunshot, and child abduction.

The security plan includes, but is not limited to, the following:

- a. Security risk assessment.
- b. Ensuring the identification of patients, visitors, and staff in the ambulatory healthcare center.
- c. Identification of vendors/contractors with the restriction of their movement within the ambulatory healthcare center.
- d. Vulnerable patients such as the elderly, infants, those with mental disorders, and handicapped should be protected from the abuse and above-mentioned harms.
- e. Children should be protected from abduction.
- f. Drill for child abduction should be performed at least annually.
- g. Monitoring of remote and isolated areas.
- h. Staff training and orientation.
- i. The plan is evaluated annually and, if needed, according to related performance measures results or major incidents.

**Survey process guide:**

- GAHAR surveyor may review security plan/s to make sure that they include suitable risk assessment surveillance, security high-risk areas and security requirements, as well as access control areas.
- GAHAR surveyor may review surveillance rounds plan. Checklist, different observations, and proper corrective actions when applicable.
- GAHAR surveyor may observe tools of security plan implementation as, cameras, monitors, staff ID and access-controlled areas.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved security plan that includes items a) through i) in the intent.
2. Security plan education is provided at least annually to all staff.
3. Security measures are implemented including identification of occupants.
4. Occupants are protected from harm, such as violence, aggression, infant/child abduction.
5. Restricted and isolated areas are protected and secured.
6. Security plan is evaluated and updated annually with aggregation and analysis of necessary data.

**Related standards:**

PCC.02 Patient and family rights, PCC.06 Patient's belongings, QPI.03 Risk Management Program, WFM.05 Orientation Program, QPI.02 Performance measures.

## Safe medical equipment

### **EFS.09 NSR.17 Medical equipment plan ensures safe selection, inspection, testing, maintenance, and safe use of medical equipment.**

*Safety*

#### **Keywords:**

Medical Equipment management plan.

#### **Intent:**

Medical equipment is critical to the diagnosis and treatment of patients.

In most ambulatory healthcare centers, a trained biomedical and engineering team manages the entire medical inventory, and is responsible for dealing with medical equipment hazards. Being responsible for such an extensive array of devices can be cumbersome, especially when the stakes are so high. Not only does lazy monitoring and management lead to inefficiency, but also it can also seriously harm patients' outcomes. As an example, poor maintenance increases the chances of downtime, and inadequate services and sterilization can be harmful to both doctors and patients.

This is why it is crucial to establish some basic equipment safety and service guidelines.

The ambulatory healthcare center develops a plan for medical equipment management that addresses at least the following:

- a. Developing criteria for selecting new medical equipment.
- b. Inspection and testing of new medical equipment upon procurement and on a predefined interval basis.
- c. Training of staff on safe usage of medical equipment upon hiring on the installation of new equipment, and on a predefined regular basis by a qualified person.
- d. Inventory of medical equipment including availability, criticality, and functionality.
- e. Identification of critical medical equipment that should be available for the operator even through provision of back- up such as life-saving equipment, ventilator, DC shock.
- f. Specialized and critical equipment(s) lists are identified.
- g. Periodic preventive maintenance according to the manufacturer's recommendations which usually recommends using tagging systems by tagging dates and due dates of periodic preventive maintenance or labelling malfunctioned equipment.
- h. Calibration of medical equipment according to the manufacturer's recommendations and/or its usage.
  - i. Malfunction and repair of medical equipment.
  - j. Dealing with equipment adverse incidents, including actions taken, backup system, and reporting.
- k. Updating, retiring and/or replacing for medical equipment in a planned and systematic way.



**Survey process guide:**

- GAHAR surveyor may review the medical equipment maintenance plan to ensure availability of all required documents, inventory of medical equipment, preventive maintenance schedule, and calibration schedule and staff training records.
- During the GAHAR survey, the surveyor may check medical equipment functionality and trace some medical equipment records.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved medical equipment management plan that addresses all elements from a) through k) in the intent.
2. The ambulatory healthcare center has qualified individuals to oversee medical equipment management.
3. Staff are educated on the medical equipment plan at least annually.
4. Records are maintained for medical equipment inventory, user training, equipment identification cards, and company emergency contact, testing on installation, periodic preventive maintenance, calibration and malfunction history.
5. The ambulatory healthcare center ensures that only trained and competent people handle the specialized equipment(s).
6. The plan is evaluated and updated annually with aggregation and analysis of necessary data.

**Related standards:**

DAS.05 Medical imaging quality control program., DAS.15 Laboratory Internal quality control -External quality control- proficiency test, EFS.10 Critical alarms, OGM.07 Supply Chain Management, OGM.09 Contract Management, WFM.07 Staff performance, evaluation

**EFS.10 NSR.18 The ambulatory healthcare center has an approved policy and procedure for managing critical alarms.**

Safety

**Keywords:**

Critical alarms

**Intent:**

Medical devices especially those related to vital functions are fitted with alarms that alert staff members on conditions of device malfunction or patient's critical situation. Losing that function exposes patients to increased risk of morbidity and mortality. Alarms are intended to induce immediate appropriate action from staff members to either check device malfunction or initiate action that will revert the situation. This can be ensured when all the staff members become fully aware of alarm settings (values and volume) and their significance and are trained on the required actions to be taken when triggered. Annual competency testing for staff members is needed to ensure the safe use of monitors and other devices that has critical

alarming systems. The ambulatory healthcare center shall develop and implement a policy and procedures for the safe management and use of critical alarms. The policy addresses at least the following:

- a. Inventory of critical alarms and their preventive maintenance.
- b. Testing of critical alarm systems.
- c. Alarms are tested and activated with appropriate settings.
- d. Priorities for competing alarms, staff members' authorization for disabling alarms or changing their settings, and monitoring of response to alarm activation.
- e. Staff members' responsibility, control measures, assurance measures and remedial action.
- f. Alarms are sufficiently audible with respect to distances and competing for noise within the unit.

**Survey process guide:**

- The GAHAR surveyor may review policy for maintenance and testing of critical alarm systems.
- The GAHAR surveyor may review inventory of all devices with critical alarms including setting guidelines.
- The GAHAR surveyor may review maintenance records, evidence of function, reporting of malfunction, and remedial actions.
- The GAHAR surveyor may review the schedules of alarm tests and list of current active settings at different care areas.
- The GAHAR surveyor may interview the responsible staff to check their awareness of critical alarm settings and response to their activation.
- The GAHAR surveyor may observe (listen) or activate critical alarms to check for suitability of alarm volume to working space.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that addresses all the elements mentioned in the intent from a) through f).
2. All staff members using devices with critical alarms are aware of the ambulatory healthcare center policy.
3. Competent individuals are responsible for the management and use of critical alarms.
4. Management and the use of critical alarms is safe.
5. Management and use of critical alarms are recorded according to policy including evidence of responsible staff members, responsible company, schedule, agreed settings, evidence of function, reporting of malfunction, and remedial action.

**Related standards:**

EFS.09 Medical Equipment management plan, OGM.07 supply chain management, WFM.07 Staff performance, evaluation.

## Safe utility plan

### **EFS.11 NSR.19 Essential utilities plan addresses regular inspection, maintenance, testing and repair.**

*Effectiveness*

#### **Keywords:**

Utilities Management plan.

#### **Intent:**

Ambulatory healthcare centers are expected to provide safe and reliable healthcare to their patients. Planning appropriate response and recovery activities for a failure of the ambulatory healthcare center's utility systems is essential to satisfy this expectation.

These systems constitute the operational infrastructure that permits safe patient care to be performed.

Some of the most important utilities include, mechanical (e.g., heating, ventilation and cooling); electrical (i.e., normal power and emergency power); domestic hot and cold water as well as other plumbing systems; waste; technology systems, including the myriad communications and data-transfer systems; vertical transportation utilities; fuel systems; access control, duress alarm and surveillance systems; medical gases, air and vacuum systems; and pneumatic tube systems.

The ambulatory healthcare center must have a utility management plan to ensure efficiency and effectiveness of all utilities that includes at least the following:

- a. Inventory of all utility key systems, for example, electricity, water supply, medical gases, heating, ventilation and air conditioning, communication systems, sewage, fuel sources, fire alarm, and elevators.
- b. Layout of the utility system.
- c. Staff training on utility plan.
- d. Regular inspection, testing, and corrective maintenance of utilities.
- e. Testing of the electric generator with and without a load on a regular basis.
- f. Providing fuel required to operate the generator in case of an emergency.
- g. Cleaning and disinfecting of water tanks and testing of water quality with regular sampling for chemical and bacteriological examination with documentation of the results at least quarterly and/or more frequently if required by local laws and regulations or conditions of the source of water.
- h. Preventive maintenance plan, according to the manufacturer's recommendations.
- i. The Ambulatory healthcare center performs regular, accurate data aggregation, and analysis for example, frequency of failure, and preventive maintenance compliance for proper monitoring, updating, and improvement of the different systems.

#### **Survey process guide:**

- GAHAR surveyor may review utility management plan to confirm availability of all required

systems, regular inspection, maintenance, and backup utilities.

- GAHAR surveyor may review inspection documents, preventive maintenance schedule, contracts, and equipment, as well as testing results of generators, tanks, and/or other key system to make sure of facility coverage 24/7.

**Evidence of compliance:**

1. There is an ambulatory healthcare center approved plan for utility management that includes items a) through i) in the intent.
2. The ambulatory healthcare center has qualified staff members to oversee utility systems.
3. Staff are educated on the utility systems plan at least annually.
4. Records are maintained for utility systems inventory, testing, periodic preventive maintenance and malfunction history.
5. Critical utility systems are identified and back up availability is ensured.
6. The plan is evaluated and updated annually with aggregation and analysis of necessary data.

**Related standards:**

EFS.12 Water services, OGM.07 Supply Chain Management, QPI.02 Performance measures, OGM.09 Contracted services management.

**EFS.12 Water services are safe and effective.**

*Safety*

**Keywords:**

Water services

**Intent:**

Water delivery systems are essential components of the environment of care in ambulatory healthcare centers that must be continually maintained in a safe way.

Failure of safe water delivery will increase infection risk either directly through unsafe water consumption or use, or indirectly due to the inability of healthcare professionals to comply with basic infection control measures such as hand hygiene.

Water of appropriate quality used in the preparation of dialysis fluid is an essential component of hemodialysis and related therapies to protect hemodialysis patients from adverse effects arising from known chemical and microbiological contaminants found in water and improperly prepared dialysis fluid.

Safe water services are dependent upon maintenance of water quality standards employed by the community public water supplier, typically a municipality in the region of the ambulatory healthcare centers.

This responsibility to maintain water quality is transmitted to the facility once water enters the facility, and the facility is responsible of the water distribution infrastructure, this reflecting the complementary role for the facility's prevention of infections (refer to WHO

WASH PROGRAM).

The ambulatory healthcare center shall develop and implement a policy and procedures for the safe process of the management of water services that addresses at least the following:

- a. Routine maintenance and monitoring of water distribution and treatment systems.
- b. Continuing training and education of operators of water treatment systems.
- c. Monitoring of water at all stages (feed, product and dialysis water).
- d. Methods and frequency of measuring microbiological and chemical contaminants.
- e. Maximum allowable concentrations of microbiological contaminants.

**Survey process guide:**

- GAHAR surveyor may review the ambulatory healthcare center policy, followed by interviewing staff members to check their awareness of the policy.
- GAHAR surveyor may observe the accessibility of water on all premises.
- GAHAR surveyor may review chemical and bacteriological analysis reports for water services and dialysis water.
- GAHAR surveyor may assess corrective actions that were taken by the ambulatory healthcare center.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that addresses all the elements mentioned in the intent from a) through e).
2. The ambulatory healthcare center has available continuous water supply.
3. Regular chemical and microbiological analyses for water services and dialysis water are performed and recorded.
4. The ambulatory healthcare center conducts appropriate corrective actions when needed.

**Related standards:**

EFS.11 Utilities Management plan.

IPC.02 IPC program, IPC.04 Infection risk assessment.

**Safe emergency preparedness plan**

**EFS.13 Emergency preparedness plan addresses responding to disasters that have the potential of occurring within the geographical area of the ambulatory healthcare center.**

*Safety*

**Keywords:**

Disaster Plan.

**Intent:**

Last few decades have witnessed an increased frequency in disasters causing tremendous human casualties, in terms of loss of life and disability in addition to huge economic losses. Although these may not be totally preventable but their impact can be minimized by

effective planning. Equally important are the peripheral emergencies like road, rail and air accidents, fire, drowning and stampedes in mass gathering, industrial accidents, explosions and terrorist attacks that have an inherent potential to convert into a mass casualty incident. The loss of life and disability are compounded by the lack of adequate medical preparedness both qualitatively and quantitatively across the country. The ambulatory healthcare center shall develop a risk assessment tool to prioritize potential emergencies based on probability and impact and shall develop an emergency preparedness plan, the frequency of reviewing and updating the plan is done in accordance to the results of the current risk assessment and analysis. The emergency preparedness plan shall include at least the following

- a. Risk assessment of potential emergencies. Internal and external disasters, such as heavy rains, earthquake, floods, hot weather, wars, bomb threats, terrorist attacks, traffic accidents, power failure, fire, gas leakage.
- b. Risk assessment of potential epidemics and/or pandemics.
- c. Degree of preparedness according to the level of risk.
- d. Communication strategies: Internal communication may be in the form of Clear call tree that includes staff titles and contact numbers, and External communication channels may include civil defence, ambulance center, and police.
- e. Clear duties and responsibilities for ambulatory healthcare center leaders and staff.
- f. Identification of required resources such as utilities, medical equipment, medical, and non-medical supplies, including alternative resources.
- g. Response and recovery procedures:
  - i. Triageing.
  - ii. Staff main task is maintained in case of emergencies: management of clinical activities during a disaster such as operating theatre and intensive care units.
  - iii. Alternative care sites, and back-up utilities.
  - iv. Safe patient transportation in case of emergency is arranged by the ambulatory healthcare center.
- h. Drill schedule. The ambulatory healthcare center must have a drill schedule for emergencies at least annually and ensure the attendance of staff; Proper evaluation and recording of the drill includes, but is not limited to:
  - i. Scenario of the drill
  - ii. Observations on: code announcement, timing, staff attendance, response, communication, triaging, and clinical management.
  - iii. Clear corrective actions if needed.
  - iv. Feedback to the environmental safety committee.
  - v. Debriefing.

**Survey process guide:**

- GAHAR surveyor may review emergency preparedness plan and its records to confirm that it covered all the identified risks.

- GAHAR surveyor may review preparations in terms of equipment, medication, supplies, action cards and others during ambulatory healthcare center tours and tracers.
- GAHAR surveyor may interview staff to check their awareness of the plan.

**Evidence of compliance:**

1. There is approved ambulatory healthcare center emergency preparedness plan that includes items a) through h) in the intent.
2. Staff training is performed, tested, and evaluated.
3. The ambulatory healthcare center performs at least one drill annually that includes item (h) in the intent.
4. The ambulatory healthcare center demonstrates preparedness for identified emergencies.
5. The plan is evaluated regularly (at least annually) with aggregation and analysis of necessary data.

**Related standards:**

EFS.02 Fire and smoke safety, EFS.04 Fire drills, WFM.05 Orientation Program, QPI.03 Risk Management Program.

## Infection Prevention and Control

### Chapter intent:

Infection Prevention and Control (IPC) is a scientific approach and practical solution designed to prevent harm caused by infection to patients and/or health workers. It is grounded in infectious diseases, epidemiology, social science, and health system strengthening. IPC occupies a unique position in the field of patient safety and quality in Universal Health Coverage since it is relevant to health workers and patients at every single healthcare encounter.

The IPC program aims at identifying and reducing or eliminating the risks of acquisition and transmission of infections among patients, healthcare providers, workers, volunteers, visitors, and the community. Usually, the IPC program is risk-based; this means that a risk assessment is required to promptly identify and proactively address possible infection risks among individuals and in the environment. Then, solutions shall be tailored accordingly by developing appropriate policies and procedures, in conjunction with proper staff education.

Therefore, IPC activities shall differ from one organization to another, depending on the ambulatory healthcare center's clinical activities, the scope of services, and served patient population.

It is the responsibility of the IPC team members to oversee the IPC program, and they should all have detailed job descriptions. The staff member(s) shall be qualified enough to meet the ambulatory healthcare center needs. These needs are driven by the ambulatory healthcare center size, complexity of activities, and level of risks, as well as the program's scope. The required qualifications could be in the form of education, training, experience, and certification.

The IPC program and its activities are based on current scientific knowledge, the national guidelines, accepted international practice guidelines (CDC, APIC, IFIC), besides applicable laws and regulations. The program shall need to be planned, disseminated, taught, and monitored.

### Chapter purpose:

1. To ensure effective structure of infection prevention and control.
2. To address the standard precautions policies and procedures, implementation, and monitoring.
3. To highlight the environmental cleaning and disinfection activities.
4. To describe safe injection practices.
5. To explain the transmission-based precautions and patient placement.
6. To explain the infection prevention and control program in all supportive services



(CSSD, kitchen, laundry, and waste management).

7. To illustrate the preventive measures during construction and renovation.
8. To link infection control activities to the organizational quality program and determine needs for IPC improvements projects.

**Implementation guiding documents:**

(All mentioned references need to be read in the context of its conditions, amendments, substitutes, updates, and annexes)

1. National guidelines for infection control
2. MOHP Ministerial decree for developing infection prevention and control departments
3. MOHP Ministerial decree 187/2004 for infection control personnel
4. Presidential decree 14/2014 for performance evaluation
5. MOHP Ministerial decree 753 / 2015 for medical waste management
6. MOHP Ministerial decree 153 / 2004 for prevention of viral hepatitis
7. MOHP Ministerial decree 523 / 2015 for reuse of single used devices and instruments
8. The Egyptian code for healthcare facilities design
9. Egyptian law of the Environment.

## **Efficient structure of the infection prevention and control program**

**IPC.01 Dedicated and qualified healthcare professional(s) oversees the infection prevention and control activities according to applicable laws and regulations, national and international guidelines.**

*Effectiveness*

**Keywords:**

IPC assigned team.

**Intent:**

The presence of a qualified and dedicated IPC professional(s) in the ambulatory healthcare center ensures increased effectiveness of the IPC program in all its phases including development, implementation, and monitoring.

The ambulatory healthcare center shall assign a qualified team to be responsible for all activities related to the IPC program, supervise, put an action plan to implement this program, and educate all staff members on their roles.

The team members' qualifications and numbers shall meet the ambulatory healthcare center needs. These needs are driven by the ambulatory healthcare center size, complexity of activities, and level of risks, as well as the program's scope.

**Survey process guide:**

- GAHAR surveyors may review the infection control structure in the organization chart.
- GAHAR surveyor may interview IPC team and inquire about their qualifications and check their awareness of their job description

**Evidence of compliance:**

1. The ambulatory healthcare center has an assigned dedicated IPC team.
2. The IPC team leader and each member has a defined job description.
3. The IPC Team members are qualified by certification and education that match their job description requirements.
4. The IPC team member(s) effectively communicate with the top management and all other relevant departments\disciplines.

**Related standards:**

IPC.02 IPC program, IPC.03 IPC committee, meetings, WFM.03 Job Description, WFM.04 Verifying credentials, OGM.02 Ambulatory healthcare center director.

## **IPC.02 A comprehensive infection prevention and control program is developed, implemented, and monitored.**

*Safety*

### **Keywords:**

IPC program.

### **Intent:**

Previously, the risk of healthcare associated infections (HAI) in ambulatory setting are relatively low because there are less invasive procedures conducted. Recently, patients are being increasingly treated in ambulatory settings because of the shift in delivery from hospitals to alternative ambulatory settings. In addition, invasive procedures and advanced technologies are being used with increasing frequency in healthcare settings. All these factors increase the potential risk for HAI in ambulatory settings.

Therefore, healthcare-associated infections can be a common risk encountered in any ambulatory healthcare center. Consequently, constructing a comprehensive IPC program is of utmost importance to effectively reduce these risks.

The IPC program is an integrated part of quality improvement and patient safety programs, using measures that are epidemiologically important to the ambulatory healthcare center. The IPC program must be based on the annual ambulatory healthcare center risk assessment plan, national and international guidelines such as CDC, APIC, IFIC, etc., accepted practices, and applicable laws and regulations.

An effective IPC program must be comprehensive and include all aspects of patient care, staff health, and the entire services provided by the ambulatory healthcare center such as (hand hygiene guidelines implementation, antimicrobial stewardship, safe injection, etc.).

The program shall also assure the education and training of all working staff members and provide necessary education to patients, visitors, and families.

Measurement information is essential to improve infection prevention and control activities and reduce healthcare-associated infection rates. Thus, the ambulatory healthcare centers can best use measurement data and information by understanding similar rates and trends in other similar organizations.

Each ambulatory healthcare center can design its own performance measures to monitor, assess, and improve the IPC program. Examples of performance measures include the percentage of hand hygiene compliance and the results of sterilization monitoring.

### **Survey process guide:**

- GAHAR surveyor may review the infection control program to evaluate the presence of a risk assessment, Risk assessment based-IPC program that covers all ambulatory healthcare center areas and includes all relevant individuals, a training plan or an annual evaluation report and update of the IPC program.

- GAHAR surveyor may review the documentation of monitoring of data, performance measures, data analysis reports, recommendations for improvement and observe the implementation.

**Evidence of compliance:**

- The ambulatory healthcare center has a program that includes the scope, objectives, expectations, and surveillance methods.
- The program included all areas of the ambulatory healthcare center and covers patients, staff, visitors according to the scope of ambulatory center.
- The IPC. Program includes a training plan for all staff.
- The ambulatory healthcare center tracks, collects, analyzes, and reports data on its infection control program.
- The ambulatory healthcare center acts on improvement opportunities identified in its infection control program.

**Related standards:**

IPC.01 IPC assigned team, IPC.03 IPC committee, meetings, IPC.04 Infection risk assessment, OGM.02 Ambulatory healthcare center director, QPI.02 Performance measures, WFM.06 continuous education program, QPI.08 Performance improvement and patient safety plan.

**IPC.03 The ambulatory healthcare center establishes a functioning multidisciplinary IPC committee that meets at least monthly.**

*Effectiveness*

**Keywords:**

IPC committee, meetings.

**Intent:**

IPC challenges continuously arise in the different ambulatory healthcare center disciplines, which in turn provide input for the IPC team for their continuous evaluation of the situation. There is a structured infection control committee; all relevant disciplines should be represented in the committee for example (but not limited to), medical department, nursing services, housekeeping, laboratory, pharmacy, and sterilization services etc., and the committee should have the right to summon whoever it deems appropriate.

The IPC committee is responsible for at least the following:

- Setting criteria to define ambulatory healthcare center associated infections.
- Surveillance methods and processes.
- Strategies to prevent infection and control risks.
- Reporting infection prevention and control activities.

**Survey process guide:**

- GAHAR surveyor may review the committee matrix, Terms of References and may review a sample of monthly minutes of meeting.
- GAHAR surveyor may review evidence of recommendations follow up and implementation.

**Evidence of compliance:**

1. There are clear terms of reference for the infection control committee that includes at least from (a) to (d) in the intent.
2. The committee meets at least monthly.
3. The committee meetings are recorded.
4. Recommendations taken by the committee are implemented and followed up at the end of each meeting.

**Related standards:**

IPC.01 IPC assigned team. IPC.02 IPC program, IPC.04 Infection risk assessment, OGM.02 Ambulatory healthcare center director, IMT.01 Documentation management system.

**IPC.04 The ambulatory healthcare center identifies the procedures and processes that are associated with an increased risk of infection.**

*Safety*

**Keywords:**

Infection risk assessment.

**Intent:**

The ambulatory healthcare center assesses and cares for patients using many simple and complex processes, each being associated with a particular level of infection risk to patients and staff. On the other hand, ambulatory healthcare settings can receive efflux and clustering of patients and may have significant number of patients in common waiting areas.

Therefore, it is important for the ambulatory healthcare center to assess and review those processes and, as appropriate, implement the required strategies, such as policies, procedures, education, and evidence-based activities, to reduce this risk.

The ambulatory healthcare center identifies the procedures associated with increased risk by defining policies, procedures followed by staff education, and evidence-based activities, to reduce these identified risks.

**Survey process guide:**

- GAHAR surveyor may review IPC risk assessment and analysis with focusing on the high risk procedures and processes.
- GAHAR surveyor may interview responsible staff to check their awareness of risk of infection identification and mitigation.

**Evidence of compliance:**

1. The ambulatory healthcare center has a process that identify departments, services, procedures with increased potential risk of infection.
2. Responsible staff is aware of process implemented for risk identification, mitigation and reporting.
3. The ambulatory healthcare center tracks, collects, analyzes, and reports data of infection

risk assessment and analysis.

4. The ambulatory healthcare center acts on improvement opportunities identified in its infection assessment and analysis process.

**Related standards:**

EFS.06 Safety Management Plan IPC.02 IPC program IPC.03 IPC committee, QPI.03 Risk Management Program, QPI.02 Performance measures, QPI.08 Performance improvement and patient safety plan.

**Safe standard precautions**

**IPC.05 NSR.03 Evidence-based hand hygiene guidelines are adopted and implemented throughout the ambulatory healthcare center to prevent healthcare-associated infections.**

Safety

**Keywords:**

Hand Hygiene.

**Intent:**

Hand hygiene is the cornerstone for reducing infection transmission in all healthcare settings. Therefore, hand hygiene practices in ambulatory care settings are the same in any other healthcare facility and it is considered the most effective and efficient strategy for infection prevention and control. Hand hygiene facilities should be present in appropriate numbers. Hand hygiene supplies (hand soap, hand antiseptics, and single-use towels) must be present in the appropriate places. Alcohol-based hand rubs are now the preferred products for routine hand hygiene in healthcare facilities, unless hands are visibly soiled, to overcome the shortage in sinks.

**Survey process guide:**

- GAHAR surveyor may review the hand hygiene policy hand hygiene guidelines.
- GAHAR surveyor may review hand hygiene education posters and records.
- GAHAR surveyor may interview ambulatory healthcare center staff, to check their awareness of hand hygiene technique and WHO five moments of hand hygiene.
- GAHAR surveyor may observe hand-washing facilities at each patient care area and check availability of supplies (soap, tissue paper, alcohol hand rub, etc.).
- GAHAR surveyor may observe compliance of healthcare professionals with hand hygiene technique and WHO five moments of hand hygiene.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved hand hygiene policies and procedures based on evidence-based guidelines.
2. Healthcare professionals are trained on how to apply this policy.
3. Hand hygiene posters are displayed in required areas, as per center policy.

4. Hand hygiene facilities are available in numbers and places, as per center policy.
5. Compliance of healthcare professionals with hand hygiene policy is monitored.
6. Results of staff compliance are linked and documented in staff appraisal\ evaluation process.

**Related standards:**

IPC.02 IPC program, IPC.03 IPC committee IPC.04 Infection risk assessment, WFM.06 Continuous Education Program, QPI.02 Performance measures, QPI.08 Performance improvement and patient safety plan, WFM.07 Staff performance evaluation.

**IPC.06 Standard precautions measures and the minimum infection prevention practices apply in any settings where healthcare is delivered.**

*Safety*

**Keywords:**

Standard precautions measures.

**Intent:**

According to CDC, standard precautions are the minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where health care is delivered. In addition to hand hygiene, standard precautions include:

- a. Use of Personal Protective Equipment (PPE) (e.g., gloves, masks, eyewear).
- b. Use of antiseptics techniques.
- c. Respiratory hygiene / cough etiquette.
- d. Clean and disinfected environmental surfaces.

Proper selection of standard precautions depends on risk assessments that are performed at the points of care, and according to the patient's suspected infection so staff education and training are therefore of utmost importance.

**Survey process guide:**

- During GAHAR Survey, the surveyor may check the availability and accessibility of PPE and may interview staff members to inquire about the constant availability, accessibility and proper use of PPE
- GAHAR surveyor may review PPE standardized products specifications.

**Evidence of compliance:**

1. The ambulatory healthcare center has PPE that is easily accessible and available.
2. Selection and use of PPE are based on the risk assessments that are performed at the points of care and according to the patient's suspected infection.
3. Responsible staff is aware of PPE proper use and disposal.

**Related standards:**

EFS.06 Safety Management Plan, IPC.02 IPC program, IPC.04 Infection risk assessment, IPC.07 Respiratory hygiene protocol, cough etiquette, QPI.03 Risk Management Program, DAS.07 Radiation safety program.

**IPC.07 Respiratory hygiene is implemented as an element of standard precautions.**

*Safety*

**Keywords:**

Respiratory hygiene protocol, cough etiquette

**Intent:**

Respiratory hygiene and cough etiquette interventions are intended to limit the spread of infectious organisms from persons with potentially undiagnosed respiratory infections.

For respiratory hygiene interventions to be effective, early implementation of infection prevention and control measures needs to exist at the first point of entry to the ambulatory healthcare center and be maintained throughout the duration of the stay.

The effort of respiratory hygiene interventions shall be targeted at patients and accompanying persons with respiratory symptoms and applies to any person entering an ambulatory healthcare center with signs of respiratory illness including cough, congestion, rhinorrhea, or increased production of respiratory secretions.

**Survey process guide:**

- During GAHAR Survey, the surveyor may observe the availability of respiratory hygiene/ cough etiquette posters in the appropriate places, accessibility and use of detergents, antiseptics, and disinfectants in the relevant areas and the availability, and accessibility of the relevant resources in proper places.
- During GAHAR Survey, the surveyor may observe assigned areas for patients with suspected respiratory infections and the implementation of respiratory patient placement.

**Evidence of compliance:**

1. Respiratory hygiene /cough etiquette posters are displayed at appropriate places.
2. Resources such as tissues and surgical masks are available in numbers matching patients' and staff members' needs.
3. Ambulatory healthcare centers designate space for patients with suspected respiratory infections to separate them from others.
4. Patients with suspected respiratory infections are identified and placed in designated areas.

**Related standards:**

IPC.02 IPC program, IPC.04 Infection risk assessment, IPC.06 Standard precautions measures



## **IPC.08 The ambulatory healthcare center ensures safe injection practices.**

*Safety*

### **Keywords:**

Safe injection practices.

### **Intent:**

In the ambulatory healthcare centers, patients are continuously in need for injections whether for diagnostic or therapeutic purposes, unfortunately however it carries an associated risk of infection for the patients. In addition to needle stick, injuries among healthcare professionals are a common accident and, unsafe injection practices are associated with transmission of blood borne pathogens.

Accordingly, safe injection practices are crucial to ensure both patient and healthcare professionals' safety.

Healthcare professionals must always use a sterile, single-use disposable syringe, needle for each injection given, and ensure that all injection equipment and medication vials remain free from contamination.

### **Survey process guide:**

- During GAHAR Survey, the surveyor may observe the availability of Intravenous bottles and their proper use, and of single dose vials and the proper use of multi-dose vials.
- GAHAR surveyor may interview staff to check their awareness of safe injection practices

### **Evidence of compliance:**

1. Intravenous bottles/bags, single use fluids infusion /administration sets (e.g., tubing and connections) are disposed directly in-between patients
2. Use of multi-dose vials is done in accordance to the manufacturers' recommendations to ensure that vials are remained free from contamination.
3. The ambulatory healthcare center ensures that all staff are trained and aware of safe injection practices.

### **Related standards:**

EFS.05 Hazardous materials safety, EFS.06 Safety Management Plan, IPC.02 IPC program, IPC.04 Infection risk assessment, IPC.06 Standard precautions measures QPI.03 Risk Management Program

## **IPC.09 Environmental cleaning activities are aligned with current evidence-based guidelines.**

*Safety*

### **Keywords:**

Environmental cleaning activities.

### **Intent:**

The healthcare environment is considered a reservoir for pathogens and may be a significant source of healthcare-associated infections so, cleaning and disinfection of environmental surfaces is an important tool to prevent the development of these infections.

Contact with contaminated surfaces in the ambulatory healthcare center can easily lead to cross-contamination of microorganisms between the environment and healthcare professionals

To provide quality of care, the ambulatory healthcare center shall develop a clear method and schedule for environmental cleaning and disinfection including walls, floors, ceilings, and furniture, this must be performed according to the classification of areas.

The environmental cleaning schedule must address the cleaning activities for each area as follows:

- a. Activities to be done every day.
- b. Activities to be done every shift.
- c. Deep cleaning activities

### **Survey process guide:**

- During GAHAR Survey, the surveyor may review the list of all environmental services that require cleaning, cleaning schedules, and spill kits.
- During GAHAR Survey, the surveyor may interview healthcare professionals and environmental cleaning staff members to inquire about the availability, accessibility and use of disinfectant, and spill kits properly.

### **Evidence of compliance:**

1. Cleaning activities with determined times are listed for each area and include all elements mentioned in the intent from a) through c).
2. Responsible staff is trained on the process of environmental cleaning activities that include; availability, accessibility, use of disinfectant, and spill kits.
3. Disinfectants selection and cleaning methods used are matching the requirements of each cleaning area.

### **Related standards**

EFS.05 Hazardous materials safety, IPC.02 IPC program, IPC.04 Infection risk

## **IPC.10 Current evidence-based aseptic techniques are followed during all medical procedures.**

*Safety*

### **Keywords:**

Aseptic techniques.

### **Intent:**

Aseptic technique refers to practices designed to render and maintain objects and areas maximally free from microorganisms.

The term 'aseptic technique' encompasses several key elements: clean environment, conscientious practicing of hand hygiene, use of appropriate personal protective equipment, and use of standardized routine cleaning, disinfection, and sterilization practices.

All healthcare professionals shall be cognizant of their movement, barrier use, and practices to prevent inadvertent breaks in aseptic techniques, alerting others when the field or objects are potentially contaminated. Choice of the level of antisepsis shall be risk assessment based. Asepsis is defined as the process of keeping away disease-producing microorganisms. The ambulatory healthcare center shall develop a policy for aseptic techniques that define and outline the procedures including at least the following:

- a. Surgical asepsis is the use of a sterile technique to prevent the transfer of any organisms from one person to another or from one body site to another. The goal of the sterile technique is to maintain the microbe count at an irreducible minimum.
- b. Surgical aseptic technique outside of the operating room refers to a practice in a setting outside the operating room that may not have the capacity to follow the same strict level of surgical asepsis applied in the operating room. However, the goal to avoid infection remains in all clinical settings.
- c. Medical asepsis, or clean technique refers to practice interventions that reduce the number of microorganisms to prevent and reduce transmission risk from one person (or place) to another.

### **Survey process guide:**

- GAHAR surveyor may review the policy for aseptic techniques.
- GAHAR surveyor may interview healthcare professionals to check their awareness of the policy and to assess that the implementation is done as relevant to their jobs.

### **Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy for aseptic techniques that defines items from a) to c) in the intent.
2. Healthcare professionals are trained on how to implement the aseptic techniques, as relevant to their jobs.
3. Choice of the level of antisepsis is based on the IPC Risk assessment and analysis.

**Related standards:**

IPC.02 IPC program, IPC.04 Infection risk assessment, IPC.06 Standard precautions measures, QPI.03 Risk Management Program, WFM.06 Continuous education program.

**Safe transmission-based precautions and precautions for immunocompromised hosts**

**IPC.11 Patients with clinically suspected and/or confirmed communicable diseases follow isolation precautions according to probable mode(s) of transmission.**

*Safety*

**Keywords:**

Isolation precautions.

**Intent:**

In addition to standard precautions, transmission-based precautions are used for patients known or suspected to be infected or colonized with certain infectious agent. Isolation precautions create barriers between people and microorganisms that help in preventing the spread of germs in the ambulatory healthcare center.

If the patient is determined to be at an increased risk for transmission of microorganisms, the patient is placed in the ambulatory healthcare center's standardized isolation room. The ambulatory healthcare center must have one or more standardized isolation room(s)

When the standardized isolation room(s) is not currently available, the patient should be separated into separate assigned areas/rooms.

Patients who present with clinical respiratory syndromes are instructed to practice respiratory hygiene and cough etiquette and given a surgical mask to wear until an examination room can be provided.

The ambulatory healthcare center shall develop a policy to identify patients with known or suspected airborne infections. Patients requiring airborne precautions are placed in a negative pressure room. If a negative pressure room is not available, place the patient in an examination room with a portable high-efficiency particulate air (HEPA) filter. If no portable HEPA filter is available, ensure that the patient wears a surgical mask. Regardless of the type of patients' room, contacting staff must always wear appropriate respiratory protection (as N95 respirator).

The safe handling of the contaminated surfaces and equipment in ambulatory healthcare settings should be done according to evidence based guidelines, approved policies and procedures.

**Survey process guide:**

- GAHAR surveyor may review the policy for infection transmission-based precautions.
- GAHAR surveyor may interview staff to check their awareness of the policy.

- GAHAR surveyor may observe the isolation room(s)
- GAHAR surveyor may observe the adherence of healthcare professionals to the suitable PPE and hand hygiene practices according to the type of isolation.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy to guide transmission-based precautions.
2. Healthcare professionals are trained and aware of the approved policies.
3. Standardized isolation room(s) and assigned areas for suspected infectious patient is designated according to the center capacity and the national laws and regulations.
4. Patients with suspected/ confirmed clinical communicable diseases are identified and separated in separate assigned areas/rooms
5. Healthcare professionals caring for patients with a suspected communicable disease are adherent to suitable PPE and hand hygiene practices according to the type of isolation.

**Related standards:**

IPC.02 IPC program, IPC.04 Infection risk assessment, IPC.06 Standard precautions measures, WFM.06 Continuous Education Program, QPI.03 Risk Management Program, IPC.07 Respiratory hygiene protocol, cough etiquette, EFS.01 Ambulatory healthcare center environment and facility safety structure.

**IPC.12 A safe and protective environment is provided to immunocompromised hosts depending on their clinical needs.**

*Safety*

**Keywords:**

Protective environment for immunocompromised hosts.

**Intent:**

An immunocompromised host is an individual who has one or more defects in the body's normal defense mechanisms which predisposing him/her to infections, which may be life threatening or due to intake of immunosuppressive agents.

There are several categories of immunity compromise and some patients may have more than one type.

The ambulatory healthcare center shall develop a policy of protective environment for immunocompromised hosts to define at least the following:

- a. The protective environment shall be provided for immunocompromised patients including positive-pressure, high-efficiency particulate absorption-filtered air handling as well as Legionella-free water supply.
- b. Required training of responsible staff including, taking care of these patients, use of standard precautions as well as transmission-based precautions conditions\ situations.
- c. Signage locations and positions, it is preferred to be prominently outside the room of

a patient in transmission-based precautions. This is to ensure staff and visitors do not enter without appropriate PPE.

**Survey process guide:**

- GAHAR surveyor may review the policy of protective environment for immunocompromised hosts.
- GAHAR surveyor may interview the responsible staff to check their awareness of transmission-based precautions.
- GAHAR surveyor may observe the center design and provision of protective environment to immunocompromised hosts.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy of protective environment for immunocompromised hosts to define items from a) to c) in the intent.
2. Responsible staff is aware and trained on transmission-based precautions.
3. Facility design supports the provision of a safe environment for immunocompromised hosts
4. Signage is positioned prominently outside the room of a patient in transmission-based precautions.
5. Transmission-based precautions are performed as per center policy.

**Related standards:**

EFS.01 Ambulatory healthcare center environment and facility safety structure, IPC.02 IPC program, IPC.04 Infection risk assessment, IPC.06 Standard precautions measures, QPI.03 Risk Management Program.

**Disinfection and sterilization**

**IPC.13 Patients care equipment are disinfected/sterilized based on evidence-based guidelines and manufacturer recommendations.**

*Safety*

**Keywords:**

Disinfection, sterilization.

**Intent:**

Processing of patient care equipment is a very critical process inside any healthcare facility. Ambulatory health care settings should perform semi-critical to critical reprocessing of the medical instruments according to applicable standard practices, guidelines, and regulations. In case of dental centers, the sterilization process for all critical dental instruments and heat-stable semi-critical instruments should be done by steam sterilization or dry heat sterilization according to manufacturer instructions for sterilizers and autoclaves. Some dental instruments such as "Contra" should be sterilized by steam sterilizer, and it is prohibited to

sterilized by hot oven sterilizer or chemical sterilizer.

The ambulatory healthcare center shall develop and implement a policy and procedures to guide the process of sterilization/disinfection that addresses at least the following:

- a. Receiving and cleaning of used items.
- b. Preparation and processing.
  - i. Processing method to be chosen according to Spaulding classification. Disinfection of medical equipment and devices involves low, intermediate, and high-level techniques. High-level disinfection is used (if sterilization is not possible) for only semi-critical items that come in contact with mucous membranes or non-intact skin as gastrointestinal endoscopes, respiratory and anesthesia equipment, bronchoscopes, and laryngoscopes etc. Chemical disinfectants approved for high-level disinfection include glutaraldehyde, ortho-phthaldehyde (OPA), and hydrogen peroxide.
  - ii. Sterilization must be used for all critical and heat-stable semi-critical items.
  - iii. Low-level disinfections (for only non-critical items) are used for items such as stethoscopes and other equipment that touching intact skin. In contrast to critical and some semi-critical items, most non-critical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area.
- c. Labeling of sterile packs.
- d. Storage of clean and sterile supplies: properly stored in designated storage areas that are clean, dry, and protected from dust, moisture, and temperature extremes. Ideally, sterile supplies are stored separately from clean supplies, and sterile storage areas must have limited access.
- e. Logbooks are used to record the sterilization process.
- f. Inventory levels.
- g. Expiration dates for sterilized items.

**Survey process guide:**

- GAHAR surveyor may review the policy for disinfection \sterilization process.
- GAHAR surveyor may interview the responsible staff to check their awareness of the policy.
- GAHAR surveyor may observe the physical barriers between cleaning, packaging, sterilizations and storage areas. the surveyor may observe the number of functioning pre-vacuum class B sterilizers and the presence of physically separated areas according to the standard with unidirectional airflow.
- GAHAR surveyor may observe clean and sterile supplies store to check for proper storage.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy to guide the process of disinfection and sterilization that addresses all elements in the intent from a) through g).

2. Healthcare professionals are trained on the approved policy.
3. Sterilization or disinfection process is performed according to the national laws and regulations, Spaulding classification, and manufacturer's requirements\recommendations.
4. Clean and sterile supplies are properly stored in designated storage areas that are clean, dry and protected from dust, moisture, and temperature extremes.

**Related standards:**

IPC.02 IPC program, IPC.04 Infection risk assessment, IPC.14 Disinfection/Sterilization quality control program, WFM.06 Continuous education program, OGM.07 Supply chain management.

**IPC.14 A disinfection/sterilization quality control program is developed and implemented**

*Safety*

**Keywords:**

Disinfection/Sterilization quality control program.

**Intent:**

Managing of the routine quality control (QC) of medical equipment disinfection/sterilization is a major responsibility to monitor and ensure the reliability of the disinfection/sterilization processes. Moreover, quality controls can identify performance problems that are not identified automatically and help to determine the safety of procedures.

QC management includes developing the protocols, implementation of the program, oversight of the program, and responsibility for determining the need for corrective action. QC data shall be reviewed at regular intervals and shall be recorded. Outliers or trends in performance, that may indicate problems in the disinfection/sterilization process, shall be analyzed, followed up and preventive actions shall be taken and recorded before major problems arise.

The ambulatory healthcare center shall develop and implement a policy for quality control, which includes at least the following:

- a. Quality control elements, method and frequency include
  - i. Physical parameters (temperature, time, and pressure), which are monitored every cycle.
  - ii. Chemical parameters (internal chemical indicator inside the sterilization pack-external chemical indicator on the outside of the sterilization pack), which are monitored every pack.
  - iii. Biological indicator, which is done at least weekly.
  - iv. The test for adequate steam penetration and rapid air removal shall be done every day before starting to use the autoclave using Class 2 internal chemical indicators and process challenge devices, which is either porous challenge device or hollow challenge device.



- v. Porous challenge Pack: Bowie-Dick Sheets (class 2 indicator) inside a porous challenge pack (every load). Hollow load challenge (Helix test): a class 2 chemical indicator (strip) inside a helix (every load).
- vi. Chemical test strips or liquid chemical monitors shall be used for determining whether an effective concentration of high-level disinfectants is present despite repeated use and dilution. The frequency of testing shall be based on how frequently these solutions are used.
- b. Quality control performance expectations and acceptable results shall be defined and readily available to staff so that they will recognize unacceptable results to respond appropriately.
- c. The quality control program is approved by the designee prior to implementation.
- d. Responsible authorized staff member reviews Quality Control results at a regular interval.
- e. Remedial actions taken for deficiencies identified through quality control measures and corrective actions taken accordingly.

**Survey process guide:**

- GAHAR surveyor may review policy for quality control of disinfection/sterilization process.
- GAHAR surveyor may interview staff involved in sterilization/disinfection process to check their awareness on quality control performance.
- GAHAR surveyor may observe quality control procedures in disinfection/sterilization areas
- GAHAR surveyor may review logbooks for chemical indicators and biological indicators documentation

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy describing the quality control process of disinfection/sterilization process addressing all elements in the intent from a) through e).
2. Quality of packaging material, as well as chemical and biological indicators, are determined based on standardized product specifications.
3. Staff who involved in sterilization/disinfection are competent in quality control performance.
4. Quality control tests for monitoring sterilization and high-level disinfectants are done regularly as per center policy.
5. Corrective action is taken whenever results are not satisfactory.

**Related standards:**

IPC.02 IPC Program, IPC.13 Disinfection, sterilization QPI.03 Risk Management Program, WFM.07 Staff performance evaluation, OGM.07 Supply chain management.

## Safe laundry and healthcare textile management

### IPC.15 Laundry service and healthcare textile management are safe.

Safety

#### Keywords:

Laundry service, textile management.

#### Intent:

Contaminated healthcare textiles can be a major source of pathogenic microorganisms that can be acquired by improper handling of healthcare textile or by direct contact with the patient.

The provision of healthcare textiles is essential and rigorous standards must be followed during the reprocessing of the textiles to reduce the risk of infection and ensure the patient safety. Physically separated areas for sorting, washing, and drying, and/or storing of laundry is needed.

The ambulatory healthcare center shall develop and implement a policy and procedures to define laundry and healthcare textile services that address at least the following:

- a. Processes of collection and storage of contaminated textiles.
- b. Cleaning of contaminated textiles.
- c. Number of washing machines needed according to center capacity.
- d. Water temperature, detergents, and disinfectants usage.
- e. Processes of storage and distribution of clean textile.
- f. Quality control program (temperature, amount of detergents and disinfectants used, and maintenance) for each washing machine.

#### Survey process guide:

- GAHAR surveyor may review policy for safe laundry and healthcare textile services management.
- GAHAR surveyor may interview staff involved in laundry and health textile management to check their awareness of the process.
- GAHAR surveyor may observe laundry and health textile management' area to check for presence of physical barriers between sorting, washing, and drying, and/or storing of laundry.
- GAHAR surveyor may review records of water temperature, detergents and disinfectants amount and other quality control records.

#### Evidence of compliance:

1. The ambulatory healthcare center has an approved policy to guide the safe laundry and healthcare textile services management that addresses all elements in the intent from a) through f).
2. Staff members involved in laundry and health textile management are aware of the approved policy.

3. Contaminated textile is collected, stored, and transported safely.
4. There are at least three physically separated areas for sorting, washing, and drying, and/or storing of laundry.
5. A quality control program, including water temperatures, is implemented, and recorded.

**Related standards:**

EFS.01 Ambulatory healthcare center environment and facility safety structure, IPC.02 IPC program, IPC.04 Infection risk assessment, QPI.03 Risk Management Program

**Effective epidemiological surveillance and monitoring**

**IPC.16 Healthcare-associated infections surveillance processes and outbreak investigations are implemented.**

*Effectiveness*

**Keywords:**

Infection surveillance process.

**Intent:**

Surveillance is an essential component of any effective IPC program that contributes to improving the healthcare quality system and helps in detecting emerging and reemerging of healthcare-associated infections. The effective surveillance program shall be based on comprehensive epidemiological and statistical principles.

Surveillance plays a critical role in identifying outbreaks, emerging infectious diseases, and multidrug-resistant organisms to institute appropriate IPC measures.

Outbreaks of infectious diseases can occur in healthcare settings and pose a threat to patient safety. The outbreak investigations aims to identify the most probable contributing factors to stop the outbreaks and prevent their recurrence. Outbreaks can be suspected in cases of increased rate of healthcare-associated infections or when new or unusual pathogens are recovered from samples. Effective management of outbreaks shall require cooperation between the infection prevention and control team and other clinical specialties. Outbreak management shall include immediate control measures, general control measures, and recovery measures.

**Survey process guide:**

- GAHAR surveyor may review the policy of surveillance process and types.
- GAHAR surveyor may interview staff to check their awareness of the surveillance process.
- GAHAR surveyor may review surveillance documents, quarterly surveillance reports that are reviewed by the IPC committee and recommendations for improvement
- GAHAR surveyor may review the reporting system for notifiable communicable diseases and outbreaks investigation analysis reports

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy to guide the surveillance process.
2. Responsible staff is trained on how to apply the policy.
3. The ambulatory healthcare center has an approved process for outbreak investigations.
4. Outbreak management includes immediate control measures, general control measures, and recovery measures.
5. Data collected from the surveillance program is analyzed, investigated and acted upon

**Related standards:**

IPC.02 IPC program, IPC.03 IPC committee, meetings IPC.04 Infection risk assessment  
IPC.17 Multi-Drug Resistant Organisms, QPI.02 Performance measures, IPC.06 Standard precautions, IPC.11 Isolation precautions.

**IPC.17 Multi-drug resistant organisms (MDROs) are controlled.**

*Safety*

**Keywords:**

Multi-Drug Resistant Organisms.

**Intent:**

MDROs have increased in prevalence over the last three decades and have become a global health-threatening problem and cause important implications for patients' safety.

This concern is due to the extremely limited treatment options for treating patients with these infections.

In addition, MDRO infections are associated with increased lengths of stay, costs, and mortality.

The ambulatory healthcare center shall develop a policy that describes the methods of successful prevention and control of MDROs, which require effective administrative and scientific leadership as well as a financial and human resources commitment.

Resources shall be provided for infection prevention and control, including expert consultation, laboratory support, adherence monitoring, and data analysis to prevent transmission.

**Survey process guide:**

- GAHAR surveyor may review policy of MDRO spread control.
- GAHAR surveyor may interview healthcare professionals to check their awareness of MDRO spread control policy.
- GAHAR surveyor may observe the taken measures to control MDRO spread.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy for MDRO spread control.
2. Healthcare professionals are fully aware and trained on the approved policy.
3. Measures are taken to control MDRO infection spread

**Related standards:**

IPC.02 IPC program, IPC.03 IPC committee, meetings IPC.04 Infection risk assessment  
IPC.16 Infection surveillance process. MMS.01 Medication management

## Organization Governance and Management

### Chapter intent

This chapter is concerned with structures for governance and accountability that may differ according to the ambulatory healthcare center and its size, mandate, and whether it is publicly or privately owned. Possible structures include an individual or group owner, government committee or ministry, or Board of Directors. Having a defined governing body structure provides clarity for everyone in the ambulatory healthcare center, including managers, clinical leadership, and staff, regarding who is accountable for making final decisions and oversight of The ambulatory healthcare center's overall direction. While governance provides oversight and support, it is the commitment and planning efforts of the ambulatory healthcare center leadership as well as the departments and services leaders that ensure the smooth and efficient management of the ambulatory healthcare center.

Effective planning initiated by identifying the stakeholders' needs and designing the service accordingly, the ambulatory healthcare center's plans should continuously be aligned with the governmental initiated campaigns addressing therapeutic, prophylactic, social, and nutritional aspects of healthcare. The chapter guides the ambulatory healthcare center to assign duties to the different levels of management and to ensure effective communication to achieve planned goals and objectives.

Recently the landscape of healthcare is shifting closer to a fully quality-driven future and pay for performance model. The chapter has focused on the financial side of healthcare, a focus that affects both patients and providers. With value-based care and higher levels of efficiency on the rise, the keys to medical practice success are evolving rapidly. The chapter handles various organization-wide topics as contracted services, ethical management, and staff engagement, which may reflect the efficient and effective collaborative management efforts.

GAHAR surveyors, through leadership/ staff interviews, observations, and process evaluation, shall assess the efficiency and effectiveness of the governing body and leadership structure. The ability of leaders to motivate and drive the staff is instrumental for the success of an ambulatory healthcare center and can be assessed throughout the survey.

### Chapter purpose:

The chapter focuses on checking the ambulatory healthcare center structure to determine the following:

1. Effectiveness of governing body
2. Effectiveness of direction
3. Effectiveness of leadership
4. Effectiveness of financial stewardship

5. Efficient contract management
6. Ethical management
7. Effective staff engagement, health, and safety

**Implementation guiding documents:**

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes.)

1. Egyptian Constitution
2. Egypt 2030 vision, Ministry of Planning
3. Law 51/1981 organization healthcare facilities
4. MOHP Ministerial 186/2001 Patient right to know the expected cost of care
5. Law 181/2018 on Egyptian Consumer Protection
6. Egyptian standards for accounting, 609/2016
7. Women council publications on gender equality
8. Professional code of ethics—prime minister decree 238, the year 2003
9. Law 206/2017 on advertisement for healthcare services
10. National Labor Law
11. WHO-ILO Health-WISE action manual
12. Staff Health and Safety regulations

## Effective governing body

### **OGM.01 The ambulatory healthcare center has a governing body structure with identified responsibilities.**

*Effectiveness*

#### **Keywords:**

Governing body Structure and clear responsibilities.

#### **Intent:**

The governing body is responsible for defining the ambulatory healthcare center's direction and ensuring the alignment of its activity with its purpose. It is also responsible for monitoring its performance and future development. Ambulatory healthcare center governing body can be a group of individuals (such as board of directors), one or more individual owners and in a centralized system several subsidiary centers are governed by one governing body, in order to ensure the proper governance and efficient management of any resources thus its structure has to be well defined. Therefore, defining the governing structure of an ambulatory healthcare center that shows lines of authority and accountability and ensures that it operates effectively and efficiently.

The mission statement is a description of any ambulatory healthcare center's core purpose. Defining the main purpose of the ambulatory healthcare center in the form of a mission is one of the fundamental roles of the governing body, as the ambulatory healthcare center's mission must be aligned with the national healthcare mission and communicated to the all relevant stakeholders, including staff, patients, and visitors.

The ambulatory healthcare center shall develop a policy that describes the structure responsibilities and accountabilities of the governing body. The governing body responsibilities includes at least the following:

- a. Developing and disseminating the mission statement
- b. Developing and achieving the strategic plan
- c. Developing the operational plan and budget
- d. Promoting and supporting the quality management, patient safety and risk management programs and performance improvement plan
- e. Allocating resources and effective financial planning
- f. Promoting and monitoring safety culture activities and reports.
- g. Responsiveness to internal and regulatory inspection reports.

The governing entity shall be represented or displayed in an organizational chart or other similar document with clear determination of the flow of orders through the approved line of authority.

Ambulatory healthcare centers shall define the types of communication channels between the governing body, leaders and the ambulatory healthcare center staff. Communication



channels may be in the form of social media, monthly meeting or annual conferences or other channels.

**Survey process guide:**

- GAHAR surveyor may review the policy that describes the structure, responsibilities and accountabilities of the governing body.
- GAHAR surveyor may observe governing body structure and flow of orders through the approved line of authority.
- GAHAR surveyor may interview staff to check their awareness of the policy.

**Evidence of compliance:**

1. The ambulatory health care center has an approved policy that define the structure, responsibilities and accountabilities of the governing body that include items from a) to g) in the intent.
2. The ambulatory healthcare center has a vision and mission statement approved by the governing body and are visible in public areas to staff, patients and visitors.
3. There is defined process of communication between the governing body and the ambulatory healthcare center' leaders and staff.
4. Staff is aware of the methods for the flow of orders through the approved line of authority.

**Related standards:**

OGM.02 Ambulatory healthcare center director, OGM.03 Ambulatory healthcare center leaders ,OGM.04 Scope of services.

OGM.05 Strategic Plan OGM.06 Operational Plan.

**Effective organization direction**

**OGM.02 The ambulatory health care center appoints a qualified director responsible to manage the center.**

*Effectiveness*

**Keywords:**

Ambulatory healthcare center director.

**Intent:**

Executive director is the person who is responsible and accountable for implementing the governing body's decisions and acts as a link between the governing body and the ambulatory healthcare center leaders and staff. Such a position requires certain qualifications guided by relevant laws and regulations and/or as further defined by the governing body.

Ambulatory healthcare center shall appoint a qualified director and define any leadership delegation authority for managing the center in the absence of the center's director. The director is responsible for the center's compliance with all applicable governmental laws and regulations.

The ambulatory healthcare center director must have appropriate training and/or experience

in healthcare management, as defined in the job description.

The job description covers at least the following:

- a. Providing oversight of day-to-day operations.
- b. Ensuring clear and accurate posting of the ambulatory healthcare center's services and hours of operation to the community.
- c. Ensuring that policies and procedures are developed, implemented by leaders, and approved by the governing body.
- d. Providing oversight of human, non-human and financial resources.
- e. Annual evaluation of the performance of the ambulatory healthcare center's committees and meeting minutes.
- f. Ensuring appropriate response to reports from any inspecting or regulatory agencies, including national or international accreditation.
- g. Ensuring that there is a functional, organization-wide program for performance improvement, patient safety, and risk management with appropriate resources.
- h. Regular reports to the governing body on how legal requirements are being met.

The director shall ensure the overall compliance of the center with the National Safety Requirements (NSR) and set priorities for improvement activities. The director shall represent an effective role in decision-making by using various tools for mixing distributed knowledge and abilities of different parties in the center such as committees, which are the most effective tool that can be used. A multidisciplinary selection of members of every committee and regular holding can enhance the overall productivity. The ambulatory healthcare center shall develop a policy that defines committee types and formulation. The policy shall include at least the following:

- I. Terms of references that include its membership, duties, accountability/reporting, frequency of meeting, quorum, and baseline agenda.
- II. Meeting minutes' documentation requirements and responsibility.
- III. Type of committee according to center's scope of services. The ambulatory healthcare center has at least the following committees:
  - i. Environmental safety committee
  - ii. Infection prevention and control committee
  - iii. Pharmacy and therapeutic committee
  - iv. Performance improvement and patient safety committee
  - v. Mortality and Morbidity Committee

#### **Survey process guide:**

- GAHAR surveyor may review ambulatory healthcare center director's staff file to check compliance with all required documents of training, job description, role and responsibilities.
- GAHAR surveyor may review the policy of the committees, types and formulation.

- GAHAR surveyor may review the delegation letters for tasks that the ambulatory healthcare center director delegated to any other staff member, when needed.

**Evidence of compliance:**

1. There is a qualified and trained director managing the ambulatory healthcare center.
2. There is a job description for the ambulatory healthcare center director covering the standard requirements from a) through h) as in the intent.
3. The ambulatory healthcare center has an approved policy for committee types and formulation that include elements from I) to III) in the intent.
4. There is evidence of delegation of authority, when needed.

**Related standards:**

OGM.01 Governing body Structure and clear responsibilities OGM.03 Ambulatory healthcare center leaders, OGM.05 Strategic Plan, IPC.03 IPC committee, meetings, EFS.01 Ambulatory healthcare center environment and facility safety structure, QPI.01 Quality management program.

**OGM.03 The responsibilities and accountabilities of the ambulatory healthcare center leaders are identified.**

*Effectiveness*

**Keywords:**

Ambulatory healthcare center leaders.

**Intent:**

While, another standard addresses ambulatory healthcare center director's responsibilities, ambulatory healthcare centers usually have nursing director, medical director, information officer, financial director, and sometimes-operational director that is why the ambulatory healthcare center shall establish a collective of responsibilities in written documents for ambulatory healthcare center leader/s. The leaders of the ambulatory healthcare center must be familiar with the concepts of quality improvement and patient safety programs, and thus can perform their roles and responsibilities. The ambulatory healthcare center leaders are responsible for:

- a. Sustaining firm ambulatory healthcare center structure:
  - i. Planning for upgrading or replacing systems, buildings, or components needed for continued, safe, and effective operation.
  - ii. Collaboratively developing a plan for staffing the ambulatory healthcare center that identifies the numbers, types, and desired qualifications of staff.
  - iii. Providing appropriate facilities and time for staff education and training.
  - iv. Ensuring all required policies, procedures, and plans have been developed and implemented.
  - v. Providing adequate space, equipment, and other resources based on strategic

and operational plans and needed services.

- vi. Selecting equipment and supplies based on defined criteria that include quality and cost-effectiveness.

b. Running smooth directed operations:

- i. Creating “Just culture” for reporting errors, near misses, and complaints, and use the information to improve the safety of processes and systems.
- ii. Designing and implementing processes that support continuity, coordination of care, and risk reduction.
- iii. Ensuring that services are developed and delivered safely according to applicable laws and regulations and approved organization strategic plan with input from the users/staff.

c. Continuous monitoring and evaluation:

- i. Ensuring that all quality management and patient safety activities are implemented, monitored, and action is taken when necessary.
- ii. Ensuring that the ambulatory healthcare center meets the conditions of facility inspection reports or citations.
- iii. Annually assessing the operational plans of the services provided to determine the required facility and equipment needs for the next operational cycle.
- iv. Annually reporting to the ambulatory healthcare center governing body or authority on system or process failures and near misses, and actions that have been taken to improve safety, both proactively and in response to the actual occurrences.

d. Continuous Improvement.

Data from all over the ambulatory healthcare center shall be collected, reviewed, analyzed, and reported to the upper management in order to determine the opportunities of improvement through an effective data driven decision-making.

**Survey process guide:**

- GAHAR surveyor may interview ambulatory healthcare center leaders to check their awareness of their roles and responsibilities.
- GAHAR surveyor may review ambulatory healthcare center leaders’ job descriptions.

**Evidence of compliance:**

1. The ambulatory healthcare center leaders are identified based on the service provided, and their accountabilities are described in written documents and includes at least items from a) through d) in the intent.
2. The ambulatory healthcare center leaders are educated in the concepts of quality improvement and patient safety plans.
3. Ambulatory healthcare center leaders are fully aware of their written responsibilities.

**Related standards:**

OGM.01 Governing body Structure and clear responsibilities, OGM.02 Ambulatory healthcare center director, OGM.05 Strategic Plan, WFM.03 Job Description, WFM.07 Staff Performance Evaluation

**OGM.04 The ambulatory health care director together with governing body and leaders develop the center's scope of services based on community needs.**

*Effectiveness*

**Keyword:**

Scope of services.

**Intent:**

The scope of services is the range of activities provided by the ambulatory healthcare center, (i.e. preventive, health promotion, curative,). The scope of services shall include the specialty services provided by the center, the number of departments and clinics for each specialty, the level of expertise needed (for example; consultant versus specialist), and the staffing plan for each department and clinic. The scope of services shall include the age group, volume and categories of patients served and the actual working hours in addition to any emergency services that may be provided.

The ambulatory healthcare center shall identify a process to involve the community to determine and analyze their health needs. The process shall help the center to prioritize the community health needs, plan and act upon the unmet community health needs. Many methods exist for conducting the community needs assessment, for example: stakeholder meetings, community focus groups, surveys, interviews with community leaders, population health and other health-related data. This assessment shall be updated on a regular basis (at least annually) or as determined by the center's governing body and leaders.

**Survey process guide:**

- GAHAR surveyor may review ambulatory healthcare center scope of services.
- GAHAR surveyor may interview the responsible staff to check their awareness of the scope of services provided by the center.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved scope of services provided.
2. Methods exist for conducting the community needs assessment
3. The ambulatory healthcare center governing body and leaders perform and update the community needs assessment (at least annually).
4. The ambulatory health care center scope of services is matched to the current community needs assessment.

**Related standards:**

OGM.01 Governing body Structure and clear responsibilities, OGM.02 Ambulatory healthcare center director, OGM.03 Ambulatory healthcare center leaders, OGM.05 Strategic Plan, PCC.01 Ambulatory healthcare center advertisement.

**OGM.05 A strategic plan is developed under oversight and guidance of the governing body.**

*Effectiveness*

**Keywords:**

Strategic Plan.

**Intent:**

Strategic planning is a process of establishing a long-term plan to achieve the ambulatory healthcare center's specified vision and mission through the attainment of high-level strategic goals.

A strategic plan looks out over an extended time- period. The plan shall describe the ambulatory healthcare center current situation, and explains where leadership wants to go, how they will get there, and how they will know when they have achieved the target.

It is essential that stakeholders are involved in developing the plan to ensure legitimacy, ownership, and commitment to the plan. A strategic plan shall be established on a higher level (governing body) with the involvement of ambulatory healthcare center leaders. The strategic plan shall be based on a comprehensive evaluation of the internal and external environmental factors (e.g., SWOT analysis, PEST analysis). The strategic plan spans shall be over a period of 3 - 5 years and shall be reviewed on a regular basis.

**Survey process guide:**

- GAHAR surveyor may review the ambulatory healthcare center strategic plan.
- GAHAR surveyor may interview the ambulatory healthcare center's leaders to check their involvement and monitoring of strategic plan.

**Evidence of compliance:**

1. The ambulatory healthcare center has a strategic plan with defined achievable timeline for each desired goal/ outcome.
2. The strategic plan includes the broad goals and objectives required to fulfill the center's mission.
3. The strategic plan addresses all clinical and non-clinical services and programs.
4. There are progress review reports to monitor the strategic plan at least annually.

**Related standards:**

OGM.01 Governing body Structure and clear responsibilities, OGM.02 Ambulatory healthcare center director, OGM.03 Ambulatory healthcare center leaders, OGM.04 scope of services, QPI.02 Performance measures.

**OGM.06 Operational plans are developed to achieve the strategic plan goals and objectives, with inputs from staff, service providers, and other stakeholders.**

*Efficiency*

**Keywords:**

Operational Plan.

**Intent:**

Operational plans are the means through which organization fulfill their mission. They are detailed, containing specific information regarding targets and related activities and needed resources within a timed framework. An operational plan is the comprehensive way in which each department or discipline plans to use its resources to achieve the center's goals.

Incorporation of operational plan to link with other main plans within the organization could make the operational plan more comprehensive and effective.

Leaders establish operational plans that include at least the following:

- a. Clear goals and objectives (in line with the center's strategic plan).
- b. Specific activities and tasks for implementation.
- c. Timetable for implementation.
- d. Assigned responsibilities.
- e. Sources of the required budget and resources.

Leaders regularly assess the annual operational plans of the services provided to determine the required resources needs for the next operational cycle. Any operating cycle ends with an analysis or an assessment phase through which planners understand what went well and what went wrong with the plan. This analysis or better-called lessons learned should feed into the new cycle of planning to improve the ambulatory healthcare center performance.

**Survey process guide:**

- GAHAR surveyor may interview staff and leaders to check their awareness of the operational plan they follow and give them an opportunity to talk about their inputs and how they are communicated.
- GAHAR surveyor may review the evidence of monitoring operational plan progress, identification of opportunities of improvement and actions taken to improve performance.

**Evidence of compliance:**

1. The ambulatory healthcare center has operational plans that include a) to e) in the intent.
2. Staff is aware and actively participate in designing for the operational plans.
3. The plans are communicated throughout the ambulatory healthcare center.
4. The governing body approves resources that are required for the operational plans implementation.
5. There are progress review reports to monitor the operational plans at least annually.



**Related standards:**

OGM.01 Governing body Structure and clear responsibilities, OGM.02 Ambulatory healthcare center director, OGM.03 Ambulatory healthcare center leaders, QPI.02 Performance measures

**Efficient supply chain management**

**OGM.07 The ambulatory healthcare center has effective supply chain management.**

*Efficiency*

**Keywords:**

Supply Chain Management.

**Intent:**

The supply chain generally refers to the resources needed to deliver goods or services to a consumer. A supply chain shall include all activities related to manufacturing, the extraction of raw materials, processing, storing and warehousing, and transportation. In healthcare, managing the supply chain is typically a very complex and fragmented process.

Healthcare supply chain management shall involve obtaining resources, managing supplies, and delivering goods and services to providers and patients. To complete the process, physical goods and information about medical products and services usually go through a number of independent stakeholders, including manufacturers, insurance companies, ambulatory healthcare centers, providers, group purchasing organizations, and several regulatory agencies.

For critical supplies, i.e. vital supplies to the support of operations, the ambulatory care center shall identify the steps in the supply chains to decide where the significant risks reside. Resources include financial, human resources, technology, information systems. The governing bodies shall develop plans for resource allocation to increase efficiency and transparency so; the ambulatory healthcare center shall develop a policy and procedures for supply chain management. The policy shall describe the process of resource procurement prioritization and selection criteria. Prioritization criteria shall be known to all leaders to ensure a fair and transparent resource allocation process.

The policy of the supply chain management addresses at least the following:

- a. Supplier's identification and selection process.
- b. Methods for suppliers and/or distributors' monitoring and evaluation, to ensure that the purchased supplies are provided from reliable sources that refrain from dealing with counterfeit, smuggled, or damaged supplies.
- c. Setting pre-defined acceptance criteria for suppliers that may include evaluation based on the suppliers' response upon request, quality of received supplies, lot number, and expiry date.
- d. Supplies monitoring and evaluation, to ensure that no recalled medications, samples, devices, medical supplies, or equipment are provided.



- e. Monitoring transportation of supplies, to ensure that it occurs according to applicable laws and regulations, and manufacturer's recommendations.
- f. The ambulatory healthcare center shall highlight in the policy the procedures for managing stock\ inventory addressing at least the following:
  - i. Compliance with the applicable laws, regulations, and organization policies
  - ii. Compliance of the stocks management with the safe storage strategies that require at least the following records for stock items: date received, lot number, expiration date, date of disposition, if not used.
  - iii. Identifying and tracking the use of critical resources and supplies.

**Survey process guide:**

- GAHAR surveyor may review supply chain management policy and records.
- GAHAR surveyor may interview responsible staff to check their awareness of the policy.
- GAHAR surveyor may observe the proper implementation of the safe storage strategies.

**Evidence of compliance:**

1. The ambulatory health care center has an approved policy of supply chain management that addresses all elements from a) through f).
2. Supplies are monitored and evaluated to ensure matching with the pre-defined acceptance criteria that determined in center's policy.
3. Critical supplies are identified and clear processes are followed in case of shortage.
4. Basic information is recorded for stock items as mentioned from i) through iii) of item f) in the intent.

**Related standards:**

OGM.02 Ambulatory healthcare center director, OGM.03 Ambulatory healthcare center leaders

EFS.11 Utilities Management plan., EFS.09 Medical Equipment management plan, OGM.09 Contracted services management., MMS.01 medication management.

**OGM.08 The ambulatory healthcare center manages the patient's billing system.**

*Efficiency*

**Keywords:**

Billing System

**Intent:**

The ambulatory healthcare center shall provide patients and their families by a receipt for services rendered, including insurance patients. It is one of the patient and family rights to receive an initial estimated cost for their treatment if requested. For third-party payer systems, the process for billing is based on the requirements of insurance companies/agencies, which generally have reimbursement rules with a pre-determined timeframe. The ambulatory healthcare center shall develop a policy and procedures for the billing

process that addresses at least the following:

- a. Availability of an approved price list for services provided to patients and their sponsors.
- b. Patients and families are informed of an initial estimated cost of required services and any potential cost pertinent to the planned care.
- c. Process to ensure that patients and families are obtained an accurate invoice for services rendered.
- d. Use of the approved codes for diagnoses, interventions, and diagnostics, if applicable.
- e. Payment methods. e.g. itemized bill, package deal.

**Survey process guide:**

- GAHAR surveyor may review the billing policy and center's price lists.
- GAHAR surveyor may interview responsible staff and some patients to check compliance with the approved policy.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy for patient's billing that include items from a) to e) in the intent.
2. In the case of a third-party payer (or health insurance), the timeliness of approval processes is monitored.
3. Responsible staff is fully aware of the various health insurance processes and different payment methods.

**Related standards:**

PCC.02 Patient and family rights, PCC.03 Patient and family responsibilities, OGM.02 Ambulatory healthcare center director, OGM.03 Ambulatory healthcare center leaders, IMT.02 Standardized symbols and Abbreviations.

**OGM.09 The ambulatory healthcare center implements a process for selection, evaluation, and continuously monitoring contracted services.**

*Effectiveness*

**Keywords:**

Contracted services management.

**Intent:**

Ambulatory healthcare center leadership defines the nature and scope of services provided by contracted services, including clinical and non-clinical services. Ambulatory healthcare center leaders shall describe, in writing, the contractual agreements that outline the nature and type of the services to be provided through the contract. For example, outsource laboratory and radiology services or laundry services.

Leaders shall participate in the selection, evaluation, and continuously monitoring contracted services to ensure that the service providers fully comply with the environmental safety, patient safety, and quality requirements and all relevant accreditation standards requirements.

The quality of services provided by the independent practitioners is monitored as a component of the ambulatory care center's quality and patient safety program.

The contracted services shall be monitored through performance measures and evaluated at least annually to determine if a contract should be renewed or terminated. Findings and results of contract monitoring shall be reported to center leaders to be acted upon. The ambulatory healthcare center leaders shall determine the reporting frequency and mechanism, and develop a process for how the ambulatory healthcare center shall respond when the quality requirements are not met.

**Survey process guide:**

- GAHAR surveyor may review the approved documents of the contracted services.
- GAHAR surveyor may interview the center's leaders and responsible staff to determine contractors' monitoring, evaluation, and renewal processes.

**Evidence of compliance:**

1. The ambulatory health care center has a documented process that describes the nature and scope of the services provided through a contractual agreement, including all outsources clinical and non-clinical services.
2. The ambulatory healthcare center has a documented process for contract monitoring and evaluation.
3. The performance measures for monitoring contracted services are integrated into the center performance improvement and patient safety plan.
4. Significant results of contracts' monitoring are reported to the center leaders.
5. If contracts are terminated, the ambulatory healthcare center has a clear process to maintain the continuity of patient care.

**Related standards:**

OGM.02 Ambulatory healthcare center director, OGM.03 Ambulatory healthcare center leaders

DAS.10 Referral Laboratory services., DAS.22 Contracted blood banks

**Leadership role in quality and patient safety**

**OGM.10 The ambulatory healthcare center leaders create and support a culture of safety and quality within the ambulatory healthcare center.**

*Effectiveness*

**Keywords:**

Safety Culture.

**Intent:**

Healthcare is complex, and sometimes, due to unintentional errors, it can harm patients and even staff. To minimize such risk, causes of errors and near misses should be explored and efforts made to prevent their occurrence in the future. Leaders shall create a just culture

to encourage reporting errors and near misses. For this to happen, a safety culture within the facility is essential where staff is engaged and feel confident when reporting on a safety incident that they will be treated fairly, in a confidential manner, and that the information they provide will be used to improve the care process and environment. Leaders shall demonstrate their commitment to the culture of safety and set rules for those who work in the center with behaviors that are not consistent with a safe culture. The ambulatory healthcare center shall develop a policy to describe safety culture. The policy shall explain the key elements for the safety culture that include at least the following;

- a. Identification of the high-risk activities and persistence to achieve safe operations;
- b. Deploy an environment in which staff is able to report errors/ incidents without fear of blame or punishment
- c. Encourage all disciplines and staff to highlight their patient safety problems and try to find a suitable solutions for it.
- d. Commitment of leaders to perform regular safety rounds.

**Survey process guide:**

- GAHAR surveyor may review records of leaders' safety rounds.
- GAHAR surveyor may interview staff to check support for quality initiatives safety culture.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy of safety culture that includes elements from a) to d) in the intent.
2. Leaders provide all required resources needed to promote and support the culture of safety.
3. There is evidence that leaders participate in safety rounds on an ongoing basis.
4. All staff is fully aware of how to apply the safety culture policy.

**Related standards:**

OGM.02 Ambulatory healthcare center director, OGM.03 Ambulatory healthcare center leaders

QPI.01 Quality management program, QPI.04 Incident reporting system, QPI.08 Performance improvement and patient safety plan, QPI.09 Sustaining Improvement

## **Safe, ethical, and positive organization culture**

### **OGM.11 The ambulatory healthcare center ensures positive workplace culture.**

*Effectiveness*

#### **Keywords:**

Positive Workplace Culture.

#### **Intent:**

Studies highlighted the importance of providing healthcare workers especially the healthcare professionals with a safe and comfortable work environment.

The ambulatory healthcare center shall develop an approved policy and procedures of positive workplace culture. The policy addresses at least the following:

- a. Workplace cleanliness, safety and security measures
- b. Management of workplace violence, discrimination, and harassment
- c. Communication channels between staff and ambulatory healthcare center leaders
- d. Staff feedback measurement
- e. Planning for staff development
- f. Planning to maintain a staff healthy lifestyle.

The ambulatory healthcare center shall plan to maintain their staff healthy lifestyle for example; promoting physical and mental health camp/activities in order to reduce stress, provide a weight management program, introduce stress consultation and counselling services for staff.

#### **Survey process guide:**

- GAHAR surveyor may review the approved policy for positive workplace culture
- GAHAR surveyor may observe workplaces and may interview staff to inquire about workplace incidents.

#### **Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy for positive workplace culture, that addresses at least item a) to f) in the intent.
2. The workplace is clean, safe, and security measures are implemented.
3. Measures of workplace violence, discrimination, and harassment are implemented.
4. Staff feedback and satisfaction are measured and periodically analyzed.

#### **Related standards:**

EFS.08 Security Plan OGM.02 Ambulatory healthcare center director, OGM.03 Ambulatory healthcare center leaders OGM.12 Ethical Management, OGM.13 Staff Health program, WFM.01 Workforce Laws and regulations QPI.02 Performance Measures,

## **OGM.12 The ambulatory healthcare center establishes appropriate ethical management.**

*Effectiveness*

### **Keywords:**

Ethical Management

### **Intent:**

Medical ethics involve examining a specific problem, usually a clinical case, and using values, facts, and logic to decide what the best course of action should be. Healthcare professionals may deal with a variety of ethical problems, for example, conflict of interest and inequity of patient care.

The policy of ethical management addresses at least the following:

- a. Developing and implementing the code of ethics
- b. Developing and implementing of ambulatory healthcare center values
- c. Handling medical errors and medico-legal cases
- d. Managing clinical research
- e. Identifying conflict of interest
- f. Gender equality

### **Survey process guide:**

- GAHAR surveyor may review ambulatory healthcare center ethical management policy.
- GAHAR surveyor may interview staff to check their awareness of center's code of ethics.
- GAHAR surveyor may observe mechanisms put in place to ensure gender equality as per the Egyptian law requirements.

### **Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy for ethical management that addresses at least a) to f) in the intent.
2. All Staff is aware of how to apply the policy.
3. The ambulatory healthcare center has a process for addressing ethical concerns that may arise, within a pre-determined time-frame as per center's policy.

### **Related standards:**

APC.05 Professional standards during surveys, PCC.01 Ambulatory healthcare center advertisement, OGM.11 Positive Workplace Culture, PCC.02 patient and family rights.

## Effective staff engagement, safety, and health

### **OGM.13 The ambulatory healthcare center has an effective staff health program in accordance with the applicable laws and regulations.**

*Safety*

#### **Keywords:**

Staff Health program.

#### **Intent:**

The ambulatory healthcare center shall implement a staff health program to ensure the safety of the staff according to workplace exposures.

A cornerstone of the staff occupational health program is the hazard/risk assessment, which identifies the hazards and risks related to each occupation.

This is done in order to take the necessary steps to control these hazards to minimize possible harm arising and, if not possible, to lessen its negative sequel.

This is achieved through the ambulatory healthcare center's wide risk assessment program that identifies high risks areas and processes.

The program scope covers all staff; the program addresses at least the following:

- a. Pre-employment medical evaluation of new staff
- b. Periodic medical evaluation of staff members
- c. Screening for exposure and/or immunity to infectious diseases.
- d. Exposure control and management to work-related hazards
  - i. Ergonomic hazards that arise from the lifting and transfer of patients or equipment, strain, repetitive movements, and poor posture
  - ii. Physical hazards such as lighting, noise, ventilation, electrical and others
  - iii. Biological hazards from blood borne and airborne pathogens and others
- e. Staff education on the risks within the ambulatory healthcare center environment as well as on their specific job-related hazards.
- f. Staff preventive immunizations.
- g. Recording and management of staff incidents (e.g., injuries or illnesses, taking corrective actions, and setting measures in place to prevent recurrences).
- h. A pre-employment medical examination is required for all employees' categories to evaluate their appropriateness for safe performance, and staff that is exposed to certain hazards, as radiation should have periodic specific medical evaluation (tests and examinations). The situational examination may be required in case of exposure to specific substances. Results of the medical evaluation are documented in staff health records, and action is taken when there are positive results, including employee awareness of these results and provision of counseling and interventions as might be needed.
- i. Infection control staff shall be involved in the development and implementation of the staff health program as the transmission of infection is a common and serious risk for

both staff and patients in healthcare facilities.

- j. All staff occupational health program-related results (medical evaluation, immunization, work injuries) shall be documented and kept according to laws and regulations

**Survey process guide:**

- GAHAR surveyor may interview staff members who are involved in developing and executing staff health program to check program structure, risks, education and orientation records
- GAHAR surveyor may review a sample of staff health records to check the evidence of immunizations, post-exposure prophylaxis and interventions and other staff's occupational health program-related results.

**Evidence of compliance:**

1. There is an approved ambulatory healthcare center's staff health program that covers a) through j) in the intent.
2. There is an occupational health risk assessment that defines occupational risks within the ambulatory healthcare center.
3. Staff members are educated about the risks within the ambulatory healthcare center environment, their specific job-related hazards, and periodic medical examination.
4. All staff members are subjected to the immunization program and to work restrictions according to the approved ambulatory healthcare center's guidelines.
5. All test results, immunizations, post-exposure prophylaxis and interventions are recorded in the staff's health record.
6. There is evidence of taking action and informing employees in case of positive results.

**Related standards:**

EFS.06 Safety Management Plan, IPC.04 Infection risk assessment, OGM.11 Positive Workplace Culture, WFM.01 Workforce Laws and regulations, QPI.03 Risk Management Program

**OGM.14 Ambulatory health care services are planned in line with international, national, regional, or local community initiatives.**

*Effectiveness*

**Keywords:**

Community Initiatives.

**Intent:**

Community is a group of individuals, families, groups, facilities, or organizations that interact with one another, cooperate in common activities, and solve mutual concerns, usually within the geographic area served by ambulatory healthcare center. The ambulatory healthcare center shall develop and implement a plan for community involvement that may include initiatives as implementation of international women health, oncology health and diabetes health initiatives or the national initiatives of Universal Health Insurance, 100 Million Healthy Lives or others.



**Survey process guide:**

- GAHAR surveyor may review community involvement plan to check that it is aligned with other national initiatives and with laws and regulations
- GAHAR surveyor may interview staff to check their awareness of community initiatives.

**Evidence of compliance:**

1. All ambulatory health care center's plans reflect alignment with international, regional, and/or national community initiatives.
2. All staff is aware of the community involvement plan and initiatives.
3. Community involvement plan is updated periodically to meet the needs of the community.

**Related standards:**

OGM.02 Ambulatory healthcare center director, OGM.03 Ambulatory healthcare center leaders, ACT.03 Physical access and comfort, OGM.04 scope of service.

## Workforce Management

### Chapter intent:

The ambulatory healthcare center workforce refers to the staff within the ambulatory healthcare center. Planning the appropriate number and skill mix of the workforce is essential. Developing clear job descriptions, strong orientation, and training programs help staff in delivering proper healthcare. A good organization must always have a clear structure of its medical staff, including departments, divisions, and medical committees.

This chapter defines the medical staff leaders' roles and responsibilities in credentialing, privileging, bylaws development, committees, and departments' management (head), as well as performance improvement.

The **medical staff** includes licensed physicians and licensed dentists, it is particularly important to review the credentials of all medical staff and other healthcare professionals carefully; the ambulatory healthcare center should provide medical staff with opportunities to learn and to advance personally and professionally.

**Independent healthcare practitioners** are other licensed healthcare professionals as (pharmacists, physiotherapist, nutritionist, nurses ...) that are permitted by law and regulation to provide patient care services independently in the ambulatory healthcare center, those special groups of healthcare professionals shall be identified by the ambulatory healthcare center and their clinical competencies shall be clarified and reviewed.

In some countries, licenses are renewable, which means that physicians, dentist, and other healthcare professionals need to go through a renewal process periodically and prove their competence and continuous development. National bodies that govern medical and nursing education are established in different countries. National performance evaluation and ranking of healthcare professionals is on the rise, with many healthcare systems moving towards the pay-per-performance concept.

Locally, Egypt also has the new Universal Health Insurance system tackled the pay-per-performance concept in its initial phases. Licenses are not linked to the frequent evaluation of professional development yet, but discussions are established to build a system for monitoring this process. MOHP licensing body requires specific lists of documents for almost all healthcare professionals. The licensing registers include physicians, dentists, physiotherapy specialists, physiotherapy practitioners, pharmacists, clinical pathologists, pathologists, medical chemists, bacteriologists, radiologists, radiology technicians, nurse supervisors, nurses, nurse technicians, Opticians, Anesthesia technicians, Biostatisticians, Prosthesis technicians, medical equipment technicians, denture technicians, and others.

GAHAR surveyors shall review the implementation of laws and regulations, medical bylaws, nursing bylaws, Policies, procedures, and plans reflecting processes of human resources department through interviews with leadership and staff and reviewing different healthcare professionals staff files.

Chapter purpose:

The main objective is to ensure that ambulatory healthcare centers maintain an effective Workforce Management program; the chapter addresses the following objectives:

1. Effective workforce planning.
2. Effective orientation, continuous medical education, and training program
3. An efficient mix of staff
4. Periodic evaluation of staff performance.

**Implementation guiding documents:**

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

1. Egyptian code of medical ethics 238/2003
2. Egyptian code of nursing ethics (Nursing Syndicate Publications)
3. Code of ethics and behavior for civil service staff, 2019, if applicable
4. Pharmacist code of ethics
5. Law 415/1954 Practicing the profession of human medicine
6. Law 140/1981 on practicing midwifery
7. Law 198/1956 Practicing of Psychotherapy
8. Law 3/1985 Practicing Physiotherapy profession
9. Law 127/1955 on practicing the profession of pharmacy
10. Law 537/1954 on Practicing of the dental profession
11. National law for laboratories, 367/ 1954
12. Law 178/1960 on organizing blood collection transport and storage
13. Law 59/1960 regulation of Medical Imaging work
14. MOHP ministerial decree 70/1996 work of foreign experts
15. MOHP ministerial decree 90/1999 for the use of foreign experts
16. MOHP Ministerial decree 236/2004 on anaesthesia service requirements
17. MOHP Ministerial Decree 153/2004 on minimum requirements for anaesthesia services
18. Law 213/2017 of trade unions and protection
19. MOHP Ministerial decree 25/2002 for medical responsibility and suspension of medical practice
20. MOHP Ministerial decree 293/2000 on the promotion of doctors
21. MOHP Ministerial decree 62/2004 on the promotion of healthcare professionals
22. MOHP Ministerial decree 244/2001 on competencies of surgeons

## Efficient workforce planning

### **WFM.01 Workforce recruitment, education, training, and appraisal processes comply with laws and regulations.**

*Efficiency*

#### **Keywords:**

Workforce Laws and regulations

#### **Intent:**

Labor laws and regulations mediate the relationship between workers, ambulatory healthcare center, syndicates and the government.

The labor law, which provides for the rights of employees to work, is enforced through the employment contracts. The ambulatory healthcare center shall identify all applicable laws and regulations including syndicates' codes and requirements and shall define the legal framework for its workforce management.

The ambulatory healthcare center shall develop a policy and procedures that guide management of staff files after recruitment including independent healthcare practitioners that addresses at least the following:

- a. Staff file initiation
- b. Standardized contents such as;
  - i. Verified certification, license, education, training and work history,
  - ii. Current job description,
  - iii. Recorded general orientation to the ambulatory healthcare center, the assigned department, and the specific job orientation,
  - iv. Evidence of initial (pre-employment) evaluation, to ensure that the staff member is able to perform the assigned job,
  - v. Ongoing In-service education received,
  - vi. Copies of the first three months' evaluations and copies of the annual evaluations
  - vii. Any required health information.
- c. Updates of file contents
- d. Storage
- e. Retention time
- f. Disposal

#### **Survey process guide:**

- During the GAHAR survey, the surveyor may review the legal framework documents, observe workforce management practices, or review staff files including independent practitioner to check compliance to laws and regulations
- GAHAR surveyor may review the policy of staff files and may check a sample to assess compliance to the policy
- GAHAR surveyor may visit the area where staff files are kept to assess storage conditions,

retention, confidentiality, and disposal mechanism

- GAHAR surveyor may interview staff involved in creation, use and storage of staff files to assess the process

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy for staff files that addresses at least elements from a) through f) in the intent.
2. Staff files are standardized, current, maintained and kept confidential according to the ambulatory healthcare center's policy.
3. Staff files contain all elements listed in the point (b) from the intent.
4. Responsible staff is aware of the staff file management policy and procedures.

**Related standards:**

WFM.02 Staffing Plan, WFM.03 Job Description, IMT .01 Documentation management system, WFM.04 Verifying credentials.

**WFM.02 Ambulatory healthcare center develops a staffing plan to ensure that provided services meet the needs of safe patient care.**

*Efficiency*

**Keywords:**

Staffing Plan

**Intent:**

Staff planning is the process of making sure that the ambulatory healthcare center has the right people to carry out the work needed for business successfully through matching up detailed staff data including skills, potential, aspirations, and location with business plans.

Shortage of competent, skilled healthcare professionals in multiple areas is an alarming sign, especially in critical care disciplines such as intensive care units and anesthesia

The ambulatory healthcare center must comply with the laws and recommendations of professional practices that define desired education levels, skills, or other requirements of individual staff members including independent practitioner or that define staffing numbers or mix of staff for the ambulatory healthcare center.

The staffing plan is reviewed on a regular basis and updated as necessary by the leaders of each clinical or managerial area who defines the individual requirements of each staff position.

Leaders consider the following factors to define staffing needs:

- a. The ambulatory healthcare center mission, strategic and operational plans
- b. Complexity and severity mix of patients served by the ambulatory healthcare center
- c. Services provided by the ambulatory healthcare center
- d. Technology and equipment used in patient care

**Survey process guide:**

- GAHAR surveyor may review the ambulatory healthcare center staffing plan.
- GAHAR surveyor may review staff files to check compliance of staffing plan with professional practices recommendations.

**Evidence of compliance:**

1. Staffing plan matches the mission, strategic and operational plans
2. Staffing plan complies with recommendations of professional practices
3. Staffing plan identifies the estimated needed staff numbers including independent practitioners and skills with staff assignments to meet the ambulatory healthcare center needs.
4. The staffing plan is reviewed at least annually.

**Related standards:**

WFM.01 Workforce Laws and regulations OGM.02 Ambulatory healthcare center director  
OGM.03 Ambulatory healthcare center leaders.

**WFM.03 Ambulatory healthcare center develops job descriptions to address each position requirements and responsibilities.**

*Effectiveness*

**Keywords:**

Job Description.

**Intent:**

The job description is a general written statement of a specific job, based on the findings of a job analysis. It generally includes duties, purpose, responsibilities, scope, and working conditions of a job.

In the ambulatory healthcare center, a job description is required to make sure that staff responsibilities are current and aligned with the ambulatory healthcare center's policy.

The ambulatory healthcare center shall ensure that the job description is based on education, training, and experience level of each staff. Job description is a process to identify and authorize the individual to practice independently in the ambulatory healthcare center. In addition, job description is a process to evaluate the extent to which the staff fulfill their job responsibilities.

Job descriptions are required for all types of staff, clinical, non-clinical, full- time, part-time, temporary staff, and those who are under training or supervision.

Each ambulatory healthcare center leader or head of department is responsible for developing staff job description that fulfills all the necessary requirements approved by the ambulatory healthcare center. It includes at least; job title, main duties and responsibilities, reporting relationships, qualifications, education, experience, training, and technical skills necessary for entry into this job and Special demands that may be needed.

**Survey process guide:**

- GAHAR surveyor may review a sample of staff files to check of staff job description' availability.
- GAHAR surveyor may interview staff to check their awareness about their job description and compliance with its items.

**Evidence of compliance:**

1. There is a current job description for every position and recorded in the staff's file.
2. Job descriptions include the all-necessary requirements as described by the ambulatory healthcare center.
3. All staff is aware of their job description specifications and requirements.

**Related standards:**

WFM.08 Medical Staff Structure, WFM.12 Nursing Structure, WFM.07 Medical Staff Performance Evaluation, OGM.03 Ambulatory healthcare center leaders, IMT.01 Documentation management system, WFM.10 clinical privileges

**WFM.04 The ambulatory healthcare center implements an effective process to verify credentials of all staff members.**

*Effectiveness*

**Keywords:**

Verifying credentials.

**Intent:**

Credentials are documents that are issued by a recognized entity to indicate completion of requirements or the meeting of eligibility requirements, such as a diploma from a medical school, specialty training (residency) completion letter or certificate, completion of the requirements of the related syndicates, authorities and/or others, a license to practice. These documents, some of which are required by law and regulations, are needed to be verified from the original source that issued the document. The ambulatory healthcare center shall develop a process of verifying credentials for all staff members (including independent practitioners) and matching the requirements of the position with the qualifications of the prospective staff member must be done.

**Survey process guide:**

- GAHAR surveyor may review the documents of the credential verification process.
- GAHAR surveyor may check a sample of staff members' (including independent practitioner's) files to check the availability of required credentials for each position.
- GAHAR surveyor may interview staff members who are involved in the credentialing process to check their awareness of the process.

**Evidence of compliance:**

1. There is a process for verifying credentials of all staff in the ambulatory healthcare center.
2. Required credentials for each position are identified and available in each staff file (including independent practitioners' files).
3. Actions are taken and documented when credentials cannot be verified.

**Related standards:**

APC.02 Registration of staff, WFM.08 Medical Staff Structure, WFM.12 Nursing Structure, WFM.01 Workforce laws and regulations

**Effective orientation program**

**WFM.05 Appointed, contracted, and outsourced staff undergo a formal orientation program.**

*Effectiveness*

**Keywords:**

Orientation Program

**Intent:**

The decision to appoint an individual to an ambulatory healthcare center sets several processes in motion.

To perform well, a new staff member, no matter what his or her employment experience, needs to understand the entire ambulatory healthcare center structure and how his/ her specific clinical or nonclinical responsibilities contribute to the ambulatory healthcare center's mission.

This is accomplished through a general orientation about the ambulatory healthcare center and his/ her role and a specific orientation on the job responsibilities of his/ her position. Staff orientation, especially when first employed, on the ambulatory healthcare center policies, ensures alignment between the ambulatory healthcare center's mission and staff activities.

It also helps to create a healthy ambulatory healthcare center culture where all staff works with a shared mental model and towards agreed-upon objectives.

Staff orientation also facilitates the integration of new staff with the existing staff to rapidly form effective teams that offer safe and quality care.

The ambulatory healthcare center builds a comprehensive orientation program that is provided to all staff members regardless of their terms of employment.

Staff orientation occurs on three levels: General orientation, departmental orientation and job-specific orientation.

General orientation program addresses at least

- a. Review of the ambulatory healthcare center's mission, vision, and values
- b. Ambulatory healthcare center's structure



- c. Ambulatory healthcare center's policies for the environment of care, infection control, performance improvement, patient safety and risk management

Department orientation program addresses at least:

- d. Review of relevant policies and procedures
- e. Operational processes,
- f. Work relations.

Job Specific orientation

- g. High risk processes
- h. Technology and equipment use
- i. Staff safety requirements and measures

The ambulatory healthcare center shall develop a staff manual that describes processes of staff appointment and reappointment, staff appraisal, staff complaints management, staff satisfaction measurement, code of ethics, disciplinary actions, and termination

**Survey process guide:**

- GAHAR surveyor may interview some staff members and inquire about the process of orientation
- GAHAR surveyor may check a sample of staff files to check evidence of attendance of the general, departmental and job specific orientation

**Evidence of compliance:**

1. General orientation program is performed and it includes at least the elements from a) through c).
2. Department orientation program is performed and it includes at least the elements from d) through f).
3. Job specific orientation program is performed and it includes at least the elements from g) through i).
4. Any staff member attends the orientation program regardless of the employment terms.
5. Orientation completion is recorded in the staff file.

**Related standards:**

WFM.03 Job Description, WFM.06 Continuous Education Program, EFS.13 Disaster Plan , IPC.05 Hand Hygiene,IPC.08 Safe injection practices, EFS.02 Fire and smoke safety, EFS.05 Hazardous materials safety

## Effective training and education

### **WFM.06 A continuing education and training program is developed and implemented.**

*Effectiveness*

#### **Keywords:**

Continuous Education Program

#### **Intent:**

For any ambulatory healthcare center to fulfill its mission, it has to ensure that its human resources have the capacity to deliver its services over time.

Continuous education and training programs help guarantee that the training plan, especially if designed to satisfy staff needs necessary to deliver the ambulatory healthcare center mission.

The program is designed in a flexible manner that satisfies all staff categories based on a process of need assessment, tailored training plan, delivery, and reflection.

The program is designed based on the services provided, new information, and evaluation of the staff needs.

Evidence-based medical and nursing practices and guidelines and other resources are accessible 24 hours to all staff.

The ambulatory healthcare center ensures that education and training are provided and recorded according to the staff member's relevant job responsibilities needs that may include the following:

- a. Patient assessment
- b. Infection control policy and procedures, needle stick injuries and exposures
- c. Environment safety plans
- d. Occupational health hazards and safety procedures, including the use of personal protective equipment
- e. Information management, including patient's medical record requirements as appropriate to responsibilities or job description
- f. Pain assessment and treatment
- g. Clinical guidelines used in the ambulatory healthcare center
- h. Valid Basic cardiopulmonary resuscitation training for all staff that provides direct patient care
- i. Quality concept, performance improvement, patient safety, and risk management.
- j. Patient rights, Patient satisfaction, and the complaint/ suggestion process.
- k. Provision of integrated care, shared decision making, informed consent, interpersonal communication between patients and other staff cultural beliefs, needs and activities of different groups served
- l. Defined abuse and neglect criteria
- m. Medical equipment and utility systems operations and maintenance

**Survey process guide:**

- GAHAR surveyor may interview some staff members and inquire about the process of continuous education and training
- GAHAR surveyor may check a sample of staff files to check evidence of attendance of education and training program

**Evidence of compliance:**

1. There is a continuing education and training program for all staff categories that may include elements in the intent from a) through m).
2. Resources needed to deliver the program are identified in the education and training program.
3. The program is based on needs assessment of all staff.
4. Results of a performance review are integrated into program design.

**Related standards:**

WFM.05 Orientation Program, QPI.02 Performance measures, OGM.02 Ambulatory healthcare center director, WFM.07 Staff performance evaluation.

**Equitable staff performance evaluation**

**WFM.07 Staff performance and competency are regularly evaluated.**

*Equity*

**Keywords:**

Staff Performance Evaluation

**Intent:**

Staff performance evaluation is an ongoing process that is also called performance appraisal or performance review, which is a formal assessment for managers to evaluate an employee's work performance, identify strengths and weaknesses, offer feedback, and set goals for future performance

Performance evaluation effectively contributes to individual, team and ambulatory healthcare center improvement when based on a defined and transparent process with clear declared criteria relevant to the job functions.

The ambulatory healthcare center shall provide written probationary evaluation after the probationary period in accordance with national laws and regulations, and then regular reevaluation is performed at least annually

It is the department head's responsibility to ensure all staff is evaluated within the prescribed cycles and that performance ratings issued by the immediate supervisor reflect staff actual performance.

Recorded process of employees' performance evaluation including performance review methods, tools, evaluation dimensions, criteria, time interval, appeal process, and responsible person for each staff category.

Performance evaluation criteria for medical staff members includes those related to patient's medical record recording and medication use. Such as:

- a. Patient's medical record review for completeness and timeliness.
- b. Utilization practice and medication use.
- c. Compliance with approved clinical guidelines
- d. Complications, outcomes of care, mortality, and morbidity
- e. Professional development

Competency is the process to determine the ability of staff to fulfill the primary responsibilities of the position for which a person was hired. Observing and measuring competency for every position in the center is one of the most important duty of the department leaders and to ensure that each staff member shall understand the expectations, responsibilities, activities and competencies required for his or her position.

Competency shall be done after the probationary period (initial competency assessment), then on an ongoing basis at least annually for at least the following (the nursing staff, staff who provide medical imaging services, laboratory services, procedural sedation services and POCT service and staff who are handling critical medical equipment).

**Survey process guide:**

- GAHAR surveyor may interview department/service or ambulatory healthcare center leaders and inquire about used tools for staff performance evaluation and competency evaluation.
- GAHAR surveyor may check a sample of staff files to assess completion of performance and competency evaluations.

**Evidence of compliance:**

1. Performance evaluation is performed at least annually for each staff member and linked to the education and training provided.
2. Performance evaluation records for medical staff members include at least all elements from a) through e) in the intent
3. Performance evaluation is performed based on the current job description.
4. Clear procedures for the effective management of underperformance.
5. There is evidence of employee feedback on performance and competency evaluation
6. Performance and competency evaluation is recorded in staff members' files.

**Related standards:**

WFM.03 Job Description, WFM.06 Continuous Education Program, WFM.10 Clinical privileges, WFM.01 Workforce laws and regulations

## Efficient medical staff structure

**WFM.08 An organized medical staff structure is developed to provide oversight on quality of care, treatment, and services.**

*Effectiveness*

### Keywords:

Medical Staff Structure

### Intent:

Medical staff are all physicians, dentists, and other professionals who are licensed to practice independently (without supervision) and who provide preventive, curative, restorative, surgical, rehabilitative, or other medical or dental services to patients; or who provide interpretative services for patients, such as radiology, or laboratory services.

The term medical staff is thus inclusive of all physicians, and other professionals permitted to treat patients with partial or full independence, regardless of their relationship to the ambulatory healthcare center

The ambulatory healthcare center defines those other practitioners, such as house officers, and junior doctors, that are no longer in training, but may or may not be permitted by the ambulatory healthcare center to practice independently.

Those medical staff have a diagram describing the line of authority within the ambulatory healthcare center.

### Survey process guide:

- GAHAR surveyor may review a document describing medical staff structure and medical staff bylaws.
- GAHAR surveyor may interview staff members to check their awareness about the medical staff structure.

### Evidence of compliance:

1. The ambulatory healthcare center has a medical staff structure that is developed according to the ambulatory healthcare center's mission, scope of services and recommendations of professional practices to meet patient needs.
2. Medical staff structure is approved by the governing body.
3. Medical staff structure clearly defines lines of authorities during working hours and after hours.
4. Medical staff bylaws are developed and approved by the governing body.

### Related standards:

OGM.01 Governing body Structure and clear responsibilities, OGM.02 Ambulatory healthcare center director, WFM.01 Workforce Laws and regulations

## Efficient medical workforce structure

**WFM.09 Appointment of medical staff members is performed according to applicable laws and regulations and approved medical staff bylaws.**

*Effectiveness*

**Keywords:**

Medical Staff Appointment

**Intent:**

The appointment is the process of reviewing an initial applicant's credentials to decide if the individual is qualified to provide patient care services that the ambulatory healthcare center patients need, and the ambulatory healthcare center can support with qualified staff and technical capabilities.

For initial applicants, the information reviewed is primarily from outside sources.

The ambulatory healthcare center policy identifies the individuals or mechanisms accountable for this review, any criteria used to make decisions, and how decisions will be documented. The policy identifies the process of appointment of independent practitioners for emergency needs or a temporary period

**Survey process guide:**

- GAHAR surveyor may check a sample of staff files to check evidence for uniform process for the appointment of medical staff.
- GAHAR surveyor may interview staff members who are involved in appointment process to check their awareness of the process.

**Evidence of compliance:**

1. There is a uniform process for the initial appointment of medical staff members.
2. Medical staff appointments are made according to the ambulatory healthcare center medical staff bylaws.
3. Medical staff appointments are consistent with the ambulatory healthcare center's mission, patient population, and services provided to meet patient needs.

**Related standards:**

WFM.01 Workforce Laws and regulations, WFM.02 Staffing Plan, WFM.03 Job Description  
WFM.10 Clinical Privileges.

## **WFM.10 Medical staff members have current and specific delineated clinical privileges**

*Safety*

### **Keywords:**

Clinical Privileges

### **Intent:**

The ambulatory healthcare centers shall define and require clinical privileges to apply for all medical staff members based on evaluation of the individual's credentials and performance. The determination of a medical staff member's current clinical competence and making a decision about what clinical services the medical staff member will be permitted to perform often called privileging is the most critical determination that the ambulatory healthcare center will make to protect the safety of patients and to advance the quality of its clinical services.

Decisions regarding a practitioner's clinical competence, and thus what clinical privileges he/she is to be granted, are based primarily on information and documentation received from outside the ambulatory healthcare center. Independent practitioners who provide patient care services on the premises of the ambulatory healthcare center but are not employees or permanent staff are privileged, and evaluated.

Specialty training programs may identify and list the general competencies of that specialty in areas of diagnosis and treatment with the ambulatory healthcare center assigning privileges to diagnose and treat patients in those specialty competency areas.

The ambulatory healthcare center shall develop a policy of clinical privileges delineation the policy shall address at least the following:

- a. Medical staff members and independent practitioners with clinical privileges are subject to bylaws
- b. Privileges indicate if the medical staff can admit, consult, and treat patients.
- c. Privileges define the scope of patient care services and types of procedures they may provide in the ambulatory healthcare center.
- d. Privileges are determined based on documented evidence of competency (experience-qualifications – certifications-skills) that are reviewed and renewed at least every three years
- e. Privileges are available in areas where medical staff provide services pertinent to granted privileges
- f. Medical staff members with privileges do not practice outside the scope of their privileges.

### **Survey process guide:**

- During the GAHAR survey, the surveyor may review the policy of clinical privileges delineation.
- GAHAR surveyor may interview medical staff members and inquire about delineated privileges.

- GAHAR surveyor may check a sample of medical staff files to check for presence of clinical privileges.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that addresses at least all elements from a) through f) in the intent
2. Medical staff members are aware of the process of clinical privileges delineation and what to do when they need to work outside their approved clinical privileges
3. Clinical privileges are delineated to medical staff members based on defined criteria
4. Clinical privileges are accessible to and used by staff involved in booking of surgery and invasive procedures
5. Physicians and dentists' files contain personalized recorded clinical privileges, including renewal when applicable.
6. Physicians and dentists comply with their clinical privileges.

**Related standards:**

DAS.02 Medical imaging services healthcare professionals.

DAS.09 Laboratory Staff, SAS.02 Qualified Anesthesiologist. SAS.07 Sedation administration and monitoring Sedation complications, SAS.10 Provision of surgeries and invasive procedures., WFM.03 Job Description, WFM.09 Medical Staff Appointment, WFM.01 Workforce laws and regulations

**WFM.11 The ambulatory healthcare center has a staff burnout and turnover preventive measures and strategies.**

*Safety*

**Keywords:**

Staff burnout and turnover.

**Intent:**

Attention to health and well-being of healthcare providers and workers become more important when we consider the fact that employees are the greatest asset in an organization. Burnout is a combination of exhaustion, cynicism, and perceived inefficacy resulting from long-term job stress. The consequences of burnout are not limited to the personal well-being of healthcare providers and workers; many studies have demonstrated that provider burnout is detrimental to patient care. The ambulatory healthcare center shall ensure management of staff working hours and application of the national laws and regulations efficiently to avoid burnout.

The policy of efficient working hours shall address at least the following:

- a. Measures to avoid staff burnout.
- b. Planned rest times.
- c. Maternity protection and arrangements for breast-feeding.
- d. Setting staff working hours according to the national laws and regulations



**Survey process guide:**

- GAHAR surveyors may review the ambulatory healthcare center policy for working hours and compliance with national laws and regulations.
- GAHAR surveyors may observe the staff rest areas and rest times.

**Evidence of Compliance:**

1. The ambulatory healthcare center has an approved policy and procedures that clearly describe the process to ensure safe and efficient working hours, the policies address a) to d) in the intent.
2. The staff schedules ensure suitable working hours with planned rest times.
3. Staff is aware of how to apply the policy.

**Related standards**

WFM.01 Workforce Laws and regulations, WFM.08 Medical Staff Structure, OGM.11 Positive Workplace Culture

**WFM.12 The ambulatory healthcare center has a defined nursing structure that is led by a qualified nurse director.**

*Effectiveness*

**Keywords:**

Nursing Structure

**Intent:**

The nursing director has an influential role in the creation of a safe, healthy, productive working environment for nursing staff that promotes collaboration, productivity, and professional growth. Successful nursing directors have qualifications and expertise in management and leadership.

Standards of nursing practice provide and outline the expectations of the professional role for nurses, including scope and standards of practice and related competencies. They reflect a desired and achievable level of performance against which a nurse's actual performance can be compared. The main role of the nursing director is to direct and maintain the safe and effective nursing practice.

Nursing staff newly hired and freshly graduate practice must be under supervision after receiving all educational and training needs for the job.

The ambulatory healthcare center clearly defines the nursing structure

The nurse director responsibilities are to include at least the following:

- a. Responsible for developing and implementing written nursing standards of practice and recording for nursing assessment, nursing care plan, nursing reassessment, and treatments
- b. Responsible for evaluating the effectiveness of the nursing treatments
- c. Be a member of the senior leadership team of the ambulatory healthcare center and

attends the senior leadership staff meetings

d. Ensuring that schedules and assigned tasks to the staff are completed

The ambulatory healthcare center defines the trainee nurses and their role in the ambulatory healthcare center during the training period. In addition, supervisors of the trainee nurses monitor and evaluate their performance during the training period

The ambulatory healthcare center sets guidelines for nursing practices

**Survey process guide:**

- GAHAR surveyor may review a document describing nursing staff structure.
- GAHAR surveyor may review staff file of nursing director
- During the GAHAR survey, the surveyor may interview nurse trainees/nurses and inquire about their performance and available scientific resources

**Evidence of compliance:**

1. There is a current, approved job description for the nursing director describing responsibilities as addressed in the intent from item a) to d).
2. The nursing director file fulfills the licensure, qualification, and expertise as required by the job description.
3. The ambulatory healthcare center defines trainee nurses and the duration of working under training
4. Trainee nurses practice under supervision through their job description and their performance is monitored and evaluated.
5. Nursing standards of practice are adopted and implemented.

**Related standards:**

WFM.01 Workforce Laws and regulations, WFM.03 Job Description, WFM.04 Verifying credentials, WFM.07 Staff Performance Evaluation

## Information Management and Technology

### Chapter intent

An effective information management system is a vital component of the healthcare service. Information management and technology in ambulatory healthcare centers includes all clinical, managerial information, and other information required by external authorities and agencies. There are major risks associated with information management and technology in healthcare. One of these risks is the potential breach of patient confidentiality. Patient confidentiality means that personal and medical information given to a healthcare professional shall not be disclosed to others unless the patient has given specific permission for such release. Maintaining patient confidentiality is an ethical and legal concern, especially with the emerging technology of implementation of electronic information systems.

Another risk is associated with the use of abbreviations that may cause misunderstanding and affect patient safety. Implementation of do-not-use abbreviation list for medication shall be guided by reliable references, e.g., The Institute for Safe Medication Practices (ISMP) list. Abbreviations also may cause harm regardless of the language used; organizations need to identify the approved reference in English or Arabic language.

Globally, Information management and technology is emerging in healthcare. Artificial intelligence is on the surge where symptom checkers and clinical decision support systems are becoming widely used. More ambulatory healthcare centers are moving to be paperless, and special certifications are dedicated to encourage that movement.

Locally, Egyptian laws and regulations have taken big steps recently to support electronic transactions. Electronic signature law was released. Electronic payment is approved. A new law on data privacy is expected. Ambulatory healthcare centers need to provide resources for the implementation of an information management system that ensures patient safety, continuity of care, security, and confidentiality of information.

During GAHAR Survey, surveyors shall be able to measure how organizations implement information management systems and technologies through reviewing documents pertinent to this chapter and doing patient tracers and interviews with staff. The leadership interview session may touch on this topic, as well.

### Chapter purpose:

1. To address Effective Information Management Processes
2. To Maintain Information Confidentiality and Security
3. To ensure Availability of patient's medical record
4. To describe effective information Technology in Healthcare.

**Standards included in this chapter applies for paper and electronic data and information.**

**Implementation guiding documents:**

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

1. Egyptian code of medical ethics 238/2003
2. Egyptian code of nursing ethics (Nursing Syndicate Publications)
3. MOHP - General Directorate of Technical Inspection. The administrative tool
4. Ministry of finance decree 270/2009: Governmental Archives list
5. Ministry of finance decree 18/2019: Non-Monetary Payment
6. MOHP Ministerial decree 254/2001 Discharge summary requirements
7. Ministry of communication and information technology decree 109/2005: Electronic signature.
8. Law 35/1960 National census and statistics
9. Law 2915/1964 Establishment of CAPMAS
10. Jeddah Declaration on Patient Safety 2019
11. HIPAA— Health Insurance Portability and Accountability Act Regulations 1996.
12. The Institute for Safe Medication Practices (ISMP): List of Error-Prone Abbreviations, Symbols, and Dose Designations
13. Egyptian consent laws

## Effective documentation management processes

### **IMT.01 Documentation management system is developed for all the ambulatory healthcare documents.**

*Effectiveness*

#### **Keywords:**

Documentation management system.

#### **Intent:**

Documentation management system is important for the standardization of the document formatting as well as developing a controlled process for creation, distribution, amendment and disposal of documents. Documents may be of internal origin as policies, instructions for use, flow charts, procedures, specifications, forms, and documents of external origin such as regulations, standards and textbooks from which the interventional procedures are taken. Unified documents formatting will allow easier tracking and searching for any information. Periodic review of the whole documents ensures that obsolete document is not used. The ambulatory healthcare center shall develop an approved process of documentation management system to cover the main organizational key functions such as emergency service, assessment, referral, discharge, procurement and other operational and clinical key functions.

The ambulatory healthcare center shall develop and implement a policy and procedures for document management system that addresses at least the following:

- a. Standardized formatting
- b. Tracking system and tracking of any changes
- c. The document control system (document to be identified by title, issue date, edition and/or current revision date, the number of pages, who is authorized to issue and/or review the document and identification of changes of version).
- d. Obsolete controlled documents are dated and marked as obsolete
- e. Required policies are available and disseminated to relevant staff
- f. Policies revisions and update.

#### **Survey process guide:**

- GAHAR surveyor may review policy of documentation management system followed by check for standardized format, tracking system, identified approver, issuing and revision date for all policies of the ambulatory healthcare center.
- GAHAR surveyor may interview staff to check their awareness of the process of developing, approving, tracking, and revising of policies
- GAHAR surveyor may check staff awareness of the proper access to relevant policies, tracking changes in the policies and process for management of retirement of documents.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that clearly describes the process of the documentation management including elements in the intent from a) to f).
2. Staff is fully aware and trained on the documentation management system and patient unique identifier.
3. There are standardized formats for all similar documents throughout the ambulatory healthcare center.
4. The implementation documentation management policy is continuously monitored, any concerns may arise are identified and corrected on time.

**Related standards:**

IMT.02 Standardized symbols and Abbreviations. IMT.05 Patient's medical record management.

**IMT.02 NSR.22 The ambulatory healthcare center defines standardized diagnosis codes, procedure codes, definitions, symbols, and abbreviations.**

*Effectiveness*

**Keywords:**

Standardized symbols and Abbreviations.

**Intent:**

The main goal of using codes, symbols and abbreviations is downsizing the writing. Uniform and consistent use of approved symbols and abbreviations across the ambulatory healthcare center shall be ensured by using a standardized diagnosis and procedure codes.

International classification of the disease (ICD) intends to define the diseases, disorders, injuries and other related health conditions, listed in a comprehensive, hierarchical fashion that allows for sharing and comparing health information between different healthcare providing settings. The ambulatory healthcare center shall adopt a well-recognized, evidence-based classification of diseases to ensure that codes and abbreviations are matched to those provided by national health authorities and/or 3rd party payers.

The ambulatory healthcare centers shall develop a policy that defines the processes implemented to prevent and reduce risk of patient safety. Patients and families may not be familiar with or understand the abbreviations and may not be comfortable asking for clarification. In addition, if a summary of the patient's care and treatment contains abbreviations and is sent with a patient being transferred to another health care organization, there is a risk to patient safety if the receiving organization uses some of the same abbreviations but with different meanings, or simply does not know the meanings of the abbreviations in the summary. The abbreviations policy shall address at least the following:

- a. Not-to- use symbols/abbreviations list. For example; adopt "do-not-use abbreviation list" for medication from reliable references, e.g., The Institute for Safe Medication

Practices (ISMP) list and includes at least the following:

- U/IU
- Q.D.,
- QD,
- q. o. d
- q.o.d
- MS
- MSO4
- MgSO4
- Trailing Zero
- No leading Zero

- b. b) Situations where Symbols and abbreviations (even the approved list) are not allowed; such as informed consent and patient rights documents, discharge/home instructions, and discharge summaries and any record that patients and families receive from the ambulatory healthcare center about the patient's care.

**Survey process guide:**

- GAHAR surveyor may review ambulatory healthcare center policy for abbreviations
- GAHAR surveyor may review sample of medical records (to check for the used abbreviations with medication orders.
- GAHAR surveyor may interview medical staff for awareness of the prohibited abbreviations.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy for abbreviations that includes all the elements in the intent from a) through b).
2. Staff who record in the patient's medical record are educated and trained on the process of the standardization and uniform use of the center's codes, symbols, and abbreviations.
3. There is a uniform use of standardized diagnosis and procedure codes across the center.
4. Approved codes are matched to those provided by health authorities and/or 3rd party payers.

**Related standards:**

MMS.05 Safe medication prescription, Medication reconciliation, OGM.08 Billing System, IMT.01 Documentation management system, IMT.05 Patient's medical record management.

## Patient-centered confidentiality and security of information

### **IMT .03 the ambulatory healthcare center ensures data and information confidentiality, security and integrity.**

*Effectiveness*

#### **Keywords:**

Confidentiality and Security of data and information.

#### **Intent:**

Patient confidentiality means that personal and medical information given to a health care provider shall not be disclosed to others unless the patient has given specific permission, for such release, information shall be protected from being accessed by unauthorized individuals.

Maintaining data integrity is an important aspect of information management. data integrity is maintained during planned and unplanned downtime of data systems. This is accomplished through implementation of downtime recovery tactics and ongoing data backup processes.

Patient's medical record and information are protected at all times and in all places. Including protecting it from water, fire, or other damage, and unauthorized access.

Medical records storage area must implement measures to ensure medical records protection, e.g., controlled access and the suitable type of fire extinguishers

All staff must be committed to information confidentiality and security by signing an agreement that they understand the details of the confidentiality policy and procedures and know their roles well.

Egyptian laws and regulations address topics related to confidentiality, release of patient information and reporting of specific information to inspecting and regulatory agencies. The ambulatory healthcare center must make the needed efforts and take steps to comply with relevant laws and regulations in the field of information management.

The ambulatory healthcare center shall develop and implement a policy and procedures to ensure data confidentiality, security and integrity that addresses at least the following:

- a. Determination of who can access (list of authorized individuals).
- b. The circumstances under which access is granted.
- c. Confidentiality agreements with all those who have access to patient data.
- d. Procedures to follow if confidentiality or security of information has been breached

#### **Survey process guide:**

- GAHAR surveyor may review the policy of data confidentiality, security and integrity.
- GAHAR surveyor may review a list of the authorized individuals to have access to the patient medical record.
- GAHAR surveyor may observe implementation of confidentiality measures including storage of patient's medical records in limited access place.



- GAHAR surveyor may interview staff to check their awareness of confidentiality, security and integrity measures

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that includes all the points in the intent from a) through d).
2. All staff are aware of the policy requirements.
3. Only authorized individuals have access to patients' medical records.
4. Procedures are followed if confidentiality or security of information has been violated.
5. The medical records department storage area has measures to ensure medical records and information protection.

**Related standards:**

PCC.02 Patient and family rights, IMT.04 Retention of data and information, IMT.05 Patient's medical record management, IMT.07 Health information technology.

**Effective, safe documents retention process**

**IMT.04 The ambulatory care center determines the retention time of records, data, and information.**

*Effectiveness*

**Keywords:**

Retention of data and information.

**Intent:**

Data, information, medical records have an important role in patient care. The ambulatory healthcare center has to retain all types of documents for a sufficient period of time. This retention time shall be determined by the national, applicable laws and regulations.

The ambulatory healthcare center shall ensure the retention of records, data, and information is consistent with the center's confidentiality and security policy.

The ambulatory healthcare center shall develop and implement a retention policy that addresses at least the following:

- a. Retention time for each type of documents.
- b. Measures to maintain information confidentiality during the retention time.
- c. Retention conditions, archival rules, and permissible means of storage, access, and encryption.
- d. Data destruction methods that respect the security and confidentiality measures.

**Survey process guide:**

- GAHAR surveyor may review retention time policy.
- GAHAR surveyor may interview staff to check awareness of the process of records retention and destruction and/or removal of records, data, and information.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that includes all the items in the intent from a) through d).
2. Responsible staff are aware of the policy requirements.
3. The information confidentiality is maintained during the retention time in accordance to the center's policy.
4. Destruction and/ or removal of records, data, and information are done as per policy.

**Related standards:**

IMT.01 information management system, IMT .03 Confidentiality and Security of data and information, IMT.05 Patient's medical record management, IMT.07 Health information technology.

**Effective patient's medical record management and review**

**IMT.05 Patient's medical record is managed effectively.**

*Effectiveness*

**Keywords:**

Patient's medical record management.

**Intent:**

The ambulatory healthcare center has a standardized process for proper medical record flow management that includes; Initiation of a patient's medical record, assigning the unique identifiers, tracking medical records movement and storing requirements.

The main goal of developing a uniform structure of the patient's medical record is facilitating the accessibility of data and information to provide more effective and efficient patient care. The ambulatory health care center shall assign a medical record's unique number to locate, retrieve patient's medical record easily and document care of patient over time and tracking medical records movement and circulation through the center.

Patients' medical records are available to assist the healthcare professionals in having quick access to patients' information and to promote continuity of care and overall patient satisfaction.

The ambulatory healthcare center shall develop a policy for medical record management that addresses at least the following:

- a. Availability of medical records within a pre-determined timeframe.
- b. Medical record contents and order uniformity.
- c. Medical record standardized use and storage methods.
- d. Patient's medical record release.
- e. Management of voluminous patient's medical record.

**Survey process guide:**

- GAHAR surveyor may review the medical record management policy followed by checking the implementation of the process
- GAHAR surveyor may check that each patient's medical record has a unique identifier.
- GAHAR surveyor may observe patient's medical record availability when needed by healthcare professional, contain up to dated information within an appropriate timeframe.
- GAHAR surveyor may interview staff to check their awareness of managing patient's medical record.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that includes all the items in the intent from a) through e)
2. Responsible staff is aware of the policy requirements.
3. The patient's medical record contents, format, and location of entries are standardized.
4. The patient's medical record is available when needed by a healthcare provider within a timeframe matched to centers' policy.
5. A patient medical record is initiated for every patient receiving care.

**Related standards:**

IMT.01 Documentation management system. IMT.02 Standardized symbols and Abbreviations. IMT .03 Confidentiality and Security of data and information, IMT.04 Retention of data and information, IMT.06 Medical Record Review.

**IMT.06 Patient's medical record is reviewed effectively.**

*Effectiveness*

**Keywords:**

Medical Record Review.

**Intent:**

Each ambulatory healthcare center shall determine the content and format of the patient medical record and has a process to assess medical record standardized content and the completeness of records. Patient medical record review is based on a sample review methodology. Random sampling and selecting approximately 5% of patient's medical record is preferable. The review process shall be conducted by authorized responsible staff. The review focuses on the timeliness, accuracy, completeness, and legibility of the medical record. Medical record review shall be done on a regular basis and in compliance with organizational -wide quality management program; the opportunities for improvements are identified from the analysis of results, when needed.

**Survey process guide:**

- GAHAR surveyor may review results of patient medical records' process and actions taken to improve performance

- GAHAR surveyor may review sample of patient medical records to ensure proper implementation of medical record review process. The review process focuses on the timeliness, completeness, and legibility of the medical record.

**Evidence of compliance:**

1. The ambulatory healthcare center has a process of tracking and monitoring data that collected and analyzed from medical record review process.
2. An authorized responsible staff performs the medical record review focusing on timeliness, accuracy, completeness, and legibility of the medical record.
3. Significant medical review' results are reported to the ambulatory healthcare center leader(s).
4. Corrective interventions are taken by the ambulatory healthcare center leader(s) when needed.

**Related standards:**

IMT.01 Documentation management system, IMT.02 Standardized symbols and Abbreviations.  
IMT.05 Patient's medical record management, QPI.02 Performance measures.

**Selection and implementation of health information technology**

**IMT.07 The use of health information technology systems is safe and efficient.**

*Effectiveness*

**Keywords:**

Health information technology.

**Intent:**

Implementation of health information technology' systems can facilitate workflow; improve the quality of patient care, and patient safety. The selection and implementation of health information technology' systems require coordination between all involved stakeholders to ensure proper selection and integration with all interacting processes. Following implementation, evaluation of the usability and effectiveness of the system shall be done.

Downtime event is any event where a health information technology system (computer system) is unavailable or fails to perform as designed. It significantly threatens the safety of the care delivery and interruption of the care provision in addition to the risk of data loss.

The ambulatory healthcare center shall develop a policy to ensure the continuity of safe patient care processes during planned and unplanned downtime including the measures / alternatives that had been undertaken. The policy shall address the downtime recovery process to ensure data integrity.

Data backup is a copy of data that is stored in a separate location from the original, which may be used to restore the original after a data loss event, having a backup is essential for data protection. Backups shall occur regularly in order to prevent data loss. The ambulatory healthcare center shall ensure the backup information is secure and accessible only by those authorized to use it for restoring lost data.

**Survey process guide:**

- The GAHAR surveyor may perform an interactive staff interview asking to demonstrate the process of selection, implementation, and evaluation of information technology, followed by checking the implementation of the process by review of the related documents, which include result of system evaluation.
- The GAHAR surveyor may review the document of the planned and unplanned downtime response, followed by checking the implementation of the process by review of the related documents, which includes work instructions for planned and unplanned downtime, stock of needed forms to be used during downtime and result of annual program testing.
- The GAHAR surveyor may interview staff to assess awareness of the response to planned and unplanned downtime.
- The GAHAR surveyor may check implementation of data backup process.

**Evidence of compliance:**

1. The ambulatory healthcare center health information technology systems are selected, implemented in collaboration to center's leaders and stakeholders.
2. The ambulatory healthcare center has an approved policy for downtime including the recovery process.
3. The staff is aware of the health information technology system.
4. Data backup process and frequency of backup is identified according to the center's policy.

**Related standards:**

IMT.01 Information management system, IMT .03 Confidentiality and Security of data and information, IMT.04 Retention of data and information

## Quality and Performance Improvement

### Chapter intent:

It is essential for organizations to have a framework to support continuous improvement and risk management activities. This requires leadership support, established processes and active participation from all heads of departments and staff. Performance improvement and risk management are parts of both strategic and departmental operational plans.

Globally, Ambulatory healthcare centers have adopted, adapted, and even created improvement tools to help enhancing the services provided to patients. Florence Nightingale, a nurse, was one of the pioneers in improving healthcare quality. Dr. Avedis Donabedian was a founder of the study of the quality of healthcare and medical outcome research. Multiple quality improvement methodologies were used in ambulatory healthcare centers such as PDCA, FOCUS PDCA, Six Sigma, Lean Methodology, and others. Ambulatory healthcare centers need to cherish the culture of continuous improvement. GAHAR standards do not mandate a specific improvement tool nor specific monitoring performance measures, yet, a minimum number of monitoring indicators are required. Among many improvement opportunities, GAHAR standards highlighted the importance of improving patient journey and supply chain. It is important that each one in the ambulatory healthcare center understands his/her role in improving healthcare quality and safety by focusing on the leadership support, department-level input and participation, measures and data collection, and sustaining improvement. The application of the standards must be according to applicable Egyptian laws and regulations.

During the GAHAR survey, surveyors are going to meet the leadership, heads of departments, and staff to discuss the QPI aspects, initiatives, and projects. Surveyors may perform tracers to check data selection, collection, analysis of data, and methods that are used to follow the improvement projects and impact of projects on improving the quality dimensions.

### Chapter purpose:

The main objective is to ensure that the ambulatory healthcare center provides an effective performance improvement program; The chapter discusses the following objectives:

1. Effective leadership support
2. Effective departmental participation
3. Effective performance measurement and data management
4. Effective improvement sustainability

**Implementation guiding documents:**

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

1. MOHP Quality and Safety Guide, 2019
2. Ambulatory healthcare center Performance Indicators Guide by HIO, 2013
3. National EFQM based excellence award [www.Egea.gov.eg](http://www.Egea.gov.eg)
4. Law 35/1960 National census and statistics
5. Law 2915/1964 Establishment of CAPMAS

## Effective quality management program

### **QPI.01 Ambulatory healthcare center's leaders plan, document, implement, and monitor an organizational- wide quality management program.**

*Effectiveness*

#### **Keyword**

Quality management program.

#### **Intent:**

It is essential for organizations to have a framework for its quality management system to support continuous improvement. This requires leadership support, well-established processes, active participation from all heads of departments and staff. To initiate and maintain quality management and improvement process, leadership planning is essential. The ambulatory healthcare center leaders are included in the planning process.

The quality management program shall be integrated, comprehensive and adequate to the size, complexity and the scope of services provided and addresses at least the following:

- a. The commitment to regulatory requirements and accreditation standards.
- b. The goals of the quality management program
- c. The quality measures (clinical and managerial)
- d. The quality management activities
- e. The quality tools
- f. Periodic review and update (at least annually).

Ambulatory healthcare center's leaders shall assign qualified individual to oversight and communicate the quality management activities to the leaders and responsible staff.

#### **Survey process guide:**

- GAHAR surveyor may interview ambulatory healthcare center's leaders to identify leadership's approach for developing quality management program.
- GAHAR surveyor may review the quality management program, related documents and tools.
- GAHAR surveyor may interview staff to check their awareness of the program

#### **Evidence of compliance:**

1. The ambulatory healthcare center leaders participate in planning a program for quality management.
2. The ambulatory healthcare center has a documented, updated and approved quality management program containing the items in intent from a) to f).
3. An individual with knowledge, skills and experienced in quality management, related tools and activities is assigned to oversight the quality management program.
4. All staff is aware of the quality management program.
5. The quality management program is updated at least annually.



**Related standards:**

OGM.02 Ambulatory healthcare center director, OGM.03 Ambulatory healthcare center leaders, OGM.10 Safety Culture QPI.02 Performance Measures, QPI.08 Performance improvement and patient safety plan.

**Efficient data management and performance measurement**

**QPI.02 Performance measures are identified and monitored for all significant processes.**

*Effectiveness*

**Keywords:**

Performance Measures.

**Intent:**

Performance measurement aims to monitor, evaluate, and communicate the extent to which various aspects of the health system meet their key objectives.

Performance measure is a quantitative variable that either directly measures or may indirectly reflect the quality of care provided and has to be aligned with accountability by enabling stakeholders to make informed decisions by collecting the data and the ability to interpret it. Performance measure must be Specific, Measurable, Achievable, Relevant, and Time-bounded (SMART). To define a measure properly, a description of at least the following is needed:

- a. Definition
- b. Defined data source
- c. Specified frequency
- d. Sampling techniques
- e. Formula
- f. Methodology of data collection and analysis

Collection of data will create a database that shall be aggregated and trended over time and used for comparison over time internally within the ambulatory healthcare center and for comparisons externally with other organizations and the performance results/data shall be made publicly available at least annually.

**Survey process guide:**

- GAHAR surveyor may review the list of ambulatory healthcare center's quality measures.
- GAHAR surveyor may interview responsible staff to check their awareness of the process or collection and interpretation of the performance measures.
- GAHAR surveyor may review a sample of results analysis of the performance measures.

**Evidence of compliance:**

1. There is an approved identification card for each selected performance measure, standardized template is preferred, that includes all elements mentioned in the intent from a) through f)

2. There is list of ambulatory healthcare center measures including both clinical and managerial processes
3. Staff responsible for the collection, interpretation and/or use of performance measurement are aware of the identification card contents.
4. The ambulatory healthcare center makes its performance results/data publicly available at least annually.
5. Results of measures analysis are regularly (at least quarterly) reported to the governing body.

**Related standards:**

OGM.02 Ambulatory healthcare center director, QPI.01 quality management program QPI.09 Sustaining Improvement, QPI.08 Performance improvement and patient safety plan.

**Adverse Event Identification, Analysis, and Prevention**

**QPI.03 A risk management plan/program is developed.**

*Safety*

**Keywords:**

Risk Management Program

**Intent:**

Risk management is designed to identify potential events that may affect the ambulatory healthcare center and to protect and minimize risks to the ambulatory healthcare center property, services, and employees.

The ambulatory healthcare center shall adopt a proactive approach for risk management such as risk analysis where it can assess the high-risk processes, including developing risk mitigation strategies. Plan, policies, procedures, a risk register and processes shall support the risk management framework.

Ambulatory healthcare center shall take reactive and proactive measures to address the identified risks. Risk management plan/program shall contain essential components that includes at least the following:

- a. Scope, objective, and criteria for assessing risks
- b. Risk management assigned responsibilities
- c. Risk identification (risk register)
- d. Risk policies and procedures that support the risk management framework.
- e. Risk prioritization
- f. Risk categorization (i.e. strategic, operational, reputational, financial, other)
- g. Risk reporting and communication with stakeholders
- h. Risk reduction plans and tools with priority given to high risks processes.

The ambulatory healthcare center shall review the risk management plan/program on a regular basis as determined by center's leaders and according to the results of the current risk analysis.

**Survey process guide:**

- GAHAR surveyor may review the risk management plan\program of ambulatory healthcare center.
- GAHAR surveyor may review the risk reduction plan \tool for the high risks

**Evidence of Compliance**

1. The ambulatory healthcare center has a risk management plan/ program that includes all the elements from a) to h) in the intent
2. High risk processes are re- designed based on the result of the analysis.
3. The ambulatory healthcare center has an approved proactive risk reduction tool for at least one high-risk process, and is updated annually.
4. The risk management plan/program and the risk register is updated at least annually

**Related standards:**

IPC.04 Infection risk assessment, EFS.06 Safety Management Plan, EFS.07 Pre-Construction and renovation risk assessment.

QPI.04 Incident reporting system, QPI.05 Significant process variations, QPI.06 Near miss events, QPI.07 Sentinel events.

**QPI.04 An effective incident-reporting system is developed.**

*Safety*

**Keywords:**

Incident Reporting System

**Intent:**

Strong risk management is supported by efficient incident reporting systems that is defined by the system, which can identify an incident that could be any event that affects patient or employee safety.

In most ambulatory healthcare center injuries, patient complaints, medication errors, equipment failure, adverse reactions to drugs or treatments, or errors in patient care are to be included and reported. The incidents reporting has an important influence on improving patient safety.

It can provide valuable insights into how and why patients can be harmed at the ambulatory healthcare center level. What happens after an event is critical to the culture of safety, the first victim, is the patient and family affected by the adverse event, attention shall be turned toward the second victims; the service providers involved in the adverse event, who are also the ambulatory healthcare center's responsibility. Evidence suggests these second victims, if not given the correct support, can contribute to further patient safety problems; and, of course, each person in a work system affects the safety culture. The ambulatory healthcare center shall clearly define how the staff who contribute in adverse event is treated.

The ambulatory healthcare center shall develop and implement Incident reporting policy

that helps to detect, monitor, assess, mitigate, and prevent risks the policy includes at least the following:

- a. Definition and classification of incidents
- b. Incident management process includes how, when, and by whom incidents are reported and investigated.
- c. Identify incidents requiring immediate notification to the management
- d. Incident analysis tools, and results reporting
- e. Indication for performing intensive analysis and its process
- f. Procedures of managing adverse events consequences including the first and second victims affected.

**Survey process guide:**

- GAHAR surveyor may review the incident reporting policy.
- GAHAR surveyor may interview staff to check their awareness of the incident reporting system and the proper implementation.
- GAHAR surveyor may check for evidence of corrective actions taken, when gaps are detected.

**Evidence of compliance:**

1. The ambulatory healthcare center has an approved policy that defines the incident-type and reporting system that includes a) through f) in the intent.
2. All staff are aware of the incident-reporting system, including contracted and outsourced staff members.
3. Ambulatory healthcare center communicates with patient's/services users about adverse events they are affected by.
4. Corrective actions are taken in a timely manner, when gaps are detected.

**Related standards:**

QPI.01 Quality management program, MMS.07 Medication errors\_ adverse drug events and near misses, QPI.06 Near miss events, QPI.07 Sentinel events.

**QPI.05 Significant process variation are easily detected, investigated and corrected using evidence based methodology.**

*Effectiveness*

**Keywords:**

Significant process variations.

**Intent:**

The ambulatory care center shall collect data on regular intervals and from all areas of patient care services. Data collection should be sufficient to detect types of process variation and to determine the corrective actions needed to prevent the risk for patients. When data represents significant change (undesirable change from what is expected), intensive analysis shall be done to determine the best actions needed. Significant changes include deviations away from recognized standards, expected performance decrement, wide variance from performance of other similar organizations.

The ambulatory healthcare center has to perform a root cause analysis to identify actions that be taken to improve processes of care and prevent event reoccurring.

The ambulatory healthcare center shall develop significant variation and events policy that describes significant unexpected events that includes at least the following

- a. List of Significant unexpected/near misses' events that can happen, such as:
  - i. Confirmed transfusion reactions
  - ii. Significant anesthesia and sedation events that cause harm or have the potential to cause harm to a patient
  - iii. Significant differences between pre- and post-operative diagnoses, including surgical pathology findings
  - iv. Significant adverse drug reactions that cause harm or have the potential to cause harm to a patient
  - v. Significant medication errors that cause harm or have the potential to cause harm to a patient
  - vi. Pulmonary Embolism or Deep Venous Thrombosis developed due to missing appropriate thrombo-prophylaxis treatment and improper VTE assessment risk
  - vii. Patient escape or attempted escape
- b. The criteria and procedures for intensive analysis when significant unexpected events occur
- c. The time required to complete the investigation and execute the required action plan.

**Survey process guide:**

- GAHAR surveyor may review the process that defines significant events and their management
- GAHAR surveyor may review all evidences ensuring that all significant events are analyzed and actions are taken to reduce recurrence.

**Evidence of compliance:**

1. The ambulatory healthcare center has a policy that describes the significant events and its intensive analysis process that includes items from a) to c) in the intent.
2. All significant events (unexpected variations) are timely investigated, analyzed and reported.
3. Corrective actions are taken with clear time- frame, when gaps are detected.

**Related standards:**

QPI.01 Quality management program, QPI.02 Performance Measures, QPI.08 Performance improvement and patient safety plan

**QPI.06 The ambulatory care center has a defined process for the identification and analysis of near-miss events.**

*Effectiveness*

**Keywords:**

Near Miss events.

**Intent:**

The ambulatory healthcare center shall collect data and information on the events identified as a near miss and evaluates it to prevent their actual occurrence in the future. Near miss is defined as any process variation that did not affect an outcome but for which a recurrence carries a significant chance of a serious adverse outcome. Effective, valid, reliable reporting mechanism is implemented to determine when proactive process is needed to reduce or eliminate the related near miss events.

**Survey process guide:**

- GAHAR surveyor may interview staff to ask about the process of reporting near misses.
- GAHAR surveyor may review evidence that near miss events are analyzed and actions are taken to reduce recurrence.

**Evidence of compliance:**

1. The ambulatory care organization has a process for identification and reporting of near misses.
2. All staff is aware of near miss identification and reporting process.
3. Near miss events are analyzed, and actions are taken to reduce re-occurrence.

**Related standards:**

QPI.01 Quality management program, QPI.02 Performance measures, QPI.04 Incident Reporting System, QPI.08 Performance improvement and patient safety plan

**QPI.07 The ambulatory healthcare center defines, investigates, analyzes and reports sentinel events, and takes corrective actions to prevent harm and recurrence.**

*Safety*

**Keywords:**

Sentinel events

**Intent:**

A sentinel event is an unexpected occurrence that ends in death or ongoing morbidity or psychological injury, including loss of limb or function. A sentinel event signals an immediate investigation and response. The ambulatory healthcare center shall develop a policy for sentinel event management that includes at least the following:

- a. Definition of sentinel events such as:
  - i. Unexpected mortality or major permanent loss of function not related to the natural course of the patient's illness or underlying condition
  - ii. Wrong patient, wrong site, wrong procedure events
  - iii. Patient suicide, attempted suicide or violence leading to death or permanent loss of function
  - iv. Unintended retention of a foreign object events in a patient after surgery or invasive procedure
  - v. transmission of a chronic or fatal disease or illness as a result of infusing blood or blood products or
  - vi. Transplanting contaminated organs or tissues;
  - vii. Wrong delivery of radiotherapy
  - viii. Infant abduction or an infant sent home with the wrong parents;
  - ix. Any peri-partum maternal death
- b. Rape, workplace violence such as assault (leading to death or permanent loss of function), or homicide (willful killing) of a patient, staff member, practitioner, medical student, trainee, visitor, or vendor
- c. Any perinatal death unrelated to a congenital condition in an infant having a birth weight greater than 2,500 grams
- d. Internal reporting of sentinel events.
- e. External reporting of sentinel events.
- f. Team member's involvement.
- g. Root cause analysis.
- h. Corrective actions plans taken.

All sentinel events are reported to GAHAR within seven days of the event or becoming aware of the event.

All events that meet the definition must have a root cause analysis in order to have a clear understanding of contributing factors behind the system gaps. The analysis and action must be completed within 45 days of the event or becoming aware of the event.

**Survey process guide:**

- GAHAR surveyor may review sentinel events management policy.
- GAHAR surveyor may review evidence of sentinel events analysis and reporting
- GAHAR surveyor may review evidence of corrective actions taken to prevent recurrence of the event.

**Evidence of compliance:**

1. The ambulatory healthcare center has a sentinel events management policy covering the intent from a) through f) and leaders are aware of the policy requirements.
2. All sentinel events are analyzed and communicated to the direct upper management by a root cause analysis in a time period specified by leadership as per center's policy.
3. All sentinel events are reported to GAHAR within seven days of the event or becoming aware of the event.
4. The root cause analysis identifies the main reason(s) behind the event and the leaders take corrective action plans to prevent recurrence in the future.

**Related standards:**

PC.03 Accurate complete information, QPI.01 Quality management program, QPI.04 Incident Reporting System, QPI.08 Performance improvement and patient safety.

**QPI.08 There is an ambulatory healthcare center-wide performance improvement, and patient safety plan.**

*Effectiveness*

**Keywords:**

Performance improvement and patient safety plan

**Intent:**

The ambulatory healthcare center needs to initiate and maintain improvement programs to reduce risks to patients and staff. Therefore, leadership and good planning are essential. The center director is responsible for establishing and providing ongoing support for ambulatory healthcare center commitment to quality.

Leaders develop the performance improvement and patient safety plan; the plan shall at least address the following:

- a. The goal(s) (clinical and operational goals) that fulfill the center's mission.
- b. Defined responsibilities of improvement activities and reporting channels.
- c. Define ambulatory healthcare center priorities.
- d. Data collection, data analysis tools, and validation process.
- e. Defined criteria for prioritization and selection of performance improvement projects.
- f. Quality improvement model(s) used.
- g. Information flow and reporting frequency.
- h. Training on quality improvement and risk management approaches.



- i. Regular evaluation of the plan (at least annually).

The leaders select the approach to be used by the center to measure, assess, improve quality and patient safety. Leaders also determine how the plan will be directed and managed daily.

**Survey process guide:**

- The GAHAR surveyor may perform a document review for the center's plan,
- The GAHAR surveyor may interview responsible staff and the leader(s) of the ambulatory healthcare center to identify leadership's approach for improving the quality of care and continuous performance improvement.

**Evidence of compliance:**

1. There is a current and approved performance improvement and patient safety plan that defines at least items from a) to i) in the intent.
2. The ambulatory healthcare center director actively participates in the planning, supporting, and monitoring of performance improvement and patient safety plan.
3. The plan is communicated to all relevant stakeholders.
4. The plan is implemented facility-wide, according to the timetable and plan of improvement.
5. The plan is reviewed, evaluated and updated annually.

**Related standards:**

OGM.02 Ambulatory healthcare center director, OGM.10 Safety Culture, QPI.01 Quality management program, QPI.02 Performance measures, QPI.09 Sustaining Improvement

**QPI.09 An appropriate and sustained improvement activities are performed within approved time frame.**

*Effectiveness*

**Keywords:**

Sustaining Improvement

**Intent:**

Although staff play a vital part in the continuous improvement process, it is the management's role to train, empower and encourage the staff to participate with ideas.

An effective continuous improvement program needs continuous measurement and feedback.

Before start, ambulatory healthcare center' baseline performance needs to be measured, as new ideas for improving performance can then follow.

Plan-Do-Check-Check-Act (PDCA) cycle, Focus PDCA or other improvement tools allow to scientifically testing improvement progress.

The cycle ensures continuous improvement by measuring the performance difference between the baseline and target condition.

This information gives immediate feedback on the effectiveness of the change that can helps in measuring the impacts of continuous improvement program and that is the most effective way of sustaining it.

**Survey process guide:**

- GAHAR surveyor may review the written process for improvement.
- GAHAR surveyor may review the improvement project, to learn how the ambulatory healthcare center utilize data to identify potential improvements and to evaluate actions' impact.
- GAHAR surveyor may review the ambulatory healthcare center monitoring and control mechanisms to sustain achieved improvements

**Evidence of compliance:**

1. There is a written process of the methodology and tools used for improvement.
2. Actions to correct problems are taken timely and appropriately.
3. Improvement activities were tested and the results were recorded and implemented.
4. There is evidence that patient safety processes are improved and controlled
5. Quality improvement activities are monitored and results are reported to the governing body.

**Related standards:**

OGM.02 Ambulatory healthcare center director, OGM.10 Safety Culture, QPI.01 Quality management program, QPI.08 Performance improvement and patient safety plan

## **ANNEX A: COMMUNITY PHARMACY ACCREDITATION STANDARDS**

### **Introduction:**

A community pharmacy, often referred to as retail pharmacy, is a place where medications are stored, dispensed, supplied or sold. Community pharmacy is defined broadly to include all those establishments that are privately owned and whose function, in varying degrees is to serve societies needs for both drug product and pharmaceutical service.

Community pharmacists are the health professionals most accessible to the public and are a cornerstone in any society. The community pharmacies are often the first point of contact for patients seeking advice for different medical conditions and treatments for minor diseases/ conditions.

The main responsibilities of a community pharmacy include counseling, compounding, and dispensing of medications to the patients with care, accuracy, and legality along with the proper procurement, storage, and documentation of medications. Community pharmacy plays a vital role in providing primary care and promoting public health in communities. The community pharmacist must be a qualified and pertinent with sound education, skills and competence to deliver the professional service to the community.

Medication management is one of the major responsibilities in any healthcare settings. It is a complex process, which involves different phases including planning, procurement, storage, prescribing, transcribing, ordering, dispensing, administration, monitoring of the medications, and evaluation of the program. Evidence suggests that, at each phase of the cycle, errors do occur adversely influencing patients' safety, which is a priority in today's practice. These issues are particularly relevant in community pharmacy.

It is further state that, morbidity from medication errors results in high financial costs for the society and adversely affects the patient's quality of life. Preventing medication errors is a major priority in health system and many international organizations such as the JCI and the WHO.

The community pharmacist, being an important member of the healthcare team and society, can make successful efforts to prevent the medication errors by counseling and guiding the sufferer.

### **Implementation guiding documents:**

1. Law No. 127/1955 on practicing the profession of pharmacy.
2. Law No. 182/1960 on narcotics
3. Law No. 151/2019 on establishment of Egyptian Drug Authority
4. Prime Minister's Decree 777/2020 about the EDA executive bylaws.
5. Decision of the Minister of Health and Population number 368- year 2012 for developing

a pharmacovigilance center.

6. Rational Drug Use Publication No: 4 for year 2017 of Antimicrobial Stewardship
7. The Egyptian Guidelines of Medication Management Standards first edition (2018)
8. The Minister of Health and Population Decree No. 380- year 2009 on the re-regulation of the health requirements for pharmaceutical institutions.
9. The Egyptian Drug Authority Decree No. 271- year 2021 on the regulation of Drug storage requirements for pharmaceutical institutions.
10. The Minister of Health and Population Decree No. 172- year 2011 on the re-regulation of handling of the pharmaceutical substances and products affecting the mental state.
11. The Minister of Health and Population Decree No. 475- year 2019 on the re-regulation of handling of the pharmaceutical substances and products affecting the mental state.
12. The Egyptian Drug Authority Decree No. 340- year 2021 on the re-regulation of handling of the pharmaceutical substances and products affecting the mental state.
13. The Egyptian Drug Authority Updated OTC drug list 2021: <https://www.edaegypt.gov.eg/ar/>

## **CPS.01 Medication use is managed to meet patient's/client's needs**

*Effectiveness*

### **Keywords:**

Medication management.

### **Intent:**

The unsafe use of medication is not the only safety problem in the healthcare system, but it is certainly one of the most significant issues. Ensuring a safe medication management program at an organizational level is a major challenge. Medication management in the community pharmacy involves patient-centered care regarding medications, which aims to provide safe, effective and appropriate medication therapy.

Safe medication management services in community pharmacy practice address the organization's medication processes, which includes the following:

- a. Planning and organization
- b. Selection and procurement
- c. Storage
- d. Prescription processing and medication preparation and dispensing
- e. Monitoring

A qualified licensed pharmacist directly manages the activities of the pharmacy and pharmaceutical service is mandatory according to the Egyptian laws and regulations.

All medication management processes in the Egyptian community pharmacies are conducted and implemented according to the applicable Egyptian laws and regulations (The Egyptian Drug Authority (EDA)). A clear organizational structure and job description of duties and activities for each staff member shall be clearly defined to support the safe and effective provision of pharmacy services.

The community pharmacy has relevant and licensed software package(s) implemented to manage different processes like prescriptions, inventory, essential drug lists, expiry date of medications, financial management, recalls, policies and procedures, quality related forms and practices, communication related to medications. The pharmacy also has a backup option(s) like using external drive, backup over the internet, or using cloud storage services. The community pharmacy leader gives special emphasis on continuing professional development(CPD) pharmacy staff to ensure pharmacist competence. Different organizations and websites offer free certified pharmacy related CPDs programs including the American Society of Healthcare system, pharmacy magazine, Medscape, Power Pak, Pharmacy Time, Pro CE, stat pearls and others.

### **Survey process guide:**

- GAHAR surveyors may review the updated list of the pharmacy staff, their related credentials and their job descriptions.
- GAHAR surveyors may observe the available computer system with its backup. Also they

may observe the selected source(s) of drug information.

- GAHAR surveyors may interview staff to check their awareness of the accessibility to the drug information source(s) and pharmacy laws and regulation

**Evidence of Compliance:**

1. The community pharmacy has a clear description of the pharmacy scope of service(s) covering elements from a) to e) in the intent and its operating hours.
2. The community pharmacy has a clear staff job description and is managed by a licensed competent pharmacist who must be physically present in the pharmacy at the time of medication sale/dispensing.
3. Updated medication-related information source(s) is/are available either as electronic or as paper-based formats to pharmacy staff members involved in medication use.
4. The community pharmacy has licensed and securely protected software package(s) implemented to manage different pharmacy processes with backup option(s) in case information system fails.

**Related standards:**

CPS.03 Medications storage.

**CPS.02 Medications are selected, and procured based on approved criteria.**

*Efficiency*

**Keywords:**

Medication selection and procurement.

**Intent:**

Identifying medications that are the most appropriate and cost-effective to best serve the community needs is a core and critical function of the community pharmacy. The community pharmacy shall develop an inventory medication list (electronic or paper based) of all the medications it stocks. The stock of medication and products is relative to the patients and clients flow to the pharmacy. The medications shall be selected from the EDA and other national authorizing bodies legally approved medications based on community needs. The list shall include (but not limited to):

- a. Name(s) of medication(s)
- b. Strength(s)/concentration(s) of medication(s)
- c. Dosage form(s) of the medication(s)
- d. Expiration date

Pharmaceutical procurement is a complex process, which involves many steps, agencies, and manufacturers. The procurement and distribution system covers the processes: to select the most cost-effective essential medications to treat commonly encountered diseases; to quantify the needs; to pre-select potential suppliers; to manage procurement and delivery; to ensure good product quality; and to monitor and evaluate the performance of suppliers and the procurement system.

The process for evaluating new suppliers can include checking the licensure, providing formal visit(s), reference checks with past clients and agencies, test purchases in small quantities and informal local information gathering.

The community pharmacy shall have well-implemented policy and procedures to select and procure medications. This policy is also expected to cover the process of investigating if the medications are contaminated, defective, or counterfeit and to trace them back to determine the cause of the problem, and to notify the manufacturer and/or distributor when something discovered when checking the supply on receiving step. In addition, the community pharmacy shall define a procedure to inform healthcare providers and physicians about non-available medications and products and respective substitutes.

### **Survey process guide**

- GAHAR surveyor may review policy and procedures that clearly describe the criteria for selection and procurement of medications and the process (es) for communication about medication shortage and outage to prescribers.
- GAHAR surveyor may review the availability of a printed/electronic copy of the medication list.

### **Evidence of Compliance:**

1. The community pharmacy has approved policy and procedures active in place for the selection and procurement of medications in accordance to the community needs, safety, and services provided.
2. The community pharmacy has an inventory list of the stocked medications which includes at least items from a) to d) in the intent.
3. The community pharmacy has a clear process of communication about medication shortage and outage to prescribers, other healthcare professionals and patients and provides suggestion of substitutes if possible.

### **Related standards:**

CPS.01 Medication management, CPS.03 Medications storage, CPS.06 Drug recall system

### **CPS.03 Medications are safely and securely stored in a manner to maintain its quality.**

*Effectiveness*

### **Keywords:**

Medications storage.

### **Intent:**

Well-designed and appropriate storage of medications can reduce waste, incorrect medication dispensing, and handling. The community pharmacy maintains proper medication storage conditions (temperature, light, and humidity) in medication storage areas to protect their stability 24 hours a day, and 7 days a week and according to the manufacturer/ marketing authorization requirements.

The stability/effectiveness of any medication depends on storing it at the correct temperature, for example, those medications requiring refrigeration. There should be clear evidence that community pharmacy ensures the storage of medications in a manner to maintain its quality and integrity. In addition, the community pharmacy limits access to medication storage areas with the level of security required to protect it against loss or theft depending on the types of medications stored like the storage requirements for narcotics and psychotropic medications.

Medications or other solutions in unlabeled containers are unidentifiable. Errors, sometimes tragic, have resulted from medications and other solutions removed from their original containers and placed into unlabeled containers. This unsafe practice neglects basic principles of safe medication management.

The labeling of all medications, medication containers, and other solutions is a risk-reduction activity consistent with safe medication management. This practice addresses a recognized risk point in the administration of medications.

Medications, medication containers, other solutions, and the components used in their preparation are clearly labeled (if not apparent on the original packages or boxes) with the following:

- a. Name of medication
- b. Concentration/strength
- c. Expiration date
- d. Batch number (doesn't include extemporaneous preparations)
- e. Any applicable warnings.

**Survey process guide:**

- GAHAR surveyor may review evidence (e.g., checklists, temperature log) ensuring the compliance with proper medication storage conditions.
- GAHAR surveyor may observe that all medications are stored as per manufacturer/marketing authorization holder recommendations and all are clearly labeled.
- GAHAR surveyor may observe narcotic and psychotropic medications storage conditions and their security

**Evidence of compliance:**

1. Medications are safely and securely stored under manufacturer/marketing authorization holder recommendations and kept clean and organized all the time.
2. Calibrated Manual, or electronic temperature and humidity recording equipment, devices, or logs are used to document proper storage conditions of stocked medications.
3. Narcotics and psychotropic medications are stored in a separate safe or securely locked cabinet according to the laws and regulations.
4. The community pharmacy has a clear process to deal with electric power outage to ensure integrity of the affected medications before use.



5. Medications, medication containers, other solutions, and the components used in their preparation are clearly labeled (if not apparent on the original packages or boxes) with elements from a) to e) in the intent.

**Related standards:**

CPS.03 Medications storage, CPS.04 High alert medications, CPS.05 Look alike-Sound alike medications, CPS.06 Drug recall system

**CPS.04 High alert medications are managed in a manner to ensure their safe dispensing.**

*Safety*

**Keywords:**

High alert medications

**Intent:**

High-alert medications are those bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these medications, the consequences of an error are clearly more devastating to patients. Examples of high alert medications include but not limited to: concentrated electrolytes, anticoagulants, hypoglycemic agents, narcotics, medications with narrow therapeutic range, chemotherapy, anesthesia medications, and inotropic agents.

The community pharmacy needs to develop its own list of high alert medications based on its own data and both national and international recognized organizations (e.g., Institute of Safe Medication Practice (ISMP) and the World Health Organization (WHO). The community pharmacy shall confirm that there are strategies in place to prevent the inadvertent use of these medications.

**Survey process guide:**

- GAHAR surveyor may review the updated list of high alert medications.
- GAHAR surveyor may observe the different strategies implemented to ensure safe storage of high-risk medications, and the process of patient education about handling and use of high alert medications.
- GAHAR surveyor may interview staff about the storage process of high alert medications and the process of patient education regarding the handling and use of high alert medications

**Evidence of Compliance:**

1. The community pharmacy has regularly updated list(s) of high alert medications.
2. The community pharmacy has uniform strategies for the safe storage and dispensing of high alert medications, including separation, and labeling.
3. The community pharmacy provides verbal and/or written education about the handling and use of high alert medications to the patients.

**Related standards:**

CPS.03 Medications storage.

**CPS.05 Look-alike and sound-alike medications are managed in a manner to ensure the safety of dispensed medications.**

*safety*

**Keyword:**

Look-alike, Sound-alike medications (LASA).

**Intent:**

Look-alike/sound-alike (LASA) medications are those visually similar in physical appearance or packaging and names of medications that have spelling similarities and/or similar phonetics. Any confusion between these medications may lead to harmful errors.

The Institute for Safe Medication Practices (ISMP) maintains an ongoing list of LASA medication names to highlight medications that may require special safeguards or strategies to help prevent healthcare providers from accidentally mistaking one medication for another.

Community pharmacies need to establish risk management strategies to minimize adverse events with LASA medications, enhance patient safety. One of the recommendations that can be used to prevent the risk of the LASA errors focuses on ensuring prescription legibility. Other recommendations aimed at minimizing name confusion include conducting a periodic review of new product names; physically separating and segregating these medications in medication storage areas prevents confusion and promotes safety. In addition, the use of specially designed labels minimizes the risks of LASA errors. Also, the community pharmacy is expected to provide an ongoing verbal and/or written education to the pharmacy staff members on managing look alike sound alike medications.

**Survey process guide**

- GAHAR surveyor may review the updated list of LASA medications.
- GAHAR surveyor may observe the different processes implemented to ensure safe management of LASA.
- GAHAR surveyor may interview staff about management of LASA and training received.

**Evidence of Compliance:**

1. The community pharmacy has a regularly updated list of look-alike/sound alike (LASA) medications.
2. The community pharmacy has clear process (es) for the management of look-alike/sound alike medications during the storage and dispensing.
3. The community pharmacy has an ongoing verbal and/or written education to the pharmacy staff members on managing look alike sound alike medications.

**Related standards**

CPS.03 Medications storage

## **CPS.06 The community pharmacy has a drug recall system in place.**

*Effectiveness*

### **Keywords:**

Drug recall system

### **Intent:**

A drug recall is required when safety issues arise, and the defective products are required to be returned to the manufacturer or distributor. This includes expired, outdated, damaged, and/or contaminated medications.

The community pharmacy shall take steps to ensure that medications meet the required standards for product integrity, and that expired medications cannot be inadvertently dispensed or administered. Regular monitoring of disposal of unused, unwanted, or expired medications assists in identifying the potential for, and actual unauthorized, diversion of medications.

The community pharmacy shall have an implemented system for the proper identification and retrieval of medications recalled by the Egyptian Drug Authority (EDA), the manufacturer, marketing authorization holder, or other well-recognized bodies. Recalled medications are clearly labeled and separated from regular stock pending removal by the manufacturer/marketing authorization holder, or destruction.

The recall system includes:

- a. Process to retrieve recalled medications
- b. Labelling
- c. Separation
- d. Disposal or removal
- e. Patient notification (when applicable).

In addition, the community pharmacy has policy and procedures to ensure that medications meet the required standards for product integrity, and that expired medications cannot be inadvertently dispensed or administered. Regular monitoring of disposal of unused, unwanted, or expired medications assists in identifying the potential for, and actual unauthorized, diversion of medications.

It is the responsibility of the community pharmacy to ensure that all staff members dealing with medications are aware of the drug recall system and the procedures of handling expired, damaged, outdated or contaminated medications.

### **Survey process guide:**

- GAHAR surveyor may observe the drug recall system for removal, storing, and disposing of expired, damaged, or contaminated medications.
- GAHAR surveyor may interview staff members to check their awareness of the drug recall policy.
- GAHAR surveyor may trace a recalled drug from the reception of drug recall notice till disposal or removal.

**Evidence of Compliance:**

1. The community pharmacy has a drug recall system that includes elements from a) to e) in the intent.
2. The community pharmacy has approved policy and procedures in place for removal, storing, and disposing of expired, damaged, or contaminated medications.
3. Recalled medications are clearly labeled and separated according to the manufacturer/ marketing recommendation.
4. Staff members involved in drug recall process are aware of the drug recall system and the process of handling of expired medication

**Related standards**

CPS.03 Medication storage

**CPS.07 Complete prescription orders are reviewed for accuracy and appropriateness.**

*Effectiveness*

**Keywords:**

Prescription appropriateness review.

**Intent:**

Balanced prescribing is a process that recommends a medication appropriate to the patient's condition and, within the limits created by the uncertainty that attends therapeutic decisions, a dosage regimen that optimizes the balance of benefit to harm. There is a considerable amount of evidence nationally and internationally to demonstrate that much needs to be done to improve the way medications are prescribed and support patients in effective medications use. Careful attention to all facets of prescribing can improve the chances of benefit, reduce the risks of medication errors, adverse reactions and interactions, and enhance adherence to therapy.

Narcotics and psychotropic medications are managed according to laws and regulations. Community pharmacy defines the elements of a complete and safe prescription and the types of orders including those for narcotics and psychotropic medications that are acceptable for use to reduce variation and minimize the potential for errors and misinterpretation when orders are written.

The required elements of complete medication prescriptions include at least the following:

- a. Patient's name, age and weight
- b. Main diagnosis.
- c. Medication name.
- d. Dosage form.
- e. Strength or concentration.
- f. Dosage and frequency.
- g. Rout of administration.
- h. Treatment duration (for medications not prescribed for chronic conditions).

i. The name of the prescriber and contact details

Community pharmacy has an implemented policy that clearly describes action(s) to be taken when medication or narcotics prescriptions are incomplete, illegible, or unclear including the cases when questions or concerns arise and how the prescriber is communicated.

All medication orders must be reviewed before dispensing. Each prescription shall be reviewed for the accuracy and appropriateness of the medication for the right patient and for the right clinical needs. The appropriateness review of any prescription is conducted by licensed pharmacist.

Each prescription is reviewed for the following elements:

- j. The suitability of the dosage regimen including the dose, frequency, route of administration, and duration of treatment considering patient's information.
- k. Therapeutic duplication.
- l. Contraindications (if any).
- m. Allergies or sensitivities.
- n. Major drug interactions

**Survey Process Guide:**

- GAHAR surveyor may review an evidence (e.g., list, poster, word electronic document etc.) that defines the elements of complete prescription and may interview the pharmacy staff to check their awareness of the elements of complete prescription
- GAHAR surveyor may review the management of incomplete prescription policy and may interview the pharmacy staff to check their awareness of the actions taken in case of incomplete prescriptions.
- GAHAR surveyor may review narcotics and psychotropic prescription policy and its implementation.
- GAHAR surveyor may observe the communication process between the pharmacist and the prescriber

**Evidence of Compliance:**

1. Community pharmacy has a process that define the elements of complete medication prescription(s) that include items from a) to i) in the intent when handling a prescription.
2. Community pharmacy has approved policy and procedures active in place to manage medication prescriptions that are incomplete, illegible, or unclear.
3. Community pharmacy has approved policy and procedures active in place to manage of narcotic and psychotropic prescriptions according to the laws and regulations.
4. Each prescription is reviewed for appropriateness by a licensed pharmacist and according to elements from j) to n) in the intent prior to dispensing using current and updated resources.
5. The community pharmacy has a process to contact the prescriber when questions or concerns arise.

**Related standards:**

CPS.01 Medication management.

**CPS.08 Medications are prepared and dispensed in a safe and clean environment.**

*Safety*

**Keywords:**

Medication safe preparation and dispensing.

**Intent:**

A safe, clean and organized working environment provides the basis for good dispensing practice. The dispensing environment includes qualified pharmacist, appropriate physical surroundings, adequate shelving and storage areas, proper work surfaces, suitable equipment, and necessary packaging materials. The community pharmacy identifies the standard of practice for a safe, and clean prescription preparation environment. Each community pharmacy is responsible for identifying those individuals by law and regulation, qualification, training, experience, or job description who can prepare medications or prepare extemporaneous preparation.

All staff members who prepare medications are requested to use techniques to ensure accuracy (e.g., double-checking calculations), and avoid contamination, including using clean or aseptic technique (for extemporaneous preparations) as appropriate; maintaining clean, uncluttered, and functionally separate areas for product preparation to minimize the possibility of contamination.

Prepared medications must be labeled in a standardized manner according to the community pharmacy's policy to minimize errors. If the medication(s) is/are not dispensed in its original container, at a minimum, labels must include the following (if not apparent from the container):

- a. Medication/preparation name.
- b. Strength/concentration.
- c. Amount.
- d. Expiration date and batch number (for non-extemporaneous preparations).
- e. Preparation and beyond use date (for extemporaneous preparation),
- f. Directions for use and any special/cautionary instructions (if needed).

**Survey Process Guide:**

- GAHAR surveyor may review an updated list of individuals that are authorized to prepare and dispense medications
- GAHAR surveyor may observe the compounding and preparation process and the preparation area
- GAHAR surveyor may interview the pharmacy staff to check their awareness of the compounding and preparation process

**Evidence of Compliance:**

1. Medications are prepared safely in clean and uncluttered areas provided with appropriate medical equipment, and supplies and adhering to the professional standards of practice.
2. The community pharmacy identifies those authorized to prepare and dispense medications in different situations.
3. The community pharmacy has a process to guide the compounding and preparation of medications in compliance with written formulas and quality standards of raw materials, calibrated equipment, and preparation processes.
4. All medications compounded and/or prepared in the community pharmacy are clearly and correctly labeled in a standardized manner with at least the elements from a) to f) in the intent and in a language and form the patient can understand.

**Related standards:**

CPS.01 Medication management, CPS.13 Infection preventions and control process

**CPS.09 The Community Pharmacy has clear criteria when non-prescription/OTC medication is requested**

*Effectiveness*

**Keywords:**

Over the Counter (OTC) Medications

**Intent:**

Traditionally, community pharmacists have advised patients on the management of minor, self-limiting illness and have referred patients with other conditions to the physician for management. However, this has changed in recent years due to the reclassification of medication from prescription-only medications to non-prescription medications/over the counter (OTC) medications. Over-the-counter (OTC) medications are those that can be sold directly to people without a prescription. The Egyptian Drug Authority (EDA) regularly releases an updated national list of the OTC medications to be sold by community pharmacists. Community pharmacists have to make daily decisions as to whether the symptoms presented are suggestive of a minor illness or a major disease.

This standard applies to situations where the patient comes to the pharmacy to consult the pharmacist on a minor health problem or request to purchase an OTC medication by name. Pharmacists shall implement policy and procedures clearly describe how health problem(s) presented to in the community pharmacy acted upon after obtaining sufficient information on the following:

- a. Who has the problem (if a child/elderly, the age to be specified).
- b. What is/are the problem(s).
- c. How long has the condition existed.
- d. Action already taken.
- e. Medications already used for the problem.



- f. Medical history: allergies, other existing health problems and medication history.
- g. To rule out possible underlying serious acute diseases.
- h. When to refer to a medical practitioner.

After the obtaining the necessary information, the pharmacist shall:

- i. Differentiate minor illnesses (such as cold, flu, allergic rhinitis, headache, sore throat, mouth ulcer, constipation, hemorrhoids, heartburn, indigestion, ect...) from major diseases based on scientific evidence.
- ii. Minimize risk factors and complications.
- iii. Offer appropriate advice (non-pharmacological and/or pharmacological).
- iv. Counsel patient on the efficacy and safety of the medication(s) recommended.
- v. Request the patient to go to the physician when appropriate.

Patient care orders given verbally over the telephone, if permitted, are some of the most error-prone communications. Different accents and pronunciations can make it difficult for the receiver to understand the order given. For example, medication names and numbers that sound alike, such as erythromycin and azithromycin, can affect the accuracy of the order. Background noise, interruptions, and unfamiliar medication names and terminology often compound the problem. When received, a telephone order must be transcribed as a written order, which adds complexity and risk to the ordering process.

The community pharmacies shall develop and implement a clear policy and procedures for handling phone call orders for non-prescription medication(s). The following shall be part of this process:

- I. Spell medication names and numbers back to caller and obtain indication for use from caller for these medications.
- II. "Read-back "of the complete order elements to the ordering person for confirmation.

#### **Survey Process Guide:**

- GAHAR surveyor may review the policy that describes the action(s) to be followed by community pharmacy before recommending/selling OTC medication(s) and may review the process of recommending/selling these medication(s).
- GAHAR surveyor may review the policy of handling phone call orders for non-prescription medications.
- GAHAR surveyor may interview pharmacists to check their awareness of the policy (ies).

#### **Evidence of Compliance:**

1. Community pharmacy has an approved policy and procedures clearly describe the steps being followed when OTC medication(s) is/are requested or health problem(s) is/are presented after obtaining sufficient information including elements from i) to v) in the intent.
2. Community pharmacist(s) is/are trained on responding to symptoms and know when to advise the patient to go to the physician.



3. Community pharmacy has approved policy and procedures active in place to manage phone call orders for non-prescription medications/OTC which cover elements I) and II) in the intent.

**Related standards**

CPS.01 Medication management, CPS.10 Medication counseling.

**CPS.10 Community pharmacy proactively provides counseling to patients/clients regarding dispensed or sold medication(s)**

*Patient-centeredness*

**Keywords:**

Medication counseling.

**Intent:**

The community pharmacist counsel patient/client and his/her family so that they have the knowledge and skills to participate and take decisions related to his/her care processes. This counseling includes but not limited to verbal explanation and instructions by a pharmacist to patients, and/or their families on the storage, safe and effective use of both the prescribed and OTC medications.

Community pharmacist is expected to do the maximum to ensure that the patient understands the information provided by asking him/her to explain what he/she understood in a plain and suitable language. The information to be provided is expected to cover at least the followings:

- a. Name of the medication.
- b. Indication (intended use).
- c. Dosage and method of use/administration.
- d. Any preparation instructions to be done at home if needed (e.g., preparation of antibiotics suspension from powder products, changing cartridge for insulin pen).
- e. Warning instructions, potential drug or food interactions and most common side effects.
- f. Action to be taken when dose is missed.
- g. Storage conditions.
- h. Duration of the therapy.
- i. Self-monitoring parameters (if any).

When counseling patient, the pharmacist shall make sure that, the patient understands the objective of the treatment. Pharmacist advises on non-pharmacological treatment when appropriate.

The process of patient counseling shall be performed in an area quiet enough away from interruption that ensures confidentiality to patient information. Confidentiality for patient counseling must be provided. Also, pharmacy practice encourages patient-initiated questions using a variety of methods and materials (through phone calls, e-mails, or websites, that connect the patient with a pharmacist to receive patient counseling).

High-alert medication(s) and high-risk populations (e.g. patients taking medication for the first time, patients taking complex regimens, elderly patients, patients with special needs) are identified and corresponding counseling takes place to ensure patient safety.

**Survey Process Guide:**

- GAHAR surveyor may review the written information used to support verbal communication for example using fliers, dosing charts, counselling checklist, etc.).
- GAHAR surveyor may observe the process of medication counseling provided to the patients covering elements from a) to i) in the intent, and the area where conversation/ counseling takes place.
- GAHAR surveyor may interview patients to check their awareness of medication counseling process.

**Evidence of Compliance:**

1. The community pharmacy has a process for the provision of medication counseling to the patients and/or their families covering elements from a) to i) in the intent, and the patients are encouraged to ask questions.
2. Written information is used to support verbal medication counselling.
3. Community pharmacy has an area for confidential conversation/counseling with the patient.
4. The community pharmacy has a process ensuring that patients with special needs are provided with suitable educational aids that help them to understand the pharmacological information.

**Related standards:**

CPS.01 Medication management, CPS.09 Over the counter medications

**CPS.11 The community pharmacy has a process for monitoring the medication effects on patients, and detecting, acting on and reporting of medication errors, near misses and suspected adverse drug reactions.**

*Effectiveness*

**Keywords:**

Medication Monitoring\_ Medication errors \_Adverse events and near misses

**Intent:**

Medications are monitored for patient clinical effectiveness, and adverse medication effects to ensure that medication therapy is appropriate and risks are minimized. Medication monitoring is an interdisciplinary process where the patient and his or her physician, pharmacist, and other healthcare professions work together to monitor patients on medications. The purpose of monitoring is to evaluate the therapeutic response of the medication(s), including safety and effectiveness in order to adjust the dosage or type of medication when required, evaluate for any medication interaction, and evaluate the patient

for adverse effects or allergic reactions.

Monitoring medication effects includes observing and documenting any adverse effects. This is done using a standardized format (e.g., The Egyptian National Forms) for reporting and educating staff on the process and the importance of reporting. Reporting to the authorized institutions is done in the most appropriate time without any delay as per national regulations.

Medication errors and near misses are particularly important given the large and growing global volume of medication use. This is especially critical in the healthcare settings where a significant proportion of prescribing occurs.

The community pharmacy shall develop a policy and procedures that describe the identification and reporting of medication error(s) and near miss(es). The procedures include defining a medication error and near miss, and educating staff on the process and importance of reporting.

**Survey Process Guide:**

- GAHAR surveyor may review policy and procedures for managing medication error(s) and near miss(es)
- GAHAR surveyor may interview staff to check their awareness of the reporting of any adverse effect(s).

**Evidence of Compliance:**

1. Actual or potential medication adverse drug reaction(s) is/are monitored and reported in a manner consistent with the national/international guidelines.
2. The community pharmacy has definitions for medication error(s), near miss(es), and medication therapy problem(s) based on national/international references
3. The community pharmacy has an approved policy and procedures for detecting, and reporting medication error(s), near miss(es), and medication therapy problem(s) in a manner consistent with the national/international guidelines.
4. The community pharmacy has a process informing prescriber when an adverse effect(s), medication error(s), near miss(es), and medication therapy problem(s) occur(s).

**Related standards:**

CPS.01 Medication management, CPS.04 High alert medications

**CPS.12 The community pharmacy is responsible for providing processes that ensure patient/client, family rights and responsibilities.**

*Patient-centeredness*

**Keywords:**

Patients/client's rights and responsibilities.

**Intent:**

Each patient/client and / or his or her family are/is unique, with their own needs, strengths, values, and beliefs. The community pharmacies work to establish trust and open communication with patients, to understand, and to protect each patient's cultural, psychosocial, and spiritual values.

The community pharmacy is primarily responsible for how it will deal with its patients/clients. Thus, it needs to know and to understand patient/client and family's rights. To protect patient/client's rights effectively, leadership works and seeks to understand their responsibilities in relation to the community served by the organization.

Patient/client's rights are stated in writing and at minimum include at least the following:

- a. The right to have access to the community pharmacy services
- b. The right to be treated with dignity and respect and without discrimination
- c. The right to have privacy and confidentiality
- d. The right for safe and secure service environment
- e. The right to make a complaint

Patients/clients shall be able to identify responsibilities related to the care process. A patient/client shall identify responsibilities for:

- f. Provision, to the best of his/her knowledge, accurate and complete information about present complaints/condition, past illnesses, medications, and other matters related to his/her health.
- g. Compliance with the provided instructions and recommendations.
- h. Following the pharmacy rules and regulations.
- i. Being respectful of the property and of the community pharmacy.

The inability to identify these responsibilities might affect the care of the services provided to the patients/clients themselves, or their families, or of other patients/clients or of staff members. The community pharmacy is responsible for making the patient responsibilities visible to patients and staff members at all times.

Patients/client's and family's rights and responsibilities are fundamental elements. Thus, there is a clear process implemented to ensure that all staff members are aware of and respond to patient/client and family rights issues when they interact with and care for patients/clients. In addition, to ensure that patients/clients are aware of their responsibilities. In addition, the community pharmacy is expected to have a system in place to manage complaints and concerns from patient/client receiving service or care from the pharmacy.

**Survey process guide:**

- GAHAR surveyor may observe the patient rights and responsibilities statements posted in the community pharmacy
- GAHAR surveyor may observe conditions under which patient rights are protected
- GAHAR surveyor may interview staff members to check their awareness of patient rights and responsibilities and the way for dealing with complaints and feedbacks.

**Evidence of Compliance:**

1. An approved statement on patient's/client's rights and responsibilities (covering elements from a) to i) in the intent is posted in a way that makes it visible to staff, patients/clients, and families.
2. All staff members are aware of patients/client's rights and responsibilities.
3. Measures are in place to secure patient's information and to protect patient privacy and data confidentiality.
4. The community pharmacy has a system in place to manage complaints and concerns from patient/client receiving service or care from the pharmacy.

**Related standards:**

CPS.01 Medication management, CPS.10 Medication counseling.

**CPS.13 The community pharmacy develops and implements infection prevention and control process.**

*Effectiveness*

**Keywords:**

Infection preventions and control process.

**Intent:**

Infection prevention and control are challenging in most healthcare settings including pharmacies, and rising rates of infections are a major concern for patients and staff. Any healthcare organization assesses and cares for patients/clients using many simple and complex processes, each associated with a level of infection risk to patients/clients and staff. It is important to measure and review these processes and, as appropriate, implement needed strategies, such as policies, procedures, education, and evidence-based activities designed to reduce the risk of infection.

One of the pillars for the elimination of infections is proper hand hygiene. Evidence-based hand-hygiene guidelines are available from the World Health Organization (WHO), the United States Centers for Disease Control and Prevention (CDC), and various other global organizations.

Community pharmacy has policy and procedures describe the early implementation of infection control measures needs to occur at the first point of entry within a healthcare setting, and be maintained throughout the duration of the visit. The community pharmacy is also

requested to adopt and implement current evidence-based hand-hygiene guidelines. Hand hygiene guidelines are posted in appropriate areas, and staff are educated in proper hand-washing and hand disinfection procedures. Soap, disinfectants, and towels or other means of drying are located in those areas where hand-washing and hand-disinfecting procedures are required. The community pharmacy has policy and procedures describe the standard precautions, dealing with sharps and lancets, and using and disposing of personal protective equipment (if used). In addition, it is the responsibility of the community pharmacy to keep the place of preparation and dispensing areas clean and well- maintained all the time.

As part of the quality management and infection prevention, cleaning and hygiene services are available and implemented in terms of guidelines, work instructions, checklists and other documents.

**Survey process guide:**

- GAHAR surveyor may review policy and procedures that describe and define sources of infection within the pharmacy setting and situation bearing risks of infection, with respective preventive and protective measures.
- GAHAR surveyor may review policy and procedures that describe processes for dealing with sharps and lancets
- GAHAR surveyor may observe the staff compliance with infection control policy, proper hand hygiene, and the availability and accessibility to disinfectants.
- GAHAR surveyor may interview staff to check their awareness of infection prevention policy.

**Evidence of Compliance:**

1. The community pharmacy has approved policy and procedures active in place that describe and define sources and situations of infection within the pharmacy setting, with respective preventive and protective measures including the standard precautions, and using and disposing of personal protective equipment (if used).
2. The community pharmacy has approved policy and procedures active in place that clearly describe processes for dealing with sharps and lancets (if used) according to national/ international guidelines.
3. Community pharmacy assures compliance to proper hand hygiene, availability of and access to hand disinfectant for staff, patients and clients.
4. Cleanliness of the place of preparation and dispensing areas is maintained all the time.
5. Community pharmacy' staff members are aware of the different infection prevention and control measures adopted in the pharmacy.

**Related standards:**

CPS.01 Medication management, CPS.08 Medication safe preparation and dispensing.

## **CPS.14 The community pharmacy ensures environmental and facility safety processes**

*Safety*

### **Keywords:**

Environmental and facility safety

### **Intent:**

Laws, regulations, and inspections by national and local authorities determine in large part how a facility is designed, used, and maintained. The community pharmacy leaders are responsible for providing a safe physical environment for staff and patients/clients. These responsibilities include:

Knowledge about applicable laws, regulations, building and fire safety measures, and other requirements;

Implementation of the applicable requirements; and

Ensuring that the community pharmacy meets the conditions of reports or citations from inspections by national authorities.

The term Safety refers to ensuring that the building, property, medical and information technology equipment, and systems do not pose a physical risk to patients, families, staff, and visitors. Examples of safety risks include sharp and broken furniture, broken windows, water leaks in the ceiling, and locations where there is no escape from fire. To be aware of safety risks in the community pharmacy, an inspection of the facilities takes place at least annually and is documented.

Security refers to protecting the community pharmacy's property from loss or damage and protecting the patients/clients, families, and staff from harm and/or aggression.

The community pharmacy implements a hazardous materials and waste process that includes identifying and safely controlling hazardous materials and waste throughout the facility. Based on the WHO, the followings are considered hazardous materials and waste: infectious, pathological and anatomical, pharmaceutical, chemical, heavy metals, pressurized containers, sharps, genotoxic/cytotoxic, and radioactive materials

The community pharmacy shall have appropriate preparedness for different types of emergencies like natural disaster (e.g., heavy rains, floods, hot weather, fires, earthquake and other community emergencies in addition to epidemics). It is just as important to identify the effects of a disaster, as it is to identify the types of disasters. This helps in planning the strategies that are needed in the event that a disaster occurs.

This preparedness allows the community pharmacy to have organized and rapid response in case of different emergencies. The development of the process shall begin by identifying the types of disasters that are likely to occur in the pharmacy's region and what the impact of these disasters would have on the pharmacy.



Fire is an ever-present risk in any healthcare organization. Thus, every organization needs to plan how it will keep its occupants safe in case of fire or smoke. The community pharmacy establishes a process to ensure:

- a. The prevention of fires through the reduction of risks, such as safe storage and handling of potentially flammable materials;
- b. The prevention of hazards related to any construction in or adjacent to the community pharmacy;
- c. Safe and unobstructed means of exit in the event of a fire;
- d. Early warning and early fire detection, such as smoke detectors, or fire alarms; and
- e. Fire suppression mechanisms, such as water hoses, chemical suppressants, or sprinkler systems.

Smoking is considered one of the most common causes of fire in healthcare facilities, so the community pharmacy shall ensure a smoking-free environment.

The community pharmacy shall have an inventory of all utilities (for example, electricity, generator, ventilation, air conditioning, communication systems, sewage, and fire alarm) with a preventive maintenance plan according to the manufacturer. The plan is expected to be focusing on regular inspection, testing, and corrective maintenance for all utilities.

#### **Surveyor Process Guide:**

- GAHAR surveyor may review the document(s) that describe(s) the fire safety process, the process of handling hazardous materials and hazardous waste. The process for safety and security including a process to protect patients/clients from harm, violence, and aggression, the process of handling external disaster and the process to ensure functioning utilities.
- GAHAR surveyor may observe the availability spill kit and the safety data sheet (SDS) for all hazardous materials. In addition, surveyor may observe the process of appropriate handling of hazardous materials and hazardous waste and the availability of protective equipment. Also, surveyor may observe the safety measures of physical environment in the community pharmacy
- GAHAR surveyor may interview pharmacy staff to check their awareness of environmental safety related processes.

#### **Evidence of compliance:**

1. The community pharmacy has an updated and documented process to ensure safety from fire in accordance with civil defense.
2. The community pharmacy has an updated and documented process to handle hazardous materials and hazardous waste.
3. The community pharmacy has an updated and documented process to ensure safety and security of patients/clients and staff.
4. The community pharmacy has an updated and documented process to handle external disasters.



5. The community pharmacy has an updated and documented process to ensure proper functioning of related utilities.
6. Community pharmacy staff members are aware of different environmental safety proceed.

**Related standards:**

CPS.01 Medication management, CPS.03 Medications storage

## **ANNEX B: PRIVATE CLINIC ACCREDITATION STANDARDS**

### **Introduction:**

Depending on the services provided, the team responsible for providing solo medical care is usually consisting of a certified medical doctor, which is the most responsible physician. However, the team may include nurses, allied health professionals as dietitians, occupational or physical therapists, social workers; administrators and clerical staff; and others as needed. The most responsible physician shall define roles, responsibilities, and determine the functions that each member is allowed to perform. Physician shall adhere to the scope of medical practice defined by laws and/or regulations, and fully comply with the national licensing bodies requirements (e.g. education, experience) to obtain the license to practice.

### **Implementation guiding documents:**

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

1. Egyptian Constitution
2. Law 51/1981 regulating the healthcare organizations
3. Universal Declaration on Human Rights, 1964
4. Egyptian Code of Medical Ethics 238, 2003
5. Law 181/2018, Egyptian Consumer Protection
6. Egyptian Consent laws
7. Law 2/2018 on Universal Health Insurance
8. MOHP Ministerial decree number 153/2004 for prevention of viral hepatitis
9. MOHP Ministerial decree number 187/2004 for infection control personnel
10. MOHP Ministerial decree 306/2002 on medication storage spaces
11. MOHP Ministerial decree 186/2001 Patient right to know expected cost of care

**PCS.01 The clinic advertisements are clear and comply with applicable laws, regulations, and ethical codes of the healthcare professionals› syndicates.**

*Patient-centeredness*

**Keywords:**

Clinic advertisements.

**Intent:**

The clinics use advertisements as an important tool to improve the utilization of services. Good advertisement aims to help the community have a better understanding of the available health services. The clinics might use newspapers, TV advertisements, banners, brochures, pamphlets, websites, social media pages, call centers, SMS messaging, mass emailing, or other media to advertise provided services. Information must be accurate, updated, and clearly communicated about types of services, healthcare professionals, cost of services, and working hours.

**Survey process guide:**

- GAHAR surveyor may check the clinic website, social media, or other forms of advertisement.
- GAHAR surveyor may compare the advertisements with the application information and with survey visit observations.

**Evidence of compliance:**

1. The clinic has a defined process guiding the advertisements of services.
2. Advertisements are done in compliance with ethical codes of healthcare professionals' syndicates.
3. Patients and their families receive clear, updated, and accurate information about the clinic's services, and working hours.

**Related standards:**

PCS.02 Registration process.

**PCS.02 The clinic schedules and registers patients in a timely and appropriate way.**

*Timeliness*

**Keywords:**

Registration process.

**Intent:**

When scheduling services, the clinic shall set criteria and gather inputs from service providers so patients with the most urgent needs or the patients who consider special population are seen first. The clinic shall develop the appointments schedule to define process for the same-day addition of urgent cases and special patient populations' appointments. The clinic shall use methods to organize attendance at scheduled appointments. Methods for

organizing attendance at appointments may include speaking directly with the patient when setting appointment times and having a reminder system that allows the clinic to confirm the scheduled time a day or two prior to the appointment. The clinic shall find ways to reduce the length of time patients wait for services beyond the time the appointment was scheduled to begin, the clinic shall develop a documented process to manage scheduling and registering patients that includes at least the following:

- a. The system for scheduling and registering patients taking into considerations the waiting area capacity.
- b. The cases that are excluded from the scheduling process such as the urgent cases and the special patient populations with defining them.
- c. The staff who is responsible for scheduling and registering patients
- d. Scheduling and registration process in case of pandemics/epidemic.

**Survey process guide:**

- The GAHAR surveyor may review the scheduling and registering process of patient and any related documents.
- The GAHAR surveyor may interview staff to check their awareness of the process.
- The GAHAR surveyor may observe the registration process and may interview patients to ask about how they were informed about the process.

**Evidence of compliance:**

1. There is a documented process for scheduling and registering patients that includes at least from (a) to (d) in the intent.
2. Responsible staff is aware of the process.
3. The scheduling and registering process is informed to the patients in a language they can understand.

**Related standards:**

PCS.01 advertisements, PCS.15 Infection prevention and control

**PCS.03 Patient, family rights and responsibilities are protected and informed to patients and families.**

*Patient-centeredness*

**Keywords:**

Patient, family rights and responsibilities.

**Intent:**

The clinic is committed to help patients/clients to gain knowledge of his/her rights and responsibilities. The clinic shall provide a clear direction to staff regarding their role in protecting patients and families' rights and responsibilities in informing them about their responsibilities. Patient and family rights shall defined as per national laws and regulations, and the ethical code of healthcare professionals' syndicates. The clinic shall develop and

implement a process to ensure that all staff members are aware of and respond to patient and family rights issues when they interact with and care for patients throughout the clinic, The clinic shall have a document that address at least the following:

**I. Patient and family rights to:**

- a. Access care that is provided by the clinic.
- b. Know the name of the treating, supervising, and/or responsible medical staff member.
- c. Receive care that respects the patient's personal values, beliefs and personal preferences.
- d. Be informed and participate in making decisions related to their care.
- e. Refuse care and discontinue treatment.
- f. Have respect to their personal privacy, confidentiality, and dignity.
- g. Have their pain assessed.
- h. Make a complaint or suggestion without fear of retribution.
- i. Know the price of services and procedures.
- j. Receive medical report describing their care journey in the clinic.

**II. Patient and family responsibilities to:**

- i. Provide clear and accurate information on the disease/condition current and past medical history.
- ii. Comply with the system and working hours of the clinic.
- iii. Comply with financial obligations according to laws and regulations and the clinic policy.
- iv. Show respect to other patients and healthcare professionals.
- v. Follow the recommended treatment plan.

**Survey process guide:**

- The GAHAR surveyor may review patient and family rights' documents and interview staff members to check their awareness.
- The GAHAR surveyor may observe patient rights and responsibilities' statements availability in the clinic.
- The GAHAR surveyor may observe how patients receive information about their rights and may check conditions under which patient rights are protected.

**Evidence of compliance:**

1. The clinic has a document that guide the process of defining patient and family rights, as mentioned in the intent from a) through j).
2. The clinic has a document that guide the process of defining patient and family responsibilities as mentioned in the intent from I) through v).
3. All staff members are aware the patients' and families' rights and responsibilities.
4. Information about patient rights and responsibilities is provided in writing or in another manner, that the patients and their families understand.

**Related standards:**

PCS.04. Informed consent, PCS.05. Patient and family complaints and suggestions.

**PCS.04 The clinic has a defined process to obtain informed consent for certain medical processes.**

*Patient-centeredness*

**Keywords:**

Informed consent.

**Intent:**

Informed consent is a process for getting permission before performing a healthcare intervention on a person, or for disclosing personal information. The physician obtaining the informed consent shall sign the form with the patient. The clinic shall develop and implement a process to describe how and where informed consent is used. The clinic shall have a document that address at least the following:

- a. The list of medical processes when informed consent is needed, this list includes:
  - i. Simple Invasive procedures.
  - ii. Local anesthesia.
  - iii. Family planning interventions
  - iv. High-risk procedures or treatments.
  - v. Photographic and promotional activities
- b. Certain situations when consent can be given by someone other than the patient, and mechanisms for obtaining and recording it according to applicable laws and regulations.
- c. Implied consent performed for services where the written consent is not required

**Survey process guide:**

- The GAHAR surveyor may review documents that describe the informed consent process.
- The GAHAR surveyor may review sample of medical records to check the completion of the informed consent.
- During the GAHAR survey, the surveyor may check the availability of consent forms.

**Evidence of compliance:**

1. The clinic has a documented process of informed consent that addresses all elements mentioned in the intent from a) through c).
2. Informed consent is obtained in a manner and language that the patient understands.
3. Informed consent is recorded and kept in the patient's medical record.

**Related standards:**

PCS.03 Patient and family rights

**PCS.05 The clinic improves the provided services based on patients' and families' complaints and suggestions.**

*Patient-centeredness*

**Keywords:**

Patient and family complaints and suggestions.

**Intent:**

Patients and families may want to give oral or anonymous complaints or suggestions about their care and to have those complaints or suggestions reviewed and acted upon.

The clinic shall develop and implement a uniform process to create system for dealing with different complaints, suggestions and feedback from patients and/or their families to make it easy to follow up, monitor, and learn from practices. The clinic shall have an effective process that addresses at least the following:

Mechanisms to inform patients and families about communication channels to voice their complaints and suggestions.

Responsibility for responding to patient complaints and suggestions.

**Survey process guide:**

- GAHAR surveyor may review the process of patient and family feedback and complaints.
- The GAHAR surveyor may interview staff to check their awareness.

**Evidence of compliance:**

1. The clinic has a uniform process for patient and family complaints and suggestions that include at least items a) and b) in the intent.
2. Staff is aware of the patient and family complaints and suggestions process.
3. The clinic responds to the patients' and families' complaints and suggestions, and act upon them.

**Related standards:**

PCS.03 Patient and family rights

**PCS.06 Initial medical assessment and subsequent reassessments are effectively performed.**

*Effectiveness*

**Keywords:**

Medical patient assessment and reassessments.

**Intent:**

Initial assessment should be standardized, comprehensive, detailed, and completed to achieve high-quality care that fulfills patient needs. The physician, or his/her designee, usually performs it. Reassessments may vary according to the patient's condition, the specialty of treatment, level of care, or diagnosis. The clinic shall develop and implement a process to

define the minimum acceptable contents for assessment and determine the frequency of clinical reassessments (if applicable). The initial assessment form includes at least the following:

- a. Chief complaint.
- b. Details of the present illness.
- c. Previous surgeries and invasive procedures.
- d. Allergies.
- e. Adverse drug reactions.
- f. Medications history.
- g. Family history.
- h. The required elements of the comprehensive physical examination.
- i. Elements of history and examination related to the specialty.

**Survey process guide:**

- GAHAR surveyor may review the initial assessment form to check its contents.
- GAHAR surveyor may observe implementation of the patient assessment process.
- GAHAR surveyor may review a patient's medical record to evaluate completeness

**Evidence of compliance:**

1. The clinic has documents that guide the assessment process.
2. The clinic has an initial assessment form that includes at least elements from (a) to (i).
3. Healthcare professionals are aware of the components of the assessment process and forms' content.
4. Medical reassessments are performed when needed and recorded in the patient's medical record.

**Related standards:**

PCS.07 Plan of Care

**PCS.07 An individualized plan of care is developed for every patient.**

*Effectiveness*

**Keywords:**

Plan of Care.

**Intent:**

A plan of care provides direction on the type of healthcare the patient may need. The focus of a plan is to facilitate standardized, evidence-based, and holistic care. The plan of care is:

- a. Based on assessments of the patient performed by the various healthcare disciplines and healthcare professionals.
- b. Developed with the involvement of the patient and/or family through shared decision making, with discussion of benefits and risks that may involve decision aids.
- c. Includes identified needs, interventions, and desired outcomes with timeframes.



- d. Updated as appropriate based on the reassessment of the patient.
- e. The progress of patient/client in achieving the goals or desired results of treatment, care or service is monitored.

**Survey process guide:**

- The GAHAR surveyor may review a sample of patient's medical record to evaluate the availability of the standardized, individualized plan of care.
- The GAHAR surveyor may interview responsible staff to check their awareness of the plan of care.

**Evidence of compliance:**

1. Plan of care is developed for each patient based on the result of the patient assessment.
2. The plan of care is developed with the participation of patient and/or family.
3. Plan of care is changed/updated based on a reassessment of patient changing condition.
4. The plan of care is documented in the patient medical record.

**Related standards:**

PCS.06 Medical patient assessment and reassessments

**PCS.08 the clinic ensures safe and effective consultation/referral process.**

*Effectiveness*

**Keywords:**

Consultation/referral process.

**Intent:**

Consultation/referral is the process of seeking an assessment by a medical staff member of a different discipline to suggest a diagnostic or treatment plan. Often, consultation/referral leads to professional communication where clinicians share their opinions and knowledge with the aim of improving their ability to provide the best care to their patients. The patient carries the ultimate risk when there is misunderstanding between care providers about their roles and responsibilities, or poor or incomplete information exchange, particularly missing diagnostic information or failure to communicate the urgency of care needed. A referring physician is expected to include sufficient detail to request consultation/referral to enable the consultant to make a meaningful determination whether the referral is appropriate to his/her practice and expertise. The clinic develops and implements a safe and appropriate consultation/referral process.

The consultation process addresses at least the following:

- a. Defined criteria for requesting a consultation/referral for patients.
- b. Elements needed to request the consultation/referral including at least (the patient diagnosis and the reason for consultation).
- c. Documentation of consultation/referral request and results.

**Survey process guide:**

- The GAHAR surveyor may review evidences of the consultation/referral process and may review medical record to check the consultation/referral request and response documentation.
- The GAHAR surveyor may also interview healthcare professionals to check their awareness of the process.

**Evidence of compliance:**

1. The clinic has a defined, clear process that guide the patients' consultation/referral including at least from (a) to (c) in the intent
2. Information exchange between consultation/referral requester and responder is complete according to the clinic-defined elements.
3. The consultation/referral request and response is documented in the patient medical record.

**Related standards:**

PCS.06 Medical patient assessment and reassessments

**PCS.09 Radiology and diagnostic imaging services are used safely.**

*Safety*

**Keywords:**

Safe Radiology and diagnostic imaging services.

**Intent:**

The medical imaging services shall meet national laws, regulations, and applicable guidelines. The clinic shall ensure the staff and patients safety from radiation while using the radiology and diagnostic imaging that emit radiation.

The radiation safety precautions are part of the clinic environment and facility safety. The clinic environment, staff, patients, relatives and vendors should be safe from radiation hazards, as medical Imaging services are provided on-site; the clinic shall define the radiation safety precautions needed for the staff and the patients such as the staff badge films results, CBC results, and lead aprons inspection.

**Survey process guide:**

- GAHAR surveyor may observe the availability of PPE for radiation.
- GAHAR surveyor may visit areas where there are medical imaging services and check the implemented precautions.
- GAHAR surveyor may interview staff to check their awareness of the radiation safety precautions

**Evidence of compliance:**

1. The radiation precaution measures are defined and implemented

2. The personal protective equipment from radiation is available
3. Staff members involved in medical imaging are aware of radiation safety precautions.

**Related standards:**

PCS.06 Medical patient assessment and reassessments PCS.14 Medical Equipment management

**PCS.10 Point-of-care testing is monitored to ensure that appropriate measures are in place to obtain an accurate test result.**

*Effectiveness*

**Keywords:**

POCT.

**Intent:**

Point-of-care testing (POCT) is tests designed to be used at or near the site where the patient is located, that do not require permanent, dedicated space, and that are performed outside the physical facilities of the clinical laboratories.” The clinic develops a process guiding the use of all point of care testing services. Periodic and episodic maintenance of equipment shall be monitored and documented. An inventory list shall be maintained of all POCT equipment including,

- a. serial number
- b. unique identification
- c. manufacturer/supplier
- d. date purchased
- e. malfunction history

**Survey process guide:**

- GAHAR surveyor may review the inventory list of POCT equipment.
- GAHAR surveyor may interview staff to ask about the POCT proper use.

**Evidence of compliance:**

1. The clinic has a defined process guiding the use of all point of care testing services
2. The clinic has inventory list for all POCT equipment that includes elements from (a) to (e) in the intent.
3. The periodic and episodic maintenance of equipment shall be monitored and documented
4. In case of abnormal results, the patient is referred to clinical laboratory for further assessment

**Related standards:**

PCS.06 Medical patient assessment and reassessments, PCS.14 Medical Equipment management

**PCS.11 Medication management is safe, appropriate and match the clinic's mission and services.**

*safety*

**Keywords:**

Medication management.

**Intent:**

Medication management remains a vital process in any healthcare clinic. The unsafe use of medication is not the only safety problem in the healthcare system, but it is certainly one of the most significant issues. Although the clinics scope rarely requires medication storage in the clinic but for the rare situations if present in a very narrow scope the clinic shall ensure safe medication management, to ensure this the clinics shall follow the manufacturer instruction for safe storage taking into consideration all the environmental requirements such as temperature, humidity and lighting. The clinic shall also implement a process to track the expiry date of its medications and ensure that the expired medications are not allowed to be used in the clinic

**Survey process guide:**

- GAHAR surveyor may interview staff to ask about the medication expiry date tracking process
- GAHAR surveyor may observe the storage conditions to check compliance with manufacturer instructions

**Evidence of compliance:**

1. There is a process for tracking the expiry date of the available medications.
2. All available medications are stored according to the manufacturer instructions.
3. The staff is aware about the expiry date tracking process and the required storage conditions.

**Related standards:**

PCS.12 Medication prescribing

**PCS.12 The clinic develops safe medication prescribing process according to laws and regulations.**

*Safety*

**Keywords**

Medication prescribing

**Intent:**

When prescribed and used effectively, medications have the potential to significantly improve the quality of life and improve patient outcomes. However, the challenges associated with prescribing the right medications and supporting patients to use them effectively should not

be underestimated.

The clinic defines a process to guide the complete prescription process. The complete prescription includes at least the following:

- a. The minimum required elements of complete medication prescriptions to include:
  - i. Patient's name and date of birth or age
  - ii. Main diagnosis.
  - iii. Drug name
  - iv. Dosage form
  - v. Strength or concentration
  - vi. Dosage, frequency and duration
  - vii. Route of administration
  - viii. Rates of administration (when intravenous infusions are ordered)
  - ix. For PRN orders: Indications for use, maximum frequency and maximum daily dose
  - x. Date and time of the order
- b. Acceptability and special required elements of certain types of orders, for example, that are weight-based or otherwise adjusted, such as for children, elderly, and other similar populations.

**Survey Process Guide:**

- GAHAR surveyor may interview the physicians to inquire about prescription processes and the used means for communication with the pharmacies.
- GAHAR surveyor may review patient's medical records to assess the completion, legibility, and clarity of medication prescription.

**Evidence of compliance:**

1. Medication prescriptions are complete according to the approved process that includes at least from a) to b) in the intent.
2. Prescribed medications are recorded in the patient's medical record.
3. Instructions about the prescribed medications is written in a language the patient can understand
4. There are certain means for communication between the dispensing pharmacist in public pharmacies and the prescribing physician, in case there are difficulties in the clarity of medication prescription.
5. The prescribing physician signs the medication prescription sheet

**Related standards:**

PCS.07 Plan of Care, PCS.11 Medication management

### **PCS.13 Patient's urgent inquiries after clinic working hours are effectively responded.**

*Effectiveness*

#### **Keywords:**

After working hours patient communication

#### **Intent:**

There's a challenge in the clinic care service that the working hours usually are not too long and this could be faced by a lot of inquiries from the clinics patients in times of the clinics closure.

For this reason, the clinic shall define communication means and inform patients to use them in case of urgent inquiries after the clinic working hours

The physician may answer the patient's inquiries, as there is no need to change the current treatment plan or to reschedule the next visit to sooner one or to advice that the patient should go to the hospital to get emergency service.

#### **Survey Process Guide:**

- GAHAR surveyor may interview staff to ask about the after-hours communication process.
- GAHAR surveyor may interview patients to check their awareness of the after-hours communication means.

#### **Evidence of compliance:**

1. The clinic has a process for after-hours communication and there's defined communication means.
2. The clinic identifies the criteria of urgent situations and inform patients and families about them
3. The clinic informs the patient about how to receive emergency care in the nearest emergency care department

#### **Related standards:**

PCS.02 Registration process.

### **PCS.14 Medical equipment management ensures safe inspection, testing, maintenance, and safe use of medical equipment.**

*Safety*

#### **Keywords:**

Medical Equipment management

#### **Intent:**

Medical equipment is critical to the diagnosis and treatment of patients. Inadequate equipment management lead to inefficiency, and can also seriously harm patient outcomes. As an example, poor maintenance increases the chances of downtime, and inadequate servicing can be harmful to both doctors and patients.

The clinic develops a medical equipment management plan that addresses at least the following:

- a. Inventory of medical equipment including availability, criticality, and functionality.
- b. Periodic preventive maintenance plan according to the manufacturer's recommendations.
- c. Calibration of medical equipment according to the manufacturer's recommendations and/or its usage.
- d. Dealing with significant equipment malfunction, including actions taken.
- e. Medical equipment inventory plan includes; equipment identification cards, company emergency contact, periodic preventive maintenance, calibration and malfunction history.

**Survey process guide:**

- GAHAR surveyor may review the medical equipment maintenance plan to ensure availability of all required documents, inventory of medical equipment, preventive maintenance schedule, calibration schedule.
- During the GAHAR survey, surveyor may check medical equipment functionality and review some medical equipment records.

**Evidence of compliance:**

1. The clinic has an approved medical equipment management plan that addresses all elements from a) through e) in the intent.
2. Staff are educated on the medical equipment plan.
3. Records are maintained for medical equipment inventory, equipment identification cards, company emergency contact, periodic preventive maintenance, calibration and malfunction history.

**Related standards:**

PCS.10 POCT, PCS.09 Safe Radiology and diagnostic imaging services

**PCS.15 infection prevention and control activities are implemented in order to prevent healthcare-associated infections.**

*Effectiveness*

**Keywords:**

Infection prevention and control activities.

**Intent:**

According to CDC (Center of Diseases Control), standard precautions are the minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where health care is delivered. In addition to hand hygiene, standard precautions include:

- i. Use of personal protective equipment (PPE) (e.g., gloves, masks, eyewear).
- ii. Use of soap, washing detergents, antiseptics, and disinfectants.

- iii. Respiratory hygiene / cough etiquette.
- iv. Sterile instruments and devices.
- v. Clean and disinfected environmental surfaces.

One of the pillars for the elimination of infections is proper hand hygiene. The clinic is requested to follow currently published, evidence-based hand hygiene guidelines. “Five Moments for Hand Hygiene” may be used to identify key moments for hand hygiene for health care professionals.

Soap, disinfectants, and towels or other means of drying are located in areas where hand washing and hand-disinfecting procedures are required.

As part of infection prevention measures cleaning and disinfection services are available and implemented, the personal protective equipment are adequate and available, facial tissues, surgical masks and respirators are available that will protect workers against infectious diseases to which they may be exposed.

An epidemic is the rapid spread of disease to a large number of people in a given population within a short period of time. During an epidemic, transmission can be anticipated in the workplace not only from patients to workers in healthcare settings, but also among co-workers and between members of the public and workers in other types of workplaces.

The clinic shall communicate effectively to the staff the main principles of worker protection that includes at least the following:

- a. Consistently practice social distancing.
- b. Cover coughs and sneezes.
- c. Maintain hand hygiene.
- d. Clean surfaces frequently
- e. Utilizing a flexible leave permission when they are sick, the available options for working remotely.

Applicable laws and regulations define the minimum infection preventive practices and precautions that should to be implemented, the response to infectious disease outbreaks, and any reporting requirements.

#### **Survey process guide:**

- GAHAR surveyor may interview staff to check their awareness of the process of infection control standard precautions and hand hygiene.
- GAHAR surveyor may observe the availability of PPE, detergents, antiseptics, and disinfectants.

#### **Evidence of Compliance:**

1. Hand-washing and hand-disinfection procedures are used in accordance with hand-hygiene guidelines throughout the clinic.
2. The PPE, detergents, antiseptics, and disinfectants are readily available, easily accessible.
3. Healthcare professionals are knowledgeable and aware of their role in case of epidemics.



**Related standards:**

PCS.09 Safe Radiology and diagnostic imaging services, PCS.10 POCT

**PCS.16 Patient billing system implemented effectively.**

*Effectiveness*

**Keywords:**

Billing System

**Intent:**

The clinic shall provide patients and their families by a receipt for services rendered, including insurance patients. It is one of the patient and family rights to receive an initial estimated cost for their treatment if requested. For third-party payer systems, the process for billing is based on the requirements of insurance companies/agencies, which generally have reimbursement rules with a pre-determined time frame.

The clinic shall develop and implement an effective billing process that addresses at least the following:

- a. Availability of an approved price list for services provided to patients and their sponsors.
- b. Process to ensure that patients and families are obtained an accurate invoice for services rendered.
- c. Payment methods. e.g. itemized bill, package deal.

**Survey process guide:**

- GAHAR surveyor may review approved price lists for services provided to patients and their sponsors.
- GAHAR surveyor may interview some responsible staff and some patients to match the actual performance against the implemented process.

**Evidence of compliance:**

1. The clinic has a process for billing system that address items from a) to c) in the intent.
2. An approved price list is available and informed to the patients.
3. Responsible staff is fully aware of the various health insurance processes and different payment methods.

**Related standards:**

PCS.02 Registration process.

**PCS.17 The clinic keeps patients' records accurate, up-to-date, and protect the patient information privacy and confidentiality.**

*Effectiveness*

**Keywords:**

Medical record, Confidentiality and privacy of data and information.

**Intent:**

The clinic shall maintain a complete and up-to-date record for each patient; it shall have a standardized process to maintain all diagnostic tests, services, and medications in the patient medical record. The clinic shall protect the confidentiality and privacy of patients' data and information. Confidentiality means the property that health information is not available to unauthorized persons or disciplines.

Methods for protecting the privacy and confidentiality of patient information depend on whether the record is electronic or paper-based. For example, for paper-based files, the team has a secure storage area; for electronic files, the team may use a password-protected system to limit access to patient information. Non-lockable files (or a non-secure computer) should only be available in working areas. If applicable, the team should meet established regulations or legal requirements for protecting the privacy and confidentiality of patient information.

**Survey process guide:**

- GAHAR surveyor may review sample of patient medical records to check the standardized content
- GAHAR surveyor may interview staff to check their awareness of the confidentiality measures

**Evidence of compliance:**

1. The clinic has a standardized medical record for each patient.
2. Up to date medical records are handled, kept in a secure, safe manner.
3. Confidentiality and privacy of data and information are maintained through defined measures.
4. Staff is aware of the confidentiality measures.

**Related standards:**

PCS.06 Medical patient assessment and reassessments, PCS.07 Plan of Care

## Survey Activities and Readiness

### Introduction:

- GAHAR survey process involves performing building tours, observations of patient's medical records, staff member files, credential files, and interviews with staff and patients.
- The survey is an information gathering activity to determine organization's compliance with the GAHAR standards.

### Readiness Tips:

- To facilitate the completion of the survey within the allotted time, all information and documents should be readily available for the surveyors to review during survey.
- If certain staff members are missing, the team will continue to perform the survey; the appropriate missing staff members may join when they are available.
- Files may be in paper or in electronic format; however, the information should, at all times, be safe and secure from unauthorized access, up-to-date, accessible, and readily retrievable by authorized staff members.
- For Ambulatory healthcare centers:**

#	Activity	Timeframe	Location in survey agenda
1	Arrival and coordination	30-20 minutes	upon arrival
2	Opening conference	15 minutes	as early as possible
3	Survey planning	30 minutes	as early as possible
4	Ambulatory healthcare center orientation	30 minutes	as early as possible
5	Document review session	120-60 minutes	At beginning of the survey
6	Patient\individual tracer	60-40 minutes	Individual tracer activity occurs throughout the survey; the number of individuals who surveyors trace varies by organization
7	Break	15 minutes	At a time negotiated with the Ambulatory healthcare center.
9	Staff members file review	60-30 minutes	After some individual tracer activity has occurred.

10	Environment and facility safety plans review	30-15 minutes	After some individual tracer activity has occurred.
11	Environment and facility safety tour	90-60 minutes	After environment and facility safety plans review
12	Leadership interview	60 minutes	During the early or middle of the survey
13	Financial stewardship review	60 minutes	After leadership interview
14	Patient's medical record review	120-60 minutes	In the middle of the survey
15	Medication management review	60-30 minutes	In the middle of the survey
16	Infection prevention and control review	60-30 minutes	In the middle of the survey
17	Quality program\plan review	60-30 minutes	Towards the end of the survey
18	Report preparation	120-60 minutes	At the end of the survey
19	Executive report	15 minutes	At the end of the survey
20	Exit conference	30 minutes	final activity of the survey

- **For Community pharmacies:**

	Activity	Timeframe	Location in survey agenda
1	Arrival and coordination	20-10 minutes	upon arrival
3	Community pharmacy orientation	20-15 minutes	In the beginning of the survey
4	Survey planning	20 minutes	In the beginning of the survey
5	Document review session	90-60 minutes	In the beginning of the survey
6	Environment and facility safety documents review	30-20 minutes	In the middle of the survey
7	Environment and facility safety tour	30-20 minutes	In the middle of the survey

8	Infection prevention and control review	30-20 minutes	In the middle of the survey
9	Report preparation	40-30 minutes	At the end of the survey
10	Executive report	15 minutes	At the end of the survey
11	Exit meeting	30 minutes	final activity of the survey

- **For private clinics:**

	Activity	Timeframe	Location in survey agenda
1	Arrival and coordination	10 minutes	upon arrival
2	Opening meeting	15 minutes	In the beginning of the survey
3	Private clinic orientation	15 minutes	In the beginning of the survey
4	Survey planning	15 minutes	In the beginning of the survey
5	Document review session	60-30 minutes	In the middle of the survey
6	Patient centered care review	60-30 minutes	In the middle of the survey
7	Infection prevention and control review	20 minutes	In the middle of the survey
8	Report preparation	15-10 minutes	At the end of the survey
9	Executive report	15 minutes	At the end of the survey
10	Exit meeting	15 minutes	final activity of the survey

### **Arrival and Coordination**

#### Why will it happen?

To start the survey process on time, the GAHAR surveyors shall use the time to review the focus of the survey in light of the submitted application.

#### What will happen?

GAHAR surveyors shall arrive at the Ambulatory healthcare center and may present

themselves to Ambulatory healthcare center security or desk. Ambulatory healthcare center survey coordinator shall be available to welcome GAHAR surveyors.

How to prepare?

Identify a location where surveyors can wait for organization staff to greet them and a location where surveyors can consider as their base throughout the survey. The suggested duration of this step is approximately 30 to 60 minutes. Surveyors need a workspace they can use as their base for the duration of the survey. This area should have a desk or table, internet and phone coverage, and access to an electrical outlet, if possible. Provide the surveyors with the name and phone number of the survey coordinator.

Who should collaborate?

Suggested participants include Ambulatory healthcare center staff and leaders.

**Opening Conference**

Why will it happen?

This is an opportunity to share a uniform understanding of the survey structure, answer questions about survey activities, and create common expectations.

What will happen?

GAHAR surveyors shall introduce themselves and describe each component of the survey agenda. Questions about the survey visit, schedule of activities, availability of documents or people, and any other related topics should be raised at this time.

How to prepare?

Designate a room or space that will hold all participants and will allow for an interactive discussion.

Who should collaborate?

Suggested participants include members of senior leadership. Attendees should be able to address the leadership's responsibilities for planning, resource allocation, management, oversight, performance improvement, and support in carrying out the organization's mission and strategic objectives.

**Survey Planning**

Why will it happen?

To ensure the efficiency of survey time.

What will happen?

Surveyors shall begin selecting patients for tracers based on the care, treatment, and services the ambulatory healthcare center provides.

How to prepare?

The survey coordinator needs to ensure that the following information is available for surveyors.

- List of sites where disinfection and sterilization are in use.
- List of clinics/units/ areas/programs/services within the ambulatory healthcare center
- List of patients that includes name, location, age, and diagnosis.

Who should collaborate?

Only GAHAR surveyors.

**Ambulatory healthcare center Orientation**

Why will it happen?

GAHAR surveyors shall learn about the Ambulatory healthcare center through a presentation or an interactive dialogue to help focus on subsequent survey activities.

What will happen?

A Ambulatory healthcare center representative (usually Ambulatory healthcare center director or their designee) shall present information about the Ambulatory healthcare center.

How to prepare?

Prepare a brief summary (or a presentation) about the ambulatory healthcare center that includes at least information about:

- Ambulatory healthcare center mission, vision, and strategic goals.
- Ambulatory healthcare center structure and geographic locations.
- Information management, especially the format and maintenance of medical records.
- Contracted services.
- Compliance with National Safety Requirements.
- Summary of community involvement.
- The ambulatory healthcare center' patient population and the most commonly provided services.
- If the ambulatory healthcare center has any academic activities.
- Whether the ambulatory healthcare center provides any home care or services outside the boundaries of the ambulatory healthcare center facility.
- Compliance with GAHAR reports and recommendations during the pre-accreditation visit period.

Who should collaborate?

Suggested participants include the same participants as the opening conference.

**Document Review Session**

Why will it happen?

To help GAHAR surveyors understand ambulatory healthcare center operations.

What will happen?

GAHAR surveyors may review required policies (or other quality management system documents) and policy components based on GAHAR standards.

How to prepare?

The survey coordinator shall ensure that all valid current and approved quality management system documents are available for review either in paper or electronic format (approval should be visible, clear, and authentic). Use of bookmarks or notes is advisable to help surveyors find the elements, including:

1. List of unapproved abbreviations.

2. Performance improvement data according to the applicable look back period
3. Documentation of performance improvement projects performed, including the reasons for performing the projects and the measurable progress achieved.
4. Patient flow documentation: dashboards and other reports reviewed by ambulatory healthcare center leadership; documentation of any patient flow projects being performed (including reasons for performing the projects); internal throughput data collected by emergency unit, and clinics; and support services such as patient transport and housekeeping.
5. Analysis from a high-risk process.
6. Emergency management policy.
7. Emergency management protocols.
8. Annual risk assessment and annual review of the program.
9. Assessment-based, prioritized goals.
10. Infection control surveillance data according to the applicable look back period.
11. All policies, procedures, and plans.

Who should collaborate?

Survey coordinator and policy stakeholders.

**Patient\individual Tracer**

Why will it happen?

Patient journey tracer is defined as «an assessment, made by surveyors shadowing the sequential steps of a patient's clinical care, of the processes in an organization that guide the quality and safety of care delivered» (Greenfield et al., 2012a: 495). GAHAR surveyors shall follow the course of care and services provided to the patient to assess relationships among disciplines and important functions and evaluate the performance of processes relevant to the individual.

What will happen?

The tracer process takes surveyors across a wide variety of services. The tracer methodology's use of face-to-face discussions with healthcare professionals, staff members, and patients, combined with a review of patient's medical records and the observations of surveyors. Quality, timeliness of entries, and legibility of recording in the patient's medical record are also crucial to safe, effective care because healthcare professionals rely on it to communicate with each other about treatment needs and decisions. This shall help guide surveyors as they trace a patient's progress. The individual tracer begins in the location where the patient and their medical record are located. The surveyor starts the tracer by reviewing a file of care with the staff person responsible for the individual's care, treatment, or services. The surveyor then begins the tracer by following the course of care, treatment, or services provided to the patient, assessing the interrelationships between disciplines, programs, services, or units (where applicable), and the important functions in the care, treatment or services provided which may lead to identifying issues related to care processes.



Most GAHAR standards can be triggered during a patient journey tracer, which may also include interviewing staff, patients, or family members. Staff members may be interviewed to assess organization processes that support or may be a barrier to patient services; communications and coordination with other staff members, Transitions-related resources and processes available through the ambulatory healthcare center and awareness of roles and responsibilities related to the various policies. Patients or family members may be interviewed to assess coordination and timeliness of services provided, education, including the perception of care and services.

How to prepare?

Every effort needs to be exerted to assure the confidentiality and privacy of patients during tracers, including no video or audio recording and no crowdedness. A surveyor may arrive in a clinic and need to wait for staff to become available. If this happens, the surveyor may use this time to evaluate the environment of care issues or observe the care, treatment, or services assessed. All efforts will be ensured to avoid having multiple tracers or tours in the same place at the same time.

Who should collaborate?

Survey coordinator and any staff member (when relevant).

**Break**

Why will it happen?

To allow time for the surveyor and for ambulatory healthcare center staff to use the information learned.

What will happen?

The GAHAR surveyor may meet in their base alone.

How to prepare?

Make sure that the place is not going to be used during the break time.

Who should collaborate?

Only GAHAR surveyors.

**Staff Members File Review**

Why will it happen?

The review of files in itself is not the primary focus of this session. However, the surveyor may verify process-related information through recorded in staff member's files. The surveyor may identify specific staff whose files they would like to review.

What will happen?

- GAHAR surveyor may ensure that a random sample of staff files is reviewed.
- The minimum number of records selected for review is 5 staff member files
- If findings are observed during the file review, the survey team may request additional file samples to substantiate the findings recorded from the initial sample.
- Throughout the review process, if a big number of findings are observed, the survey team may document whether the findings constitute a level of non-compliance

### How to prepare?

The ambulatory healthcare center shall produce a complete list of all staff members, including those who are outsourced, contracted, full-timers, fixed-timers, part-timers, visitors, volunteers, and others.

### Who should collaborate?

Representatives from medical management, nursing management, and administrative teams.

## **Environment and Facility Safety Plans Review**

### Why will it happen?

The GAHAR surveyor may assess the ambulatory healthcare center degree of compliance with relevant standards and identify vulnerabilities and strengths in the environment and facility safety plans.

### What will happen?

There shall be a group discussion. Surveyors are not the primary speakers during this time; they are listeners to the discussion, the surveyor may review the environment of care risk categories as indicated in the ambulatory healthcare center risk assessment and safety data analysis and actions taken by the ambulatory healthcare center.

### How to prepare?

Make sure that those responsible for environment and facility safety plans are available for discussion. Also, the following documents have to be available:

- Ambulatory healthcare center licenses or equivalent.
- An organization chart.
- A map of the ambulatory healthcare center, if available.
- List of all sites that are eligible for a survey.
- Environment and facility safety data.
- Environment and facility safety plans and annual evaluations.
- Environment and facility safety multidisciplinary team meeting minutes prior to the survey.
- Emergency Operations Plan (EOP) and a recorded annual review and update, including communications plans.
- Annual training.

### Who should collaborate?

Environment and facility safety responsible staff members such as safety management representatives, information technology (IT) representatives, and the person responsible for emergency management.

## **Environment and Facility Safety Tour**

### Why will it happen?

The GAHAR surveyor may observe and evaluate the ambulatory healthcare center's actual performance in managing environment and facility risks.

### What will happen?

The GAHAR surveyor may begin where the risk is encountered, first occurs, or take a top-down/ bottom-up approach. The GAHAR surveyor may interview staff to describe or demonstrate their roles and responsibilities for minimizing the risk, what they are to do if a problem or incident occurs, and how to report the problem or incident.

The surveyor may assess any physical controls for minimizing the risk (i.e., equipment, alarms, building features), assess the emergency plan for responding to utility system disruptions or failures(e.g., an alternative source of utilities, notifying staff, how and when to perform emergency clinical interventions when utility systems fail, and obtaining repair services), assess If equipment, alarms, or building features are present for controlling the particular risk, reviewing the implementation of relevant inspection, testing, or maintenance procedures. The surveyor may also assess hazardous materials management, waste management, and safety or security measures.

### How to prepare?

Ensure that keys, communication tools, and contacts are available so the GAHAR surveyor may be able to access all ambulatory healthcare center facilities smoothly.

### Who should collaborate?

Environment and facility safety responsible staff members such as representatives of safety management, information technology (IT) representative, and the person responsible for emergency management.

## **Leadership Interview**

### Why will it happen?

The surveyor will learn about ambulatory healthcare center governance and management structure and processes.

### What will happen?

GAHAR surveyor may address the following issues

- The structure and composition of the governing body.
- The functioning, participation, and involvement of the governing body in the oversight and operation.
- The governing body's perception and implementation of its role in the ambulatory healthcare center
- Governing body members understanding of performance improvement approaches and methods.
- Pertinent GAHAR Leadership standards relevant to the governing body, direction, and leadership in the ambulatory healthcare center, including organizational culture.
- Surveyors may explore, through ambulatory healthcare center -specific examples, leadership commitment to the improvement of quality and safety, creating a culture of safety, robust process improvement, and observations that may be indicative of system-level concerns.

### How to prepare?

The GAHAR surveyor may need a quiet area for a brief interactive discussion with ambulatory healthcare center leaders.

The following documents may be reviewed during this session.

- Ambulatory healthcare center structure.
- ambulatory healthcare center strategic plan.
- ambulatory healthcare center ethical framework.
- Leadership safety rounds.
- Safety culture assessment.
- Patient centeredness initiatives medical staff bylaws, rules, and regulations.
- Peer Review process and results.

### Who should collaborate?

Required participants include at least the following: ambulatory healthcare center director, governing body representative, and performance improvement coordinator.

## **Financial Stewardship Review**

### Why will it happen?

The surveyor will learn about ambulatory healthcare center financial stewardship structure and processes.

### What will happen?

The GAHAR surveyor may address topics related to financial stewardship, such as observations noted during ambulatory healthcare center tours and tracers, the billing process, contractor's performance, availability of staff, supplies, and equipment.

### How to prepare?

The GAHAR surveyor may need a quiet area for a brief interactive discussion with financial stewardship representatives.

The following documents may be reviewed during this session.

- List of all contracted services.
- Agreement with outsourced providers of laundry, sterilization, housekeeping, referral laboratory, radiology, and other services.
- Contractor monitoring data.
- Feedback reports from payers.
- Cost reduction projects.

### Who should collaborate?

Required participants include at least the following: ambulatory healthcare center director, procurement responsible staff member, clinical responsible staff member, and finance responsible staff member.

## **Patient's medical record Review**

### Why will it happen?

The review of files, in itself, is not the primary focus of this session. However, the surveyor may verify process-related information through recording in patients' medical records. The surveyor may identify specific patients whose files they would like to review.

### What will happen?

The GAHAR surveyor may ensure that a random sample of the patient's medical record is reviewed. A sample of both open and closed cases should be reviewed. Record review should include a random sample. The sample selected shall represent a cross-section of the cases performed at the ambulatory healthcare center. The minimum number of case file records required to be selected by the surveyor for review is no more than five records IN total. If findings are observed during the file review, the survey team may request additional file samples to substantiate the findings recorded from the initial sample. Throughout the review process, if a large number of findings are observed, the survey team may document whether the findings constitute a level of non-compliance. The total number of records within the six-month case period should be recorded in the review form.

### How to prepare?

The ambulatory healthcare center is required to produce a log or other record of closed cases for the previous six-month period, and the surveyor may select a sample of medical records to review.

### Who should collaborate?

Representatives from ambulatory healthcare center medical, nursing, and other healthcare teams in addition to information management representatives.

## **Medication Management Review**

### Why will it happen?

The GAHAR surveyor may learn about the planning, implementation, and evaluation of the medication management program, identify who is responsible for its day-to-day implementation, evaluate its outcome and understand the processes used by the ambulatory healthcare center to reduce medication errors and antibiotics stewardship.

### What will happen?

The GAHAR surveyor may evaluate ambulatory healthcare center's medication management systems by performing system tracers. Discussions in this interactive session with staff include:

- The flow of the processes, including identification and management of risk points, integration of key activities, and communication among staff/units involved in the process with a focus on the management of high-alert medications, look-alike, sound-alike, concentrated electrolytes, and medication errors.
- Strengths in the processes and possible actions to be taken in areas needing improvement, with a special focus on:

- Antimicrobial stewardship, including a document that describes how the ambulatory healthcare center uses the antibiotic stewardship program and activities.
- Process for reporting errors, system breakdowns, near misses or overrides, data collection, analysis, systems evaluation, and performance improvement initiatives.

#### How to prepare?

The GAHAR surveyor may need a quiet area for a brief interactive discussion with staff who oversee the medication management program. Then time may be spent where the medication is received, stored, dispensed, prepared, or administered.

The following documents may be reviewed during this session.

- Medication management policies.
- Core elements of ambulatory healthcare center antibiotic stewardship programs.
- Antimicrobial stewardship data.
- Antimicrobial stewardship reports documenting improvement.

#### Who should collaborate?

Suggested participants include clinical and support staff responsible for medication management processes.

### **Infection Prevention and Control Program Review**

#### Why will it happen?

The GAHAR surveyor may learn about the planning, implementation, and evaluation of the infection prevention and control program, identify who is responsible for its day-to-day implementation, evaluate its outcome and Understand the processes used by the ambulatory healthcare center to reduce infection.

#### What will happen?

The GAHAR surveyor may evaluate the ambulatory healthcare center's IPC systems by performing system tracers.

Discussions in this interactive session with staff include:

- The flow of the processes, including identification and management of risk points, integration of key activities and communication among staff/units involved in the process; how individuals with infections are identified, laboratory testing and confirmation process, if applicable; staff orientation and training activities and, current and past surveillance activity.
- Strengths in the processes and possible actions to be taken in areas needing improvement; analysis of infection control data; reporting of infection control data; prevention and control activities (for example, staff training, staff vaccinations and other health-related requirements, housekeeping procedures, ambulatory healthcare center -wide hand hygiene, and the storage, cleaning, disinfection, sterilization and/or disposal of supplies and equipment); staff exposure; physical facility changes that can impact infection control; and actions taken as a result of surveillance and outcomes of those actions.

### How to prepare?

The GAHAR surveyor may need a quiet area for a brief interactive discussion with staff who oversee the infection prevention and control process. Then a tour may follow.

The following documents may be reviewed during this session:

- Infection prevention and control policies.
- Infection control education and training records.
- Infection control measures data.

### Who should collaborate?

Suggested participants include the infection control coordinator, physician member of the infection control team, healthcare professionals from the laboratory, safety management staff, ambulatory healthcare center leadership, and staff involved in the direct provision of care or services.

## **Quality Program Review**

### Why will it happen?

The GAHAR surveyor may learn about the planning, implementation, and evaluation of the quality management program; identify who is responsible for its day-to-day implementation; evaluate its outcome; and understand the processes used by the Ambulatory healthcare center to reduce risks.

### What will happen?

Discussions in this interactive session with staff include:

- The flow of the processes, including identification and management of risk points, integration of key activities and communication among staff/units involved in the process.
- Strengths in the processes and possible actions to be taken in areas needing improvement.
- Use of data.
- Issues requiring further exploration in other survey activities.
- A baseline assessment of standards compliance.

### How to prepare?

The GAHAR surveyor may need a quiet area for a brief interactive discussion with staff who oversee the quality management program. Then time may be spent where improvement was implemented.

The following documents may be reviewed during this session:

- Quality management program.
- Performance improvement projects.
- Performance management measures.
- Risk management registers, records, and logs.

### Who should collaborate?

Suggested staff members include quality management staff, healthcare professionals involved in data collection, aggregation, and interpretation, performance improvement teams.



## **Report Preparation**

### Why will it happen?

To provide an opportunity for clarification and consolidation of any findings.

### What will happen?

Surveyors use this session to compile, analyze, and organize the data collected during the survey into a report reflecting the ambulatory healthcare center compliance with the standards. Surveyors may also ask organization representatives for additional information during this session.

### How to prepare?

GAHAR surveyors may need a room that includes a conference table, power outlets, telephone access, and internet coverage.

### Who should collaborate?

Only GAHAR surveyors.

## **Executive Report**

### Why will it happen?

To give an opportunity to brief the most relevant outcomes of the survey and help the prioritization of post-accreditation activities.

### What will happen?

GAHAR surveyors may review the survey findings with the most senior leader and discuss any concerns about the report.

### How to prepare?

The GAHAR surveyor may need a quiet private area for a brief interactive discussion with the most senior leader.

### Who should collaborate?

The available ambulatory healthcare center most senior leaders and others at their discretion.

## **Exit Conference**

### Why will it happen?

To thank the ambulatory healthcare center team for participation and share the important findings in the accreditation journey.

### What will happen?

Surveyors shall verbally review the survey findings summary if desired by the most senior leader, and review identified standards compliance issues.

### How to prepare?

Ambulatory healthcare center available most senior leader may invite staff to attend, an area that can accommodate attending staff is required.

### Who should collaborate?

Suggested participants include the available ambulatory healthcare center most senior leader or designee, other leaders, and staff as identified by the most senior leader or designee.



## Glossary

**Adverse drug event (ADE)** This is an injury resulting from medication intervention related to a drug.

**Adverse drug reaction (ADR)** A response to a medication which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.

**Adverse effect** Medical occurrence temporally associated with the use of a medicinal product, but not necessarily causally related.

**Airborne** They are particles  $\leq 5\mu$  in size that remain suspended in the air and travel great distances.

**Antimicrobial stewardship** Is a coordinated program that promotes the appropriate use of antimicrobials (including antibiotics), improves patient outcomes, reduces microbial resistance, and decreases the spread of infections caused by multidrug-resistant organisms.

**Antiseptics** They are substances that reduce or stop the growth of potentially harmful microorganisms on the skin and mucous membranes. Or Antimicrobial substances that are applied to the skin to reduce the number of microbial flora.

**Appointment** The process of reviewing an initial applicant's credentials to decide if the applicant is qualified to provide patient care services that the ambulatory healthcare centers' patients need and that the ambulatory healthcare centers can support with qualified staff and technical capabilities.

**Aseptic technique** It is a method designed to reduce the risk of microbial contamination in a vulnerable body site. This may include procedures like undertaking a wound dressing or performing an invasive procedure such as inserting a urinary catheter or preparing an intravenous infusion.

**Beyond use date** The date or time after which a compounded sterile preparation (CSP) or compounded non-sterile preparation (CNSP) may not be stored or transported or used and are calculated from the date or time of compounding.

**Biohazardous** it is a biological agent or condition that is carries a risk of danger to humans or the environment.

**Certification** The procedure and action by which an authorized organization evaluates and certifies that a person, institution, or program meets requirements.

**Cleaning** It is the process of removing foreign material (e.g. soil, organic material, micro-organisms) from an object.

**Clinical pathway** An agreed-upon treatment regime that includes all elements of care.

**Clinical guidelines** Statements that help ambulatory healthcare professionals and patients to choose appropriate health care for specific clinical conditions. The healthcare professionals is guided through all steps of consultation (questions to ask, physical signs to look for, assessment of the situation, and care to prescribe).

**Communicable disease** it is a disease that is capable of spreading from one person to another through a variety of ways, including contact with blood, body fluids and breathing, etc.

**Community pharmacy** It is the healthcare facility that is responsible for the provision of pharmaceutical service to a specific community group or region.

**Competence or competency** A determination of the staff's job knowledge, skills, and behaviours to meet defined expectations. Knowledge is the understanding of facts and procedures. Skill is the ability to perform specific actions, behaviours, such as the ability to work in teams, are frequently considered as a part of competence.

**Contamination** The presence of unwanted material or organism, such as an infectious agent, bacteria, parasite, or another contaminant, that is introduced to an environment, surface, object, or substance, such as water, food, or sterile medical supplies.

**Credentialing** The process of obtaining, verifying, assessing, and attesting the qualifications of a physician. The process determines if a staff member can provide patient care services in or for a healthcare organization. The process of periodically checking the physician's qualifications is called re-credentialing.

**Credentials** Evidence of competence, current and relevant licensure, education, training, and experience. Other defined criteria may be added by a healthcare organization.

**Discharge summary** A section of the patient's medical record that summarizes the reasons for admission, significant findings, procedures performed, treatment rendered, patient's condition on discharge, and any specific instructions given to the patient or family

**Disinfectants** they are substances that are applied to the surface of non-living objects in order to destroy microorganisms but not necessarily bacterial spores.

**Disinfection** It is the process of reducing the number of pathogenic microorganisms, but not necessarily bacterial spores to a level which is no longer harmful to health. It may be high level, intermediate level or low level disinfection depending on the level of probable risk.

**Dispensing** preparing, packaging, and distributing to a patient a course of therapy on the basis of a prescription.

**Drug Recall** Is action taken at any time to call back or remove a defective or harmful drug product from the market when it is being discovered to be in violation of laws and regulations. This includes expired, outdated, damaged, dispensed but not used, and/or contaminated medications.

**Drug Recall System:** A system defined that alerts appropriate individuals when a company/manufacturer is calling back a drug product due to a defect in manufacturing, contamination or being discovered to be in violation of laws and regulation.

**Expired medication** is one that is past the expiry date listed on the original packaging from the manufacturer.

**Failure mode and effects analysis (FMEA)** A systematic approach to examining a design prospectively for possible ways failure may occur. The ways failure may occur are then prioritized to help organizations create or design improvements that shall have the most benefit. This tool assumes that no matter how knowledgeable or careful people are, errors shall occur in some situations and may even be likely to occur.

**Hand hygiene** A general term that applies to hand washing, antiseptic hand wash, antiseptic hand rub, or surgical hand antisepsis.

**Handover** The transfer of responsibility for a patient and patient care that occurs in the healthcare setting. For example, in the ambulatory healthcare centers from one healthcare professional to another, from one level of care to another level, from an inpatient unit to a diagnostic or another treatment unit, and from staff to patients/families at discharge.

**Hazardous materials and waste plan** The ambulatory healthcare centers written document that describes the process it would implement for managing the hazardous materials and waste from source to disposal. The plan describes activities selected and implemented by the ambulatory healthcare centers to assess and control occupational and environmental hazards of materials and waste (anything that can cause harm, injury, ill-health, or damage) that require special handling. Hazardous materials include radioactive or chemical materials. Hazardous wastes include the biologic waste that can transmit disease (for example, blood, and tissues), radioactive materials, toxic chemicals, and infectious waste, such as used needles and used bandages.

**Head of department** The staff member who manages and directs the subgroups of the organization, commonly referred to as departments, services, units, or wards.

**Healthcare professional** Any person working in a healthcare center, whether he is a physician, nurse, technician, housekeeper, administrator etc.

**HEPA filter** High-efficiency particulate air filter, is defined as a filter with efficiency of 99.97% in removing particles 0.3 microns or more in size, which makes it suitable for prevention of airborne pathogens.

**High alert medication:** Medications that bear a heightened risk of causing significant patient harm when they are used in error.

**Hygiene** The practice that serves to keep people and environments clean and prevent infection.

**Immunization** is the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine (active immunisation) or serum containing desired antibodies (passive immunisation). Vaccines stimulate the body's own immune system to protect the person against subsequent infection or disease. Infection control practitioner

**Infection control program** an organized system of services designed to meet the needs of the ambulatory healthcare centers in relation to the surveillance, prevention, and control of infection, which impacts patients, staff, physicians, and/or visitors.

**Infection** The transmission of a pathogenic microorganism.

**Inventory** A written list of all the objects, abilities, assets, or resources in a particular place.

**IPC committee** The Infection Control Committee is generally comprised of members from a variety of disciplines within the healthcare facility; bringing together individuals with expertise in different areas of healthcare.

**Job description** Statements or directions specifying required decisions and actions. Penalties, legal or otherwise, are normally assessed when laws and regulations are not followed.

**Laws and regulations** Statements or directions specifying required decisions and actions. Penalties, legal or otherwise, are normally assessed when laws and regulations are not followed.

**Leader** A person who sets expectations plans and implements procedures to assess and improve the quality of the ambulatory healthcare centers' governance, management, clinical, and support functions and processes.

**Legibility** The possibility to read or decipher. The writing is clearly written so that no letter or number can be misinterpreted. It is legible when any individual can read the handwritten documentation or physician order.

**Look-alike Sound-Alike Medications** These are medications that are visually similar in physical appearance or packaging and names of medications that have spelling similarities and/or similar phonetics.

**Medical staff bylaws** Regulations and/or rules adopted by the medical staff and the governing body of the ambulatory care center for governance, defining rights and obligations of various officers, persons, or groups within the medical staff's structure.

**Medical staff** Licensed physician and licensed dentist.

**Medication** Any prescription medications including narcotics; herbal remedies; vitamins; nutraceuticals, over-the-counter medications; vaccines; biological, diagnostic and contrast agent used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications; respiratory therapy treatments; parenteral nutrition; blood products; medication containing products, and intravenous solutions with

electrolytes and/or medications. The definition of the medication does not include enteral nutrition solutions (which are considered food products), oxygen, and other medical gases unless explicitly stated.

**Medication error** Any preventable event that may cause inappropriate medication use or endangers patient safety. Examples are wrong patient, medication, dose, time, and the route; incorrect ordering dispensing, or transcribing; missed or delayed treatments. Any professional/discipline/staff who handle medications can be involved in the error.

**Medication reconciliation** Medication reconciliation is a formal process that has been demonstrated to improve the continuity of medicines management,

**Medication-related problem** is an event or circumstance involving medication therapy that actually or potentially interferes with desired health outcomes.

**N95 respirator** it is a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles. The 'N95' designation means that when subjected to careful testing, the respirator blocks at least 95 percent of very small (0.3 micron) test particles.

**Near miss** is an unplanned event that did not result in injury, illness, or damage – but had the potential to do so.

**Ordering** is written directions provided by a prescribing practitioner for a specific medication to be administered to an individual. The prescribing practitioner may also give a medication order verbally to a licensed person such as a pharmacist or a nurse.

**Outbreak** an excess over the expected (usual) level of a disease within a geographic area; however, one case of an unusual disease may constitute an outbreak.

**Outdated medication** is one that is opened and is typically safe and effective to use for a short period of time after opening (shelf life)

**Performance measures** it is a quantifiable measure used to evaluate the success of ambulatory care center employee, etc.

**Personal protective equipment** it is equipment worn to minimize exposure to hazards that cause serious workplace injuries and/or illnesses.

**Plan of care** A plan that identifies the patient's care needs lists the strategy to meet those needs, records treatment goals and objectives, defined criteria for ending interventions, and records the patient's progress in meeting specified goals and objectives. It is based on data gathered during patient assessment.

**Practice guidelines** Tools that describe processes found by clinical trials or by consensus opinion of experts to be the most effective in evaluating and/or treating a patient who has a specific symptom, condition, or diagnosis, or describe a specific procedure. Synonyms include practice parameters, protocol, preferred practice pattern, and guideline. Also, see

evidence- (scientific) - based guidelines and clinical practice guidelines.

**Prescribing** advising and authorizing the use of a medication or treatment for someone, especially in writing.

**Privileging** The process whereby specific scope and content of patient care services (clinical privileges) are authorized for all medical staff members by the organization, based on the evaluation of the physician's credentials and performance.

**PRN** Latin abbreviation Pro re nata frequently used to denote whenever necessary or as needed.

**Processing** All operations performed to render a contaminated reusable or single-use (disposable) device ready again for patient use. The steps may include cleaning and disinfection/sterilization. The manufacturer of reusable devices and single-use devices that are marketed as non-sterile should provide validated reprocessing instructions in the labelling.

**Procurement** The process of acquiring supplies, including those obtained by purchase, donation, and manufacture. It involves efforts to quantify requirements, select appropriate procurement methods, and prequalify suppliers and products. It also involves managing tenders, establishing contract terms, assuring medications quality, obtaining the best prices, and ensuring adherence to contract terms.

**Project** A planned set of interrelated tasks to be executed over a fixed period and within certain cost and other limitations.

**Referral** The sending of a patient from one clinician to another clinician or specialist or from one setting or service to another or another resource.

**Respiratory hygiene** This comprises infection prevention measures designed to limit the transmission of respiratory pathogens spread by droplet or airborne routes.

**Risk assessment** The identification, evaluation, and estimation of the levels of risks involved in a situation, their comparison against benchmarks or standards, and determination of an acceptable level of risk.

**Root cause analysis** A process for identifying the basic or causal factor(s) that underlies variation in performance, including the occurrence or possible occurrence of a sentinel event.

**Safe injection** It is a practice intended to prevent needle stick injuries and other possible contamination during syringe introduction in a patient; ultimately preventing transmission of blood borne infectious diseases between one patient and another, or between a patient and a healthcare professional.

**Sentinel event** is an unexpected occurrence involving death or serious physical or psychological injury or the risk thereof.



**Side effect** The pharmacological effect of a medication, normally adverse, other than the one(s) for which the medication is prescribed.

**Single-use device (disposable device)** it is intended for use on one patient during a single procedure. It is not intended to be reprocessed (cleaned and disinfected or sterilized) and used on another patient. Using disposable items improves patient safety by eliminating the risk of patient-to-patient contamination because the item is discarded and not used on another patient (According to the Food and Drug Administration).

**Spaulding classification** it is a method of classification of the different medical instrumentation based on device usage and body contact into three categories, critical, semi-critical and non-critical dictated by the infection risk involved by using it.

**Stock** A quantity of something accumulated, as for future use, regularly kept on hand, as for use or sale; staple; standard.

**Surveillance** A systemic and ongoing method of data collection, presentation and analysis, followed by dissemination of that information to those who can improve outcomes.

**Therapeutic duplication** One person using two medications, usually unnecessarily, from the same therapeutic category at the same time.

**Transmissible** it is a disease with the ability to be passed on from one person or organism to another.

**Utilization** The use, patterns of use, or rates of use of specified healthcare service. Overuse occurs when a healthcare service is provided under circumstances in which its potential for harm exceeds the possible benefits. Underuse is the failure to use a necessary healthcare service when it would have produced a favourable outcome for a patient. Misuse occurs when an appropriate service has been selected, but a preventable complication occurs. All three reflect a problem in the quality of healthcare. They can increase mortality risk and diminish the quality of life.

**Variation** The differences in results obtained in measuring the same event more than once. The sources of variation can be grouped into two major classes' common causes and special causes. Too much variation often leads to waste and loss, such as the occurrence of undesirable patient health outcomes and increased cost of health service.

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