



دائرة الصحة
DEPARTMENT OF HEALTH

HEALTHCARE REGULATOR MANUAL

November 17

PREAMBLE

The Department of Health (DOH), previously known as the Health Authority - Abu Dhabi (HAAD), is the regulator of the Abu Dhabi health system. The Health Regulations comprising of Policies, Standards and Circulars, collectively translate federal UAE and Abu Dhabi Laws into a simple, practical set of tools to help drive compliance and improve access, quality and affordability of care.

This document is an update of the “Policy Manuals” that were published in 2012. The Manuals were drafted in collaboration with Abu Dhabi and international healthcare experts including the Joint Commission International (‘JCI’), other health regulators, local and international legal advisors (Al Tamimi and Wragge and Co.), and delegates from Abu Dhabi and international Providers, Professionals and Insurers. The 2012 Manuals followed a structured consultation process comprising the formation of a permanent HAAD Policy Advisory and Consultative Panel and formal sector-wide consultation (8-12 weeks). The current document has been updated in light of the new relevant regulations published since 2012.

STRUCTURE OF ABU DHABI HEALTH REGULATIONS

The Department of Health (DOH), previously known as the Health Authority - Abu Dhabi, was established by Law No. 1 of (2007) concerning the establishment of the Health Authority - Abu Dhabi. DOH's purposes are defined in Article 1 (clauses 1 and 2) of Law No. 1 (2007), which are to achieve the highest standards in health, curative, preventive and medicinal services and health insurance and to advance these in the health sector, and to follow-up and monitor the operations of the health sector to achieve an exemplary standard in provision of health, curative, preventive and medicinal services and health insurance.

In order to achieve its purpose, the DOH establishing Law No. 1 of (2007) empowers DOH, in particular:

- a) To apply the laws, rules, regulations and policies which are issued as they are related to its purposes and responsibilities, in addition to what is issued by respective international and regional organisations in line with the development of the health sector (Article 5 clause 2),
- b) To approve rules and procedures which are required for operating health and curative establishments, to approve procedures and methods of treatment, and to lay down policies and programs for satisfying the needs of the health sector in the Emirate (Article 5 clause 4),
- c) To develop and apply integrated systems for the control of government and private health sectors in the Emirate (Article 8 clause 12).

With this mandate, and by virtue of Article 8 clause 12, DOH has created an integrated Health Regulations system, comprised of Policies, Standards and Circulars for the Emirate to regulate, control and monitor the implementation of federal and local health laws and best practices in health, curative, preventive and medicinal services and health insurance in the health sector.

All health entities operating, or to be established in the future, in the health field, be it governmental or private, must carry out their responsibilities in accordance with the rules, regulations and decisions issued by DOH (Article 6). Governmental health sector entities include the Abu Dhabi Health Services Company (SEHA) incorporated by virtue of Emiri Decree no. (10) of 2007 and the National Insurance Company (DAMAN) incorporated by virtue of Emiri Decree no. (39) of 2005, and are responsible for executing their objectives as incorporated companies in accordance with the rules, regulations and decisions issued by DOH.

Policies

Refer to decisions, plans, and actions that are undertaken to achieve DOH's health care goals for Abu Dhabi. DOH's policies define a vision for the future, which in turn helps to establish targets and points of reference for the short and medium term. They outline priorities and the expected roles of different groups, and it builds consensus and informs people.

DOH will consistently monitor the effectiveness of its Policies in improving access, quality and accessibility of care and will make changes where these are required. However, DOH intends that Policies will remain stable over time,

Standards

Standards add further definition around practice, establishing both acceptable minimum and aspirational levels. Standards set the minimum requirements for specific structures, processes and services and define the related roles and responsibilities of Providers, Professionals and Insurers and their interactions with respect to the Standards. Whereas Policy is intended to provide regulatory consistency, Standards are intended to adapt as medical practice and the Abu Dhabi health system continue to evolve.

DOH may issue Standards in order to determine an expected level of specification, quality, or safety for products, processes, services, or performance.

KEY PRINCIPLES

This section sets out the principles that underpin all DOH regulations.

Evidence-Based Regulation

DOH regulatory controls will be evidence based as far as possible.

Seamless, Coherent and Transparent Regulation

DOH regulatory framework will be seamless, transparent and coherent across the healthcare continuum.

Efficient and Effective Interventions

DOH regulatory framework seeks to optimise resources and reduce administrative burdens (cutting red tape where possible)

Consistent and Equitable Sector Regulation

Regulatory requirements will be applied consistently and equitably across the health sector.

Accountability

DOH is accountable to its stakeholders, through its consultative policy process.

Proportionality

DOH's regulatory framework is proportional, appropriate, necessary and reasonable in order to achieve the objective, which is intended.



VISION, MISSION, VALUES AND STRATEGY

Vision

A Healthier Abu Dhabi.

Mission

DOH aims to regulate and develop the healthcare sector and to protect the health of individuals by ensuring better access to services, continually improving quality of care, and sustainability of resources.

Values

- **Commitment to society:** Commitment to our society's needs and expectations.
- **Creativity and innovation:** Encourage creative thinking and continuous improvement of our services.
- **Accountability:** All are responsible for his/her actions and their consequences
- **Integrity:** Honesty, commitment to the policies of DOH, and avoiding acts contrary to the code of conduct.
- **Excellence:** Spreading and promoting the culture of excellence and continuously improving corporate performance.

Strategy

DOH periodically develops healthcare strategies that are in line with the wider Abu Dhabi Government Plans. At the time of publication, DOH pursued 7 priorities for Health sector improvement

1. Integrated continuum of care for individuals

- "Cradle-to-grave", the individual's care throughout life,
- Access to care (all types of care: ER, primary, secondary, tertiary, quaternary, home, pre-hospital, rehabilitation, preventive measures/vaccination etc), this will reduce need for IPC,
- Capacity planning – including rural areas in the Western and Eastern Regions,
- Address healthcare issues specific to the Emiratis.

2. Drive quality and safety as well as enhance patient experience

- Track outcomes and processes from healthcare providers to drive quality improvement,
- Publish outcomes and processes once data is validated.



3. Attract/retain/train workforce

- Particularly Emiratis,
- Encourage Research, Innovation, Education/Training.

4. Emergency preparedness

- The Emirate of Abu Dhabi has to be prepared at anytime for a major disaster or disease outbreak.

5. Wellness and prevention—public Health approach

- Community initiatives to enhance wellness and awareness.

6. Ensure value for money + Sustainability of healthcare spend

- Reduce waste,
- Encourage Private Sector (“level playing field”),
- Elimination of loss transfer for non-mandated healthcare provision,
- Effective management of funded mandates,
- Ensure appropriate reimbursement framework.

7. Integrated Health Informatics and eHealth

- Including Telemedicine,
- Tool to drive 1, 2, 3, 4, 5, 6 above.



HEALTH REGULATOR MANUAL

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CHAPTER I. INTRODUCTION

1. Purpose

- 1.1. This Manual describes DOH's functions and its roles and responsibilities, which are key to achieve its objectives.

2. Background

- 2.1. The principal objective of DOH's regulation is to develop the healthcare sector and to protect the health of individuals by ensuring better access to service¹ and continually improving the quality of care² and sustainability of resources.
- 2.2. The DOH establishing Law No. 1 of (2007) articulates DOH roles and responsibilities and as such empowers DOH to develop plans, policies, strategies, rules, regulations, and decisions, which are required for achieving its purpose. This includes Standards and Guidelines where necessary. This wide regulatory framework allows DOH to fulfil its functions with respect to the following areas:
 - Healthcare planning,
 - Healthcare Quality,
 - Public Health, including health prevention and health research,
 - Regulations and Licensing of health facilities, health professionals and medical products,
 - International Patient Care,
 - Finance and efficiency of the health sector,
 - Data collection and analysis.

3. Relationship with Other DOH Manuals

- 3.1. DOH has also issued:
 - 3.1.1 the Healthcare Providers Manual, the principal function of which is to set out the duties which apply to the operators of Healthcare Facilities in Abu Dhabi,
 - 3.1.2 the Healthcare Professionals Manual, the principal function of which is to set out the duties which apply to those individuals who are members of a Healthcare Profession in Abu Dhabi,

¹ CHAPTER V: Healthcare Regulators Manual.

² DOH Policy for Quality and Patient Safety.



- 3.1.3 the Health Insurers Manual, the principal function of which is to set out the duties which apply to Authorised Insurance Providers, Insurers and associated persons in Abu Dhabi.
- 3.2. This Healthcare Regulator Manual describes the main functions of DOH in relation to the above six areas in Abu Dhabi.
- 3.3. Those functions are relevant to the subject matter of each of the other Manuals, and relate to the way in which DOH will perform its functions in respect of those persons who are subject to duties under those other Manuals. It is therefore of importance to all those whom those Manuals apply to.
- 3.4. In addition, the Manuals impose further duties on Healthcare Providers, Healthcare Professionals, Authorised Insurance Providers, and other persons. They must be aware of and comply with these duties.

4. Policies, Standards and other Regulatory Tools

- 4.1. DOH will periodically revise its Policies and Standards in the light of its analysis of health data and in order to promote improved health outcomes.
- 4.2. DOH's issued regulations should be clear, proportionate and targeted only at cases in which it is needed. DOH will therefore apply the tools of regulation flexibly so as to ensure that it intervenes only where appropriate in relation to each part of the market.
- 4.3. DOH will also ensure compliance with its regulations through periodic auditing and enforcement, complemented by an appeals process.
- 4.4. DOH:
 - 4.4.1. has established a mechanism for managing healthcare capacity in Abu Dhabi,
 - 4.4.2. may set up Professional Boards to oversee the practice of various Healthcare Professions in Abu Dhabi,
 - 4.4.3. requires Medical Products to be on an approved list before they may be placed on the market in Abu Dhabi, and provide for the continuing monitoring of the safety, quality and efficacy of those Products,
 - 4.4.4. may establish an Abu Dhabi Health Research Council to advise on Policies and Standards for, and support of, human subject research in the Emirate, and require those Healthcare Providers conducting human subject research to be licensed and to be subject to appropriate standards of ethical governance,



4.4.5. has and will take steps to protect and promote public health,

4.4.6. has created and communicated mechanisms by which it can investigate the compliance of regulated persons with all DOH regulations, and take action to enforce compliance or to penalise any failures where it is necessary to do so, has appropriate procedures in place to allow regulated persons to appeal those decisions.



CHAPTER II. GENERAL POWERS

5. Purpose

5.1. This Chapter sets out general powers, which DOH may exercise in order to protect the health of individuals by ensuring better access to services³, continually improving quality of care⁴, and sustainability of resources in the Emirate of Abu Dhabi.

6. Background

- 6.1. DOH has been given authority under its establishing law and UAE federal laws to use a range of interventions in relation to the healthcare market in Abu Dhabi. It proposes to do so flexibly in order to ensure that regulatory action is targeted at cases where it is needed.
- 6.2. For these purposes, DOH uses certain general powers to impose obligations in the best interests of the health economy and of patients.
- 6.3. Where DOH uses those powers, those to whom they relate must comply with them.

7. Policies

7.1. Refer to decisions, plans, and actions that are undertaken to achieve DOH's health care goals for Abu Dhabi. DOH's policies define a vision for the future, which in turn helps to establish targets and points of reference for the short and medium term. They outline priorities and the expected roles of different groups, and it builds consensus and informs people.⁵

8. Standards

8.1. Standards add further definition around practice, establishing both acceptable minimum and aspirational levels. Standards set the minimum requirements for specific structures, processes and services and define the related roles and responsibilities of Providers, Professionals and Insurers and their interactions with respect to the Standards. Whereas Policy is intended to provide regulatory consistency, Standards are intended to adapt as medical practice and the Abu Dhabi health system continue to evolve.

³ CHAPTER V: Healthcare Regulators Manual.

⁴ DOH Policy for Quality and Patient Safety.

⁵ http://www.who.int/topics/health_policy/en/

- 8.2. DOH may issue Standards in order to determine an expected level of specification, quality, or safety for products, processes, services, or performance.
- 8.3. DOH may issue Standards in relation, but not limited to:
 - 8.3.1. Service Specifications,
 - 8.3.2. Healthcare providers' specifications,
 - 8.3.3. Quality of care expectations.

9. Advice and Guidance

- 9.1. DOH may issue, and revise, advice or guidance addressed to any person or group of persons in relation to how to comply with or self-assess against the implementation of a Policy or Standard.
- 9.2. However, any Regulated Person to whom advice or guidance is addressed must:
 - 9.2.1. ensure that he is familiar with that advice or guidance to the extent that it is relevant to his compliance with any Regulations,
 - 9.2.2. has full regard to that advice or guidance in the actions he takes to comply with those Regulations.

10. Professional Boards and Assessment Committees

- 10.1. DOH may establish one or more bodies which shall be known as Professional Boards⁶.
- 10.2. The role of a Professional Board will be to advise DOH on Policies and Standards, including those relating to the activities of a category of Healthcare Professionals specified by DOH.

⁶ Chapter I: DOH Healthcare Professionals Manual.



CHAPTER III. OVERVIEW OF THE HEALTH INSURANCE SCHEME IN ABU DHABI

11. Health Insurance Scheme

1.1. The Health Insurance Scheme in Abu Dhabi is established and regulated by the following:

- 11.1.1. Law 23 of 2005 Regarding the Health Insurance Scheme for the Emirate of Abu Dhabi (the Law),
- 11.1.2. Executive Regulations for Law 23 of 2005 Regarding the Health Insurance Scheme for the Emirate of Abu Dhabi (the Regulations),
- 11.1.3. any Decision of the Executive Council relating to, or amending the Law or the Regulations (Executive Decisions),
- 11.1.4. any applicable laws in the UAE,
- 11.1.5. this Manual,
- 11.1.6. any relevant Policies, Standards and Circulars issued by DOH.

11.2. The Health Insurance Scheme places responsibilities on any Insurer, Broker, Third Party Administrator, Healthcare Provider, Employer, Sponsor (including educational establishments), Limited Income Investor and Insured Person who is required to participate in the Health Insurance Scheme.

11.3. All people involved in the Health Insurance Scheme or who may require the use of health services in Abu Dhabi under the Health Insurance Scheme must ensure that they are fully aware of the provisions of each of the above legislative instruments that apply to them.

11.4. The contents of this Manual and the Standards are supplementary to the Law, Policies, DOH Circulars and any Executive Decisions. Where this Manual or any Policy or Standard refers to the provisions of the Law and the Regulations, such references will:

- 11.4.1. be selective, and be used in order to provide appropriate background to the supplementary obligations imposed by the Manual, Policy, Standard or Circular,
- 11.4.2. not repeat the provisions of the Law, the Regulations or the Executive Decisions in full.



12. Regulator's Responsibilities

12.1. DOH plays key roles in relation to the management of an efficient private health insurance system.

In particular, DOH is responsible for⁷:

- 12.1.1. enforcing the provisions of the Law and the Regulations,⁸
- 12.1.2. administering and overseeing the operation of the Health Insurance Scheme and its compliance,
- 12.1.3. licensing, registering and inspecting Insurers and Authorised Healthcare Providers, TPAs, Brokers, Public and private Employers in relation to the Health Insurance Scheme,
- 12.1.4. prescribing and collecting fees for the registration and licensing of Insurers, Authorised Healthcare Providers, TPAs and Brokers,
- 12.1.5. setting the reimbursement rates (Standard Tariff), rules and mechanism for the Health Insurance Scheme,
- 12.1.6. determining and enforcing the implementation of applicable standards to be met by Insurers and Authorised Healthcare Providers relating to the Health Insurance Scheme,
- 12.1.7. investigating and resolving disputes⁹, suspected cases of fraud and abuse, and complaints regarding other parties in the Health Insurance Scheme,
- 12.1.8. conducting inspections and investigations to ensure that all participants in the Health Insurance Scheme comply with the Law and the Regulations, DOH Circulars and any Executive Decisions,
- 12.1.9. overseeing and conducting the appointment of authorised inspection officers, and working where appropriate with other Emirates and federal authorities to ensure compliance with the Law and Regulations.
- 12.1.10. collecting, monitoring and publishing health statistical data on the rates of participation in and utilisation of the Health Insurance Scheme^{10 11}
- 12.1.11. collecting and disseminating information about private health insurance to enable consumers to make informed choices.

⁷ Regulations: article 2.

⁸ Law: article 22.

⁹ Standard for Claims Adjudication, Mandatory Tariff and Associated DOH Claims and Adjudication Rules, Standard Provider Contract, Chapter VII DOH Regulations – Inspections, Complaints, Appeals and Sanctions (Healthcare Insurers Manual).

¹⁰ Chapter VIII: Healthcare Regulator Manual.

¹¹ DOH Data Standards and Procedures Standard.



CHAPTER IV. HEALTHCARE PLANNING

13. Purpose

13.1. This Chapter sets out the capacity planning powers of DOH, namely to review the requirement for healthcare capacity. This involves both the ability to promote or restrict the development of new Healthcare Facilities, services, or clinical specialties in the Emirate of Abu Dhabi.

14. Background

14.1. It may be in the public interest within Abu Dhabi for the future development of certain types of Healthcare facilities, healthcare professionals or healthcare specialisations or the provision of such services by location to be promoted or restricted.

14.2. DOH must therefore be able to promote increases in, or impose restrictions on, the number and type of new facilities that may be developed in order to manage the entry of capacity into the healthcare market.

Capacity Planning

15. The Capacity Review

15.1. DOH will review the requirement for additional healthcare capacity in Abu Dhabi in the light of the available information as to the existing and future health needs of the population of the Emirate. Any such review may relate to healthcare capacity generally, or only to capacity in relation to the provision of such healthcare services or treatments as DOH may specify.

15.2. DOH is responsible for the development of Abu Dhabi healthcare capacity management tools. The methodology, tools and initiatives contained within the capacity management tools will provide both the framework and the future plans that underpin the sustainable development of the Abu Dhabi healthcare system.

16. The Capacity Master Plan

16.1. Following a review, DOH may issue one or more statements, which shall together be known as the Capacity Master Plan (CMP).



- 16.2. The CMP is designed to help Abu Dhabi respond to its current and future healthcare demands, establish a healthcare planning culture and introduce guiding principles and specific plans for healthcare capacity and provision.
- 16.3. The CMP is a conceptual document that distils all analyses, themes, methodologies and regulatory requirements relating to healthcare supply into a single cohesive review of Abu Dhabi healthcare requirements. It articulates the conclusions as a clear plan for sustainable future healthcare in Abu Dhabi and provides implementation plans to address the major issues identified. The healthcare demand projections articulated throughout the CMP take full account of the projected population rises, population ageing and expected changes in burden of disease and efficiency of the delivery of healthcare
- 16.4. The CMP will identify the over and under supply of healthcare capacity in Abu Dhabi by reference to the type, level, and geographical distribution of healthcare services and treatments required. DOH may use this information to promote or restrict the development of new facilities and services.
- 16.5. Healthcare providers, operators and investors should take full account of the analysis, information, plans and recommendations contained within this plan when planning their investments or developing their services.
- 16.6. DOH is committed to supporting providers and investors with information regarding health service use, supply and demand and to meet DOH regulatory requirements (available at www.DOH.ae).

Health Workforce Planning and Emiratisation

17. Health Workforce Planning and Emiratisation

- 17.1. DOH mandates the requirement for healthcare facilities to put in place specific recruitment, development and retention strategies for UAE national healthcare professionals in support of the Abu Dhabi Government Emiratisation policy. The Health Workforce Planning is to lead Emiratisation Efforts in Abu Dhabi's healthcare sector, in collaboration with stakeholders, to support sector sustainability.
- 17.2. DOH to carry review on the Abu Dhabi Health workforce plan to build and maintain comprehensive model that projects the supply vs demand for national health professionals over 5 to 10 years in the future, and use it to align universities' programs and scholarship to the projected sector demands.



- 17.3. DOH must, therefore, be able to promote an increase in the number of Nationals joining the healthcare sector, in capacity gap specialties identified in the Capacity Master Plan in collaboration with stakeholders.
- 17.4. DOH to set and monitor Emiratisation targets in the Abu Dhabi healthcare sector in collaboration with stakeholders.
- 17.5. DOH may reassess and revise (whether or not following a further capacity review) the Emiratisation and Health workforce targets identified in the Health Workforce Plan.



CHAPTER V. Integrated Continuum of care

18. Purpose

18.1. This Chapter sets out DOH vision and goal for integrated care as well as DOH's sector-wide objectives and strategies for the health services to achieve the vision.

19. Background

19.1. An integrated continuum of care is an effective solution to dealing with the many healthcare needs especially of the ageing population, and with the increasing prevalence of chronic conditions that require specialist care in both primary and secondary care settings.

19.2. Meeting patient needs through integrated continuity of care makes a positive impact on the quality and value of care. Therefore, DOH is regularly supplementing and strengthening existing healthcare policies, strategies and regulatory framework to accommodate DOH's strategic direction on integrated care.

20. Vision of Integrated Continuum of care Vision

20.1. To achieve an integrated patient-centric model of care in Abu Dhabi, where the right care is coordinated and delivered in the right place, by the right expertise, at the right time without interruption, unless clinically justified. This model seeks to bring about improvements in health services in relation to access, quality and value of service delivery.

21. Characteristics of Integrated Continuum of Care

21.1. Patient centric, whereby:

21.1.1. Individuals' needs, and those of their carer(s) are assessed, recognised and addressed,

21.1.2. Individuals are involved in planning and choosing the care that is right for them,

21.1.3. Secured choice of communication channels are open both ways (from and to the patient and their carer(s)),

21.1.4. Individuals have access to accurate, clear and easy to understand information to make informed choices and decisions about their care, and



- 21.1.5. When patients move across providers or levels of care they know in advance where they are going, what care will be provided with, and who will be the main point of professional contact.
- 21.2. The right type and level of care are provided, whereby:
- 21.2.1. Care and treatment are provided in the right place by the right team, with the right skills and competencies, based on the best evidence and practice available,
- 21.2.2. Care and treatment are not undersupplied, repeated or duplicated, and
- 21.2.3. Care and treatment takes into account of the individual's psychological, cultural, religious and physical needs.
- 21.3. Care is delivered at the right time without interruption, whereby:
- 21.3.1. Care and treatment are neither delayed nor interrupted when moving to, within and across providers and healthcare settings along the continuum of care. This is particularly critical in emergencies and referral cases, and
- 21.3.2. Care and treatment seamlessly transitions with the patient within and across providers and healthcare settings without interruption, and a plan is in place for what happens next, including following discharge.
- 21.4. Care is coordinated, whereby:
- 21.4.1. Healthcare staff involved in the disparate activities in a patient's care, within and across providers and healthcare settings, have adequate knowledge about their own and others' roles, information and available resources, and
- 21.4.2. Healthcare staff in each activity communicate properly and securely to handover the necessary information for the next stage of the patient's care.

22. Priorities Areas for of Integrated Continuum of Care

22.1. PRIORITY 1

22.1.1. Improve informational continuity and information accessibility.

22.2. PRIORITY 2

22.2.1. Facilitate patients' and healthcare providers' ability to choose their care.

22.3. PRIORITY 3

22.3.1. Optimise primary healthcare.

22.4. PRIORITY 4



22.4.1. Improve patients transfer, referrals and care coordination between levels of care especially in emergencies.

22.5. PRIORITY 5

22.5.1. Align payment mechanisms to incentivise coordination and integration of care.

23. Policy Objectives and Strategies to achieve them

23.1. Information Management

Efficient and effective management of information is an important enabler of continuity and integration of care. DOH shall work towards creation of information standards and systems to ensure that the right information is available at the right place and time as following:

- Patients and their carers have up-to-date information on the services available within the health system for their condition.
- All healthcare providers along the continuum of care have access to relevant information that allows them to efficiently and effectively coordinate and provide care to the patient.
- The exchange of information among all relevant parties is standardised and based on a unified language that allows clear and unambiguous communication.
- The information available will be useful to improve the system.

23.1.1. Policy objective 1: Improve informational continuity

23.1.2. Policy strategy 1: In order to achieve this DOH shall:

- Define the common language and Data Standards that must be used to exchange information.
- Define the information security standards required to be used across the Emirate, either directly or in collaboration with federal entities.
- Define the controls to be carried out on the stakeholder for compliance with the new standards and regulations.
- Define the methods by which the patient can access their personal records of the information collected across the system. An eHealth strategy will define if the centralising of patient data will be compulsory for all patients or optional.
- Establish a common IT infrastructure to enable exchange of information among relevant healthcare entities.



23.1.3. All healthcare entities shall:

- Adopt DOH's defined Data Standards. This means not only updating the systems but also training their staff in the use of the common language and common IT infrastructure.
- Acquire new software or adjust their existing ones to be able to exchange data as per DOH standards.
- Establish processes and procedures required to collect all the data during the patient care in electronic format using the defined language.
- Adopt all information security measures required to maintain patient information confidentiality. In particular, the person identification security measures have to be followed to be able to minimise the chance of information tampering.
- Establish programmes for adoption of Electronic Medical Records and continuous improvement of quality of data.¹²

23.1.4. Policy objective 2: Facilitate patients' and healthcare providers' ability to choose the nature and location of best available care.

23.1.5. Policy strategy 2: In order to achieve this DOH shall:

- Establish an accessible database that gathers under one platform healthcare related data (such as on healthcare facilities, healthcare professionals, specialties and expertise) to enable the user-friendly search of detailed available services in the emirate by facility.
- Link the services with the DOH quality rating system, patient experience and waiting time.

23.2. Managed and Coordinated Care Structure

Mechanisms of care management and coordination within the Abu Dhabi healthcare system delivery need strengthening. Such structures are necessary to:

- Inhibit fragmentation of care and “doctor hopping” behavior. Fragmentation in turns leads to poor quality, repetition and duplication of care, which can ultimately inflate activity and costs of unnecessary visits and diagnostic tests, especially to emergency departments, which increases the pressure on such units.

¹² As a guidance, healthcare providers can use the EMRAM score to assess their current adoption level <http://www.himssanalytics.eu/emram>. Achieving high Data quality requires a continuous improvement process and dedicated resources.



- Strengthen relational continuity between primary care providers and their patients. This is an implicit contract of patient loyalty to the provider, which encourages ongoing provider responsibility to the patient, while strengthening the link between healthcare and long-term care or social care.

23.2.1. Policy objective 3: Optimise primary healthcare

23.2.2. Policy strategy 3: In order to achieve this DOH shall:

- Define the primary care model of care for Abu Dhabi.
- Develop a primary care capacity plan, which involves mapping primary care services and identify gaps for residential and transient populations.
- Develop primary care workforce and training plan.
- Develop the regulatory infrastructure necessary for optimising primary healthcare including statement of requirements, licence category, community involvement requirements and reimbursement plans.
- Design strategies to increase attractiveness of primary care and drive progressive adoption through pull and push factors (registration, incentives, disincentives, regulation), redesigning reimbursement mechanisms, etc.
- Develop explicit safeguard to prevent conflict of interest in vertically integrated providers. This can include, but is not limited to, the database discussed under 4.1.
- Integrate primary care in quality assurance frameworks and tools.

23.3. Organisational Structure and Mechanisms

The organisational structure of healthcare facilities can affect the extent of care coordination as well as the smooth transfer and referral of patients across levels of care and facilities, local and international, especially in emergencies. For example, some necessary structures and tools that favour coordination and patients movements might be weak or even absent.

23.3.1. Policy Objective 4: Improve patients transfer and referrals between levels of care across and within facilities, local and international, especially in emergencies.

23.3.2. Policy strategy 4: In order to achieve this DOH shall:



- Revise DOH's Standards related to transfer of patients to remove any obstacles affecting the smooth movement of patients across facilities.
- Identify and tackle organisation related obstacles to movement of patients.
- Develop quality indicators to measure the extent of which patients safely and effectively transfer between levels of care across and within facilities, local and international, especially in emergencies.

23.3.3. In order to achieve this all DOH licensed facilities shall:

- Adopt DOH's revised Standards for patient transfer and revise their existing referral protocols and guidance accordingly.
- Comply with relevant DOH quality submission and improvement requirements.

23.3.4. Policy Objective 5: Ensure safe, continuous and effective care coordination between levels of care across and within facilities, local and international.

23.3.5. Policy strategy 5: In order to achieve this DOH shall:

- Explore opportunities to develop financial instruments to incentivise inter-professional and inter-facility high quality care teams.
- Develop quality indicators and outcome measures to assess the effectiveness and safety of care coordination.

In order to achieve this all DOH licensed facilities shall:

- Clearly define responsibility and accountability for coordination in work descriptions, contracts and other internal policies and procedures.
- Supply DOH with necessary data to fulfill care coordination indicators requirements.

23.4. Financial Regulations

Payment systems are one of the key factors that influence provider behaviour and help to link what health care providers do with what insurers of care want or value.

23.4.1. Policy Objective 6: Align payment mechanisms to incentivise coordination and integration of care.

23.4.2. Policy strategy 6: In order to achieve this DOH shall:



- Identify and implement evidence-based payment mechanisms for priority chronic health problems with the aim of:
 - a) Incentivising effective coordination and integration of care across multiple services and/or providers.
 - b) Improving providers' payment systems to stimulate the integration of care and ensure its financial sustainability.
 - c) Incentivising improvements in quality of care and efficiency.
 - d) Reducing unnecessary duplication.

23.4.3. In order to achieve this objective all DOH licensed insurers shall:

- Identify and develop mechanisms to incentivise their providers to coordinate care.



CHAPTER VI. MEDICAL PRODUCTS

24. Purpose

24.1. This Chapter establishes a regulatory framework governing Pharmaceutical Medicinal Products, Medical Devices and Complementary Medicines (together referred to as Medical Products) intended for human use in Abu Dhabi.

25. Background

25.1. DOH seeks to ensure that all Medical Products which are supplied and used in Abu Dhabi are safe, efficacious and of high quality.

25.2. In order to achieve this, DOH maintains an approved list of Medicinal Products¹³ to be available in the Emirate of Abu Dhabi.

25.3. DOH regulates the use of Medicinal Products that contain narcotic or psychotropic substances¹⁴.

25.4. DOH conducts post-marketing surveillance to ensure the safety of medical products supplied and used in Abu Dhabi. DOH ensures that appropriate action is taken when any safety risk is discovered.

¹⁵ 16 17

PART A. APPROVED MEDICAL PRODUCTS

26. The DOH Approved List

26.1. DOH maintains, publishes, and revises a list of all Pharmaceutical Medicinal Products that are authorised to be, supplied and used in Abu Dhabi.

26.2. This list shall be known as the DOH Approved List.

26.3. The DOH Approved List will comprise a database of information about each of the Medicinal Products listed on it.

¹³ DOH Approved Drug List Products: <https://www.DOH.ae/DOH/tabid/1505/Default.aspx>

¹⁴ DOH Standard for Narcotics and Controlled and Semi-Controlled Medicinal Products, 2015, (DOH/MNCM/0.9).

¹⁵ DOH Policy Adverse Reaction reporting.

¹⁶ DOH Policy on Medication Error reporting.

¹⁷ DOH Circular HRD/022/16.



The Listing Procedure

27. The General Condition

27.1. A Medicinal Product may be listed on the DOH Approved List only if that Product:

- 27.1.1. has been approved by the UAE Ministry of Health and Prevention (MOHAP) and is listed on the Ministry's List of Approved Medical Products, or
- 27.1.2. is a Special Medicinal Product approved by DOH Approved List Advisory Panel.

Special Medicinal Products

28. Definition

28.1. A Special Medicinal Product is a Product:

- 28.1.1. the supply of which is for a named Patient or group of Patients,
- 28.1.2. which was prescribed to that Patient or group of Patients by a Licensed Healthcare Professional acting within his Scope of Practice,
- 28.1.3. which will be solely for the use of that Patient or group of Patients under the supervision of that Professional,
- 28.1.4. for which there is no other equivalent Product listed on the DOH Approved List that would provide the same health benefit to that Patient or group of Patients.
- 28.1.5. is not registered by MOHAP but authorised for use in case of unavailability of registered alternatives

PART B. CONTROLLED MEDICINAL PRODUCTS

29. Introduction

29.1. This Part B contains regulation of Medical Products which are classed as Controlled Medicinal Products.

30. Controlled Medicinal Products

30.1. A Controlled Medicinal Product is a Medical Product, which contains either or both of:

- 30.1.1. a narcotic substance, as defined by the Single Convention on Narcotic Drugs 1961 (as amended by the 1972 Protocol to that Convention),



30.1.2. a psychotropic substance, as defined by the United Nations Convention on Psychotropic Substances 1971.

31. The Standard on Controlled Medicinal Products

31.1. DOH governs the use of Controlled Medicinal Products by DOH Narcotic Standard¹⁸.

31.2. The Standard sets out requirements to:

31.2.1. monitor and report the use of Controlled Medicinal Products,

31.2.2. manage the storage, prescribing and dispensing of those Products,

31.2.3. ensure the proper disposal of those Products.

PART C. PHARMACOVIGILANCE

32. Introduction

This Part C contains regulations governing the monitoring of Medical Products to ensure that they continue to be safe for use in the Emirate of Abu Dhabi.

33. The General Duty

33.1. The Authorised Supplier/ Manufacturer of a Medical Product must ensure that the Product is, and remains at all times, safe, efficacious and of high quality.

34. The Reporting Duty

34.1. Each Healthcare Provider and Licensed Healthcare Professional must, on becoming aware of any actual or suspected Adverse Event related to the use of a Medical Product:

34.1.1. promptly notify DOH of that Event,

34.1.2. provide DOH with all relevant information in accordance with DOH Reporting requirements^{3,4,5,7}.

34.2. DOH will maintain a database of all actual and suspected Adverse Events relating to the use of Medical Products in Abu Dhabi.

¹⁸ DOH Standard for Narcotics and Controlled and Semi-Controlled Medicinal Products, 2015, (DOH/MNCM/0.9).



35. Quality Control

- 35.1. DOH may at any time carry out any activities that it considers appropriate in order to assess whether a Medical Product available in Abu Dhabi is or will continue to be safe, efficacious and of high quality.
- 35.2. For these purposes, DOH may engage in any audit, quality control tests or investigation in accordance with Chapter XI of this Manual.
- 35.3. Authorised Supplier / Manufacturer of a Medical Product must give DOH all the assistance and co-operation that it may request for the purpose of carrying out any audit, quality control test or investigation.

36. Product Recall

- 36.1. When a Medical Product is likely to pose a risk to Public Health in Abu Dhabi, the Supplier/ Manufacturer of the product must:
 - 36.1.1. immediately instigate a recall of that Product in a manner that is proportionate to the risk,
 - 36.1.2. take all other appropriate actions – including the provision of relevant information to Healthcare Providers, Healthcare Professionals and members of the public – to minimise that risk as far as is possible,
 - 36.1.3. promptly notify DOH of the actions that are taken or proposes to take.
- 36.2. Where DOH has reason to consider that any Medical Product is likely to pose a risk to public health in the Emirate, it may:
 - 36.2.1. take all necessary steps to instigate a recall of that Product that is proportionate to the risk, this is initiated by Drugs and medical products department and in coordination with the Ministry of Health and Prevention.
 - 36.2.2. take all other appropriate actions – including the provision of relevant information to Healthcare Providers, Healthcare Professionals and members of the public – to minimise that risk as far as is possible,
 - 36.2.3. coordinate with the UAE Ministry of Health and Prevention and any other relevant government agency,
 - 36.2.4. direct the Supplier/ Manufacturer of the Product to give necessary information and assistance and to take steps as it may specify.



PART D. DEFINITIONS

37. Introduction

37.1. This Part D sets out definitions, which apply for the purposes of this Chapter.

Definitions

Adverse Drug Reaction	Any response to a Medical Product which is noxious and unintended, and which occurs at doses that are normally used in humans for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.
Adverse Event	An unexpected medical problem that happens during treatment with a drug or other therapy. Adverse events do not have to be caused by the drug or therapy, and they may be mild, moderate, or severe.
Controlled Medicinal Product	Means a Medical Product that satisfies the criteria set out at Part B of this Chapter.
DOH Approved List	The list, maintained by DOH, of all DOH Approved List Medicinal Products which can be supplied and used in Abu Dhabi.
Medical Device	Any instrument, apparatus, appliance, software, material or other item – whether it is used alone or in combination (including in combination with the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application) – that is designed by its manufacturer to be used by human beings for the purpose of the: <ul style="list-style-type: none"> a) diagnosis, prevention, monitoring, treatment or alleviation of disease, b) investigation, replacement or modification of the anatomy or of a physiological process, or c) control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
Medical Product	A Pharmaceutical Medicinal Product, Medical Device or Complementary Medicine that is intended for human use.
MOHAP List	The List of Approved Medical Products that is maintained by the UAE Ministry of Health and Prevention.
Pharmaceutical Medicinal Product	Any substance or combination of substances which <ul style="list-style-type: none"> a) is presented as having properties for the diagnosis, treatment or prevention of disease in human beings, or b) which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.
Pharmacovigilance	A body of science and range of activities that are concerned with the understanding, assessment, detection and prevention of Adverse Effects and of problems relating to the safety of Medical Products.
Special Medical Product	Means a Medical Product that satisfies the criteria set out at Part A of this Chapter.

CHAPTER VII. HUMAN SUBJECT RESEARCH

38. Purpose

38.1. This Chapter provides a framework for the promotion of health research and the governance and regulation of human subject research carried out by Healthcare Providers in Abu Dhabi.

39. Background

39.1. According to Decreed Federal Law No. (4) of 2016 Concerning Medical Liability, DOH is one of the authorities responsible for regulating human subject research in Abu Dhabi.

39.2. DOH seeks to encourage world class, cost-effective, and clinically beneficial human subject research that is carried out to the highest internationally recognised ethical standards. In particular, DOH seeks to promote research that will contribute to addressing the healthcare needs and improving the health of the people of Abu Dhabi.

39.3. In order to achieve these goals, DOH may establish an Abu Dhabi Health Research Council to oversee and support human subject research carried out by Healthcare Providers, and to advise on and promote health research in the Emirate.

39.4. For this purpose, DOH requires that all Healthcare Providers seeking to engage in human subject research must hold both DOH Health Facility Licence and Facility Research Authorisation. The Facility Research Authorisation, is an explicit authorisation to conduct human subject research, and is contingent upon Healthcare Providers putting into place arrangements for the proper governance and control of their research activities.

PART A. AUTHORISATION REQUIREMENTS FOR HUMAN SUBJECT RESEARCH

40. Introduction

40.1. This Part A requires Healthcare Providers¹⁹ seeking to engage in Human Subject Research to obtain a Facility Research Authorisation from DOH.

40.2. For the purposes of this Chapter, a Healthcare Provider is treated as 'responsible' for Human Subject Research if all or part of that research is carried out at a Healthcare Facility operated by it, whether or not it is carried out by or on behalf of the Provider.

41. The Facility Research Authorisation Requirement

41.1. A Healthcare Provider must not permit Human Subject Research to be carried out at a Facility²⁰ operated by it unless:

- 41.1.1. it holds a valid Facility Research Authorisation granted by DOH, applicable to that Facility, and

¹⁹ As defined in the Healthcare Providers Manual.

²⁰ As defined in the Healthcare Providers Manual.



41.1.2. the Human Subject Research carried out at the Facility is within the description of research that is permitted to be carried out in accordance with the Facility Research Authorisation.

42. The Facility Research Authorisation

42.1. A Facility Research Authorisation may contain conditions which:

- 42.1.1. describe the Human Subject Research that is permitted to be carried out,
- 42.1.2. impose restrictions on the carrying out of that research,
- 42.1.3. require the research to be carried out in a specified manner, and
- 42.1.4. make provision for the research to be monitored, recorded, controlled or reviewed.

42.2. In order to obtain a Facility Research Authorisation, a Healthcare Provider must comply with DOH's requirements as part of the Application for Authorisation to Conduct Human Subject Research.

42.3. DOH's Application for Authorisation to Conduct Human Subject Research provides for all matters relating to Facility Research Authorisation, including in particular:

- 42.3.1. the process relating to applications for, and the criteria for, granting Facility Research Authorisation,
- 42.3.2. the conditions of Facility Research Authorisation, and
- 42.3.3. the duration, renewal, and revocation of Facility Research Authorisation.

42.4. Any Healthcare Provider applying for or holding a Facility Research Authorisation must comply with the duties set out in the DOH Application for Authorisation to Conduct Human Subject Research.

PART B. HUMAN SUBJECT RESEARCH – ETHICS AND STANDARDS

43. Introduction

43.1. This Part B provides for the establishment of arrangements for the governance of Human Subject Research in Abu Dhabi, and sets out standards of ethics and conduct to be maintained by all Healthcare Providers and Investigators involved in research.

43.2. Providers and Investigators must comply with The Integrated Addendum to the International Conference on Harmonisation Good Clinical Practice (E6) (R2), the international standard for ethical research conduct, with this Chapter VII, and all other applicable Laws and Regulations.

Establishment of Research Ethics Committees

44. The Abu Dhabi Research Ethics Committee

44.1. DOH may establish or delegate a committee to be known as the Abu Dhabi Research Ethics Committee (ADREC).



44.2. The ADREC would be empowered by DOH to provide ethical review of research proposals at institutions lacking their own Research Ethics Committee. Investigators engaged in research through these institutions may submit applications for ethical review via DOH to the ADREC.

45. Facility Research Ethics Committees

45.1. A Healthcare Provider seeking DOH Authorisation to Conduct Human Subject Research must ensure that a Research Ethics Committee is established and maintained for each Healthcare Facility that holds a Facility Research Authorisation.

45.2. A Research Ethics Committee established for, or affiliated with, a Facility shall be referred to as the Facility REC.

45.3. The Healthcare Provider must ensure that the Facility REC relating to a Facility for which it holds a Facility Research Authorisation is constituted and operates in accordance with DOH Standard Operating Procedures for Research Ethics Committees.

45.4. A decision or approval by the Facility REC shall not be valid, and will be treated as having no effect, if there is a defect in the constitution of the Facility REC or if it does not establish and follow the procedures or carry out the functions in accordance with this Part B.

46. General Duties of Healthcare Providers

46.1. A Healthcare Provider that holds a Facility Research Authorisation must ensure that – in carrying out, monitoring, recording or controlling Human Subject Research for which it is responsible – it complies with the conditions of the Facility Research Authorisation, the requirements of this Chapter, the International Conference on Harmonisation Integrated Addendum to Good Clinical Practice (E6) (R2), and every other Law and Regulation that is applicable to the research.

46.2. That Provider must also ensure that:

46.2.1. no Human Subject Research is carried out at a Facility operated by it unless that research has first been the subject of a Research Proposal that has obtained the approval of the Facility REC (an Authorised Research Proposal),

46.2.2. Human Subject Research for which it is responsible is undertaken in accordance with the terms of the relevant Authorised Research Proposal and its approval conditions,

46.2.3. each Investigator engaged in Human Subject Research at the Facility complies at all times with his obligations under this Policy and with all other applicable Laws and Regulations, and

46.2.4. it actively monitors its compliance with, and promptly reports to DOH any breach of, the conditions of its Facility Research Authorisation and Laws and Regulations applicable to the research.

47. General Duties of Investigators

47.1. An Investigator must not carry out Human Subject Research at a Healthcare Facility unless:



- 47.1.1. he is competent to do so by virtue of having the qualifications, education, training, experience and knowledge of applicable Regulations that is adequate to his degree of responsibility for the research,
- 47.1.2. he is certified to do so by DOH following completion of any course in research ethics which has been accredited by DOH,
- 47.1.3. the research is the subject of an Authorised Research Proposal, and
- 47.1.4. each Subject, or the Subject's legally authorised representative, has given Informed Consent²¹ to the research.
- 47.1.5. In carrying out Human Subject Research, an Investigator must at all times:
- 47.1.6. act in accordance with the terms of the Authorised Research Proposal,
- 47.1.7. comply with all of his duties under this Manual and all other applicable Laws and Regulations, and
- 47.1.8. act in a manner that is consistent with and facilitates the compliance of the Provider with this Manual, the Integrated Addendum to the International Conference on Harmonisation Good Clinical Practice (E6) (R2), and all other applicable Laws and Regulations.

48. Suspension and Early Termination

- 48.1. A Healthcare Provider must promptly suspend or terminate Human Subject Research for which it is responsible where:
 - 48.1.1. it is (or should be) apparent to the Provider that the risks to Subjects are greater than were anticipated at the time when the Research Proposal was approved, to the extent that they are no longer justified by the benefits arising from the research, or
 - 48.1.2. the research causes unexpected serious harm to any one or more Subjects.

49. Treatment of Personal Information

- 49.1. Any personal information provided by (or on behalf of) Subjects for the purposes of Human Subject Research must be treated as confidential²² :
 - 49.1.1. by each Investigator who has access to that information,
 - 49.1.2. by the Healthcare Provider that is responsible for the research.
- 49.2. No Healthcare Provider or Investigator may disclose any personal information obtained for the purposes of Human Subject Research without first having obtained the express consent of the Subject (or the Subject's legally authorised representative), except in any case where the disclosure is:
 - 49.2.1. made in accordance with an order by DOH or by a court of law, or

²¹ DOH Standard on Informed Consent.

²² DOH Standard on General Confidentiality and Chapter VIII. Data Management.



49.2.2. necessary to eliminate any apparent immediate risk of harm to the Subject or any other person, and is the minimum disclosure necessary for the purpose of eliminating such harm.

49.3. A Healthcare Provider and an Investigator must each respect the right of a Subject to be informed of research results that directly affect the Subject's interests, unless the Subject has chosen not to exercise that right.

50. Data and Record Keeping

50.1. A Healthcare Provider must ensure that all information related to Human Subject Research for which it is responsible is recorded, handled and stored in a way that allows its accurate reporting, interpretation, and verification in accordance with all applicable Regulations on document retention and information management²³.

²³ DOH Standard for Record Keeping and Information Management.

PART C. DEFINITIONS

51. Introduction

51.1. This Part C sets out certain rules of interpretation and definitions, which apply for the purposes of this Chapter.

52. General Definitions

52.1. In this Chapter, the following words shall have the meanings given to them:

Abu Dhabi Research Ethics Committee (ADREC)	The body established by DOH in accordance with Part B of this Chapter
Authorised Research Proposal	Means a Research Proposal approved by a Facility REC in accordance with Part B of this Chapter
Facility REC	Means a Research Ethics Committee established by a Healthcare Provider in accordance with Part B of this Chapter
Facility Research Authorisation (or simply Authorisation)	Means an authorisation granted by DOH to a Healthcare Provider, in accordance with the provisions of this Policy, authorising Human Subject Research to be conducted at a licensed Healthcare Facility operated by the Provider
Human Subject Research	Means any activity falling within one or more of the following categories: 1) studies of a physiological, biochemical, or pathological process, or of the response to a specific intervention whether physical, chemical or psychological – in healthy subjects or in Patients 2) controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons, designed to demonstrate a specific generalisable response to these measures against a background of individual biological variation 3) studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures 4) studies concerning human health-related behaviour in a variety of circumstances and environments
Human Tissue	Means any part of the human body, which has been separated from a human being (whether living or dead).
Informed Consent	Has the meaning given in the DOH Standard on Informed Consent.
Integrated Addendum to the International Conference on Harmonisation Good Clinical Practice (E6) (R2)	The international standard guideline for the conduct of ethical human health research.
Investigator	Means any person who carries out Human Subject Research at a Healthcare Facility.
Research Proposal	Means a detailed description of proposed Human Subject Research submitted to a Facility REC or the ADREC for approval in accordance with Part B of this Chapter.
Standard Operating Procedures for Research Ethics Committees	A document issued by DOH setting out the manner in which each Facility REC is to be constituted and operated.
Subject	Means an individual, living or dead, who is the subject of, participant, or source of human tissue, in Human Subject Research.

CHAPTER VIII. DATA MANAGEMENT

53. Purpose

53.1. This Chapter sets out the powers of DOH and its role and responsibilities with regards to healthcare data collected within the Abu Dhabi health system. It also defines the reciprocal responsibilities and duties of Healthcare Providers and Insurers in data management, and the rights of individuals in accessing their own healthcare data.

54. Background

- 54.1. In this Chapter, 'healthcare data' shall be read as a reference to information relating to human health or the provision of healthcare in Abu Dhabi, as defined within the DOH Data Standards and Procedures.
- 54.2. DOH will regulate and oversee the development and maintenance of healthcare data systems that are able to meet the evolving needs of the population of Abu Dhabi.
- 54.3. For this purpose, DOH will collaborate with Healthcare Professionals, Healthcare Providers, and Health Insurers to ensure that healthcare data are collected and used in accordance with the DOH Data Standards and Procedures and industry good practice.
- 54.4. DOH will regularly consult stakeholders on healthcare data management to inform the ongoing development of healthcare data systems through www.DOH.ae/shafafiya.

55. The Role of DOH

- 55.1. As the Health Regulator, with regards to healthcare data DOH is empowered to:
- 55.1.1. define, approve and communicate the DOH Data Standards and Procedures,
 - 55.1.2. audit and enforce regulatory compliance and conformance to the DOH Data Standards and Procedures,
 - 55.1.3. develop (with stakeholder input) and maintain the Abu Dhabi healthcare data strategy,
 - 55.1.4. develop healthcare data systems,
 - 55.1.5. establish data governing bodies and define the custodianship for healthcare data assets and for access to, the use and release of data, and to set out the functions, accountabilities and terms of reference for data governing bodies it establishes,
 - 55.1.6. obtain, analyse and use healthcare data to inform decisions on policy, planning and regulation of healthcare in Abu Dhabi,
 - 55.1.7. subject to the provisions of the DOH Data Standards and Procedures. Abu Dhabi human subject research regulations, regulations established by the Abu Dhabi Systems and Information Centre (ADSIC), and to international, UAE, and Abu Dhabi provisions regarding confidentiality, privacy, and data protection, release data to other bodies or persons to aid improvements in health system performance (quality, access and cost efficiency) in the Emirate of Abu Dhabi.

56. DOH Data Standards and Procedures

56.1. DOH may publish, and revise, Data Standards and Procedures.

56.2. The DOH Data Standards and Procedures may make provision for all matters relating to the collection, management, reporting and exchange of healthcare data, including in particular:

56.2.1. Data Standards:

- 56.2.1.1. available healthcare data exchange, such as, 'transaction types',
- 56.2.1.2. technical format of healthcare data exchange between stakeholders,
- 56.2.1.3. data elements to be exchanged by stakeholders (including mandatory elements),
- 56.2.1.4. mode of transmission of healthcare data,
- 56.2.1.5. frequency of transmission of healthcare data, and
- 56.2.1.6. Systems policies.

56.2.2. requirements for the collection, storage, transmission and exchange of healthcare data by Healthcare Providers, Professionals, Insurers, and DOH (the Regulator),

56.2.3. rights of patient access to their own healthcare data,

56.2.4. data governance and mandated bodies,

56.2.5. considerations with respect to the confidentiality and privacy of healthcare data (whether stored in paper-based form or electronically), and

56.2.6. obligations of Healthcare Entities in relation to data management.

56.3. DOH shall maintain a comprehensive list of healthcare data specifications, published on www.DOH.ae/shafafiya/dictionary.

57. General Duties of Healthcare Entities

57.1. All healthcare entities are required to monitor www.DOH.ae/shafafiya/notices page of DOH website and treat any announcements published there as direct guidance and integral part of DOH Data Standards and Procedures.

57.2. DOH may consult with Healthcare Entities on future changes to Data Standards and Procedures in relation to which all Healthcare Entities are required to acknowledge and provide timely feedback.

57.3. Healthcare Entities must comply with the requirements of this Chapter including the duties set out in the DOH Data Standards and Procedures,

57.3.1. The Provider and Insurer must particularly ensure that healthcare data are collected by its Staff unless the patient has provided their Informed Consent to:

- 57.3.1.1. the collection of healthcare data, including required for the provision of and reimbursement of healthcare services,
- 57.3.1.2. the sharing of certain data required for healthcare insurance reimbursement purposes, and
- 57.3.1.3. the use of certain data by DOH and other authorised government entities for the purposes of planning and improvement of healthcare services.

- 57.3.2. no patient identifiable data are to be disclosed to third parties, and that where disclosure is approved only anonymised and aggregated data may be released, subject to satisfying the data release approval requirements of the DOH Data Standards and Procedures,
- 57.3.3. the use of healthcare data is subject to this Chapter, including the requirements set out in the DOH Data Standards and Procedures,
- 57.3.4. patients are granted, upon their request, full access to their own healthcare data within a reasonable timeframe,
- 57.3.5. a staff employed by the Healthcare Provider or Healthcare Insurer complies with his obligations in respect of the confidentiality, security and privacy of healthcare data including obligations under this Chapter, the DOH Data Standards and Procedures, and all other applicable Regulations regarding healthcare data, and
- 57.3.6. Healthcare Entity actively monitors its compliance with, and promptly reports to DOH any breach of, the requirements set out in this Chapter, the DOH Data Standards and Procedures, and all other applicable Regulations regarding healthcare data.

58. General Duties of Healthcare Professionals

58.1. A Healthcare Professional must ensure that:

- 58.1.1. he complies with the requirements of this Chapter, including the DOH Data Standards and Procedures, and all other applicable Regulations regarding healthcare data,
- 58.1.2. each patient, or the patient's legally authorised representative, has given Informed Consent to the collection, sharing and use of healthcare data in accordance with the requirements of this Policy and of the DOH Standard on Informed Consent ¹⁴, and
- 58.1.3. he acts in a manner that is consistent with and facilitates the compliance of the Healthcare Provider with this Chapter and all other applicable Regulations regarding healthcare data.

59. Data Reporting Requirements

59.1. Healthcare Providers and Healthcare Insurers must submit healthcare data to DOH, as specified in the DOH Data Standards and Procedures, within the following three broad sources and reporting systems:

- 59.1.1. routine transactions,
- (a) ClaimSubmission within 24 hours following the EncounterEnd
 - (b) RemittanceAdvice within 45 working days of receiving the corresponding ClaimSubmission
 - (c) PersonRegister within 24 hours following the change of Membership status of an individual
 - (d) PriorRequest/PriorAuthorisation as defined by the Data Standards and Procedures
- 59.1.2. public health notifications regarding²⁴.
- (e) vital statistics,
 - (f) notifiable diseases,
 - (g) injury and poison surveillance, and

²⁴ DOH Standard for Notifying Vital Statistics, Non-fatal Injuries and Poisoning Cases and Communicable Diseases in the Emirate of Abu Dhabi.

(h) others for which DOH may provide custom online interfaces.

59.1.3. additional healthcare data which may be requested by DOH in accordance with its mandate as Abu Dhabi Health Regulator.

59.2. In relation to any healthcare data to be submitted to it, DOH will clearly set out the format in which they are to be reported, the means by which they are to be reported, and the time period within which they are to be reported,

59.3. DOH undertakes to develop healthcare data systems that are both comprehensive and efficient,

59.4. Healthcare Entities must submit to DOH healthcare data according to the required standards, within the timeframe specified by DOH.

60. Data Analysis and Use

60.1. DOH has established a body known as the 'Data Access Panel', and subject to governance by the Panel maintains data warehouses (known as 'Knowledge Engine for Health' and eNotification) of all healthcare and public health data reported to it.

60.2. DOH may:

60.2.1. authorise access to healthcare and public health data that have been submitted to it, in accordance with the following criteria:

60.2.1.1. requirement by UAE or Abu Dhabi Law,

60.2.1.2. request by the Police or Courts (case specific),

60.2.1.3. in national interest,

60.2.1.4. under approval by higher authority, and

60.2.1.5. where data are publically available.

60.2.2. authorise use of healthcare and public health data for the purpose of health research²⁵,

60.2.3. disclose or publish that healthcare and public health data, or any product of those data based on their further analysis by DOH.

60.3. DOH will ensure that any such access, use, disclosure or publication of data is consistent with UAE and Abu Dhabi law, DOH Policies and Standards, and DOH's objective to promote the highest standards of public health and healthcare in Abu Dhabi.

²⁵ Chapter VII: Human Subject Research, Healthcare Regulator Manual.

CHAPTER IX. HEALTH PROTECTION

61. Purpose

61.1. This Chapter provides for DOH to have the function of leading, planning and coordinating the delivery of health protection, response and monitoring actions across all government agencies in Abu Dhabi, and establishes the duties of Healthcare Providers and Insurers to work under the direction of DOH to achieve this outcome.

62. Background

62.1. DOH seeks to protect the health and wellbeing of the population of Abu Dhabi, in particular from adverse incidents related to the delivery of healthcare and from the effects of public health emergencies.

62.2. DOH will achieve this objective by building the capacity to identify, monitor and implement effective and sustained responses to health threats or emergencies.

62.3. The objective of protecting health is complemented by DOH's role in maintaining the health of the population and minimising the incidence of preventable mortality, illness and injury.

62.4. For these purposes, DOH works across the healthcare sector in Abu Dhabi and with relevant agencies in the government of the Emirate.

62.5. DOH will take preventative action where necessary in order to ensure that the risks of adverse effects on health are minimised. It will also continually monitor the occurrence of such risks and will take direct action to lead and coordinate the response to them.

PART A. MEDICAL PRODUCTS

63. Introduction

63.1. This Part A provides for the management of shortages of Medicinal Products, and the maintenance of adequate stocks of antidotes in Abu Dhabi.

Shortages of Medicinal Products

64. The Duty of Healthcare Providers

64.1. Where there is a critical shortage of supply of a medicinal product at any one or more of the Healthcare Facilities operated by a Healthcare Provider, that Provider must:

- 64.1.1. promptly notify the shortage to DOH,
 - a) as specified in the DOH Standard on Managing Medical Drug Shortages, and
 - b) in the form, by the means and within the time frames specified in that Standard.



64.1.2. mandate practice changes across all clinical disciplines at each relevant Facility, to include the ability of Healthcare Professionals to approve the use of therapeutic alternatives, the prioritisation of patients, and product rationing,

64.1.3. take all reasonable steps to obtain an alternative source of supply of the product.

64.2. Each Healthcare Provider must have a policy designed to ensure that it communicates with and educates those Healthcare Professionals who are employed by it in the means of dealing with critical shortages of medicinal products.

65. The Role of DOH

65.1. Where DOH obtains information about a critical shortage of supply of any medicinal product, it will coordinate all communications relating to that shortage to Healthcare Providers, the UAE Ministry of Health and Prevention, and other relevant Government Agencies.

65.2. In particular, DOH will:

65.2.1. inform those affected by the critical shortage of DOH's intervention,

65.2.2. initiate, apply and monitor a management plan for addressing the shortage, from the time of the initial reports until its resolution.

65.3. where, as a result of the critical shortage, a medical necessity arises, DOH will coordinate an action plan designed to prevent or mitigate further supply disruption.

Maintenance of Adequate Stocks of Antidotes in the Emirate of Abu Dhabi

66. The Duties of Healthcare Facilities

66.1. Maintain a minimum stock amount of each antidote sufficient to treat a 70kg adult for the first 24 hours of admission for treatment, where indicated,

66.2. Report to DOH through DOH E-notification system of antidote stocks level on a monthly basis,

66.3. Establish policies and procedures for effective sharing agreements of antidotes, including during but not limited to stock shortages, with other healthcare facilities,

66.4. Ensure that appropriately licensed and privileged health professionals are responsible for prescribing and administering antidotes, in accordance with their competence and scope of practice.

67. The Role of DOH

67.1. The DOH will

67.1.1. Establish and review the list of antidotes to be maintained by healthcare facilities with Emergency Services, and to determine the range of antidotes to be stocked,

67.1.2. Monitor and evaluate potential risks of antidote shortages, monitor the safe and quality use of antidotes and share information and alerts with healthcare providers to facilitate adequate management of risks, where necessary,

67.1.3. Ensure that potential shortages of antidotes are managed promptly and effectively,

67.1.4. Co-ordinate communications with local and international suppliers in cases of likely stock shortages in order to maintain safe and quality care.

PART B. ADVERSE DRUGS REACTIONS, SENTINEL EVENTS AND MEDICATION ERRORS

68. Introduction

68.1. This Part B requires Healthcare Providers to collect data relating to Adverse Drugs Reactions, Sentinel Events and Medication Errors, report data to DOH, and take action in order to improve Patient Safety.

69. Adverse Drugs Reactions and Medication Errors

69.1. Each Healthcare Provider must:

- 69.1.1. establish a process to monitor all adverse drugs reactions and medication errors which occur in relation to Patients at any Healthcare Facility which is operated by it,
- 69.1.2. internally collate all evidence of such events,
- 69.1.3. analyse that evidence for patterns and trends and use the results of that analysis to improve its Patient care.

69.2. Each Healthcare Provider must report to DOH, at intervals, which are defined by DOH Adverse reaction and medication errors reporting policies, the details of all adverse drugs reactions and/or medication errors which occur in relation to Patients at any Healthcare Facility which is operated by it.

70. Sentinel Events

70.1. For the purposes of this Part B, a Sentinel Event means any event occurring at a Healthcare Facility that is of such seriousness as to require immediate action by the Healthcare Provider who operates that Facility in order to prevent any similar event occurring in the future.

70.2. Sentinel Events are more particularly defined:

- 70.2.1. by DOH in the Standard on Adverse Events Management and Reporting in the Emirate of Abu Dhabi,
- 70.2.2. The Standard includes events that may lead to death, disablement or impairment of function as a result of suspected medical errors or systemic faults within a Facility.

70.3. A Healthcare Provider may also, at its discretion, choose to class additional events occurring at a Facility operated by it as falling within the definition of Sentinel Events for the purposes of its compliance with this Part B.

70.4. The Standard on Adverse Events Management and Reporting establishes rules relating to the:

- 70.4.1. establishment of a Facility Sentinel Events Management system,
- 70.4.2. collation, analysis and management of Sentinel Events,
- 70.4.3. use the results of analysis of the Event to improve its processes,
- 70.4.4. reporting to DOH on Sentinel Events.

70.5. Healthcare Providers must comply with the requirements of the Standard on Adverse Events Management and Reporting in the Emirate of Abu Dhabi.

71. The Role of DOH

71.1. DOH will:

71.1.1. collect relevant data and perform an analysis to establish whether trends or patterns of Adverse Drugs Reactions, Medication Errors or Sentinel Events exist across Facilities throughout Abu Dhabi,

71.1.2. where such trends or patterns are detected, develop Policies or Regulations which are intended to address the situation in order to improve Patient safety.

PART C. PUBLIC HEALTH EMERGENCIES

72. Introduction

72.1. This Part C provides for DOH to plan for and manage any emergencies that challenge the health system and the health of the population.

73. Public Health Emergencies

73.1. For the purposes of this Part C, a 'public health emergency' is an occurrence or imminent threat of an illness or health condition, caused by bio terrorism, epidemic or pandemic disease, or (a) novel and highly fatal infectious agent or biological toxin, that poses a substantial risk of a significant number of human fatalities or incidents or permanent or long-term disability (WHO/DCD, 2001). These emergencies could be a result of / but not limited to:

73.1.1. military operations of whatever type,

73.1.2. war,

73.1.3. an act of terrorism,

73.1.4. contamination caused by chemical spillage or nuclear radiation,

73.1.5. any type of natural disaster (including major weather-related events),

73.1.6. an epidemic,

73.1.7. a major unanticipated event of any type which has a potential immediate adverse effect on the health of a large number of individuals.

74. The General Duties

74.1. Emergency Mitigation, where DOH may decide to take steps in anticipation of a potential public health emergencies in order to prepare for, prevent, or reduce the health risks associated with that emergency, and, where it does so, DOH:

74.1.1. may, at any time before that emergency has occurred, issue such directions as it considers appropriate to Healthcare Providers^{26,27,28} or Authorised Healthcare Insurers,

²⁶ DOH Standard for Emergency Preparedness, Response and Risk Management in Mass Gathering Events.

²⁷ DOH Standard for Adverse Events Management and Reporting in the Emirate of Abu Dhabi.

²⁸ DOH Standards for Major Incident and Disaster Preparedness in Healthcare.



74.1.2. may in particular direct Providers to take steps to ensure that they are ready to provide appropriate treatment and take preventative measures when the emergency occurs,

74.1.3. may in particular direct Insurers to take steps to ensure that they are ready to provide information, assistance and advice, and to take other actions, when the emergency occurs.

74.2. Emergency Preparedness:

74.2.1. DOH will plan, direct and coordinate the emergency preparedness of the healthcare sector in Abu Dhabi and of other relevant agencies of government in the Emirate.

74.2.2. In particular, DOH will fulfill the related requirements as set out in the DOH Policy for Emergency Management.

74.2.3. Each Healthcare Provider must comply with any Standards issued by DOH in relation to emergency preparedness.

74.2.4. Each Healthcare Provider which operates one or more Hospitals must in particular ensure that the requirements set out in the DOH Policy for Emergency Management are met.

74.3. Emergency Response, where any healthcare emergency occurs, DOH in accordance with the DOH Policy on Healthcare Emergency Management²⁹, may issue such directions as it considers appropriate to Healthcare Providers, and Authorised Health Insurers in relation to:

74.3.1. the treatment to be given to individuals who are suffering illness or injury as a result of the emergency,

74.3.2. any measures to be taken for the benefit of individuals in order to prevent or reduce the risk of their becoming ill or injured as a result of the emergency,

74.3.3. the provision to DOH, or to any other relevant agency, of information, assistance and advice,

74.3.4. DOH may issue directions only to certain categories of Healthcare Provider or Authorised Health Insurers, or different directions to different categories of Provider or Insurer,

74.4. each Healthcare Provider and Authorised Healthcare Insurer must comply with any direction issued to it by DOH.

74.5. In the advent of a public health emergency, DOH will direct and coordinate the response of the healthcare sector in Abu Dhabi and of other relevant bodies and agencies of government in the Emirate.

74.6. In particular, DOH will fulfill the related requirements as set out in the DOH Policy for Emergency Management.

74.7. Emergency Recovery and Continuous Improvement:

74.7.1. in particular, DOH will fulfill the related requirements as set out in the DOH Policy for Emergency Management.

74.7.2. each Healthcare Provider must comply with any Standards issued by DOH in relation to business continuity, emergency recovery, and Continuous improvement of Emergency management system.

74.7.3. each Healthcare Provider which operates one or more Hospitals must in particular ensure that the requirements set out in the DOH Policy for Emergency Management are met.

²⁹ DOH Policy for Healthcare Emergency Management.



CHAPTER X. HEALTH PROMOTION & DISEASE PREVENTION

75. Purpose

75.1. This Chapter provides for DOH to promote improved health outcomes in the Emirate of Abu Dhabi, in particular through public health interventions, health promotion and disease prevention.

76. Background

76.1. DOH aims to achieve its Health Sector's Strategic objectives of protecting, promoting and improving the health outcomes of the population.

76.2. DOH seeks to promote the health and wellbeing of the population of Abu Dhabi, in particular through measures to minimise the incidence of preventable mortality, illness and injury and by means of promoting healthy living.

76.3. DOH is committed to fulfilling this objective through the development of collaborative health initiatives working in partnership with the healthcare sector, other agencies of the Abu Dhabi government, the Ministry of Health and Prevention (MOHAP), the community, and international organisations including in particular the World Health Organisation (WHO).

76.4. The UAE has developed a collaboration plan with WHO which states that enjoyment of the highest standard of health is a basic right for each citizen, and that ensuring good health for all citizens is essential for realising welfare and prosperity.

76.5. DOH adopts the Centers for Disease Control and Preventions (CDC's) Public Health definition³⁰ as "the science and art of preventing disease, prolonging life, and promoting health through the organised efforts and informed choices of society, organisations, public and private communities, and individuals." The aim is preventing problems from happening or recurring through implementing educational programs, recommending policies, administering services and conducting research.

76.6. DOH adopts WHO's definition of disease prevention³¹ and uses its resources for the reduction or elimination of diseases in Abu Dhabi, in particular by promoting immunisation as one of the most successful and cost-effective interventions in reducing mortality.

77. Health Promotion

77.1. This Chapter provides for DOH to have the function of overseeing, leading and planning the delivery of Health Promotion and Disease Prevention activities, including, establishing partnerships, capacity building and building alliances. By this, DOH aims to:

³⁰ What is Public Health? CDC 2017 Available at: <https://www.cdcfoundation.org/content/what-public-health>.

³¹ WHO/EU Disease prevention 2017 Available at: <http://www.euro.who.int/en/health-topics/disease-prevention>



- 77.1.1. Achieve its health sector's strategic objectives of protecting, promoting and improving the health of the population,
 - 77.1.2. Ensure health promotion practice throughout the health service is in line with international evidence,
 - 77.1.3. Build the capacity of the organisation to improve health and wellbeing within the population,
 - 77.1.4. Integrate health promotion into all aspects of the services,
 - 77.1.5. Promoting health service based on international best practice,
 - 77.1.6. Develop a robust multi-sectoral approach, in all settings, to addressing the social determinants of health and health inequalities,
 - 77.1.7. Increase the effective and efficient use of resources to promote the health of the population thus reducing the cost burden of chronic disease.
 - 77.1.8. Establish partnerships and alliances with public and private organisations to promote healthy lifestyles, develop innovative and simple lifestyle interventions, promote educational activities to raise awareness of health matters, and to build capacity within the community.
- 77.2. DOH adheres to a structured participatory model for conceiving, planning, implementing, and evaluating a community health promotion programs, which incorporates health behavior theories, thus has adopted the Precede/Proceed Model for Health Promotion³².
- 77.3. DOH seeks to provide effective health education to the residents of the Emirate through a variety of methods to improve their ability to make informed healthcare decisions, and will provide resources to encourage self-regulation and management of individual lifestyles.

78. Health Education

- 78.1. DOH identifies the health education needs of the residents of Abu Dhabi.
- 78.2. DOH seeks to promote the adoption of healthy lifestyles, by empowering people to increase control over their health and its determinants through health literacy efforts and multi-sectoral action to increase healthy behaviors.
- 78.3. This process includes activities for the community-at-large or for populations at increased risk of negative health outcomes. Health promotion usually addresses behavioral risk factors such as tobacco use, obesity, diet and physical inactivity, as well as the areas of mental health, oral health and injury prevention.
- 78.4. DOH provides resources and materials to Healthcare Providers, schools and other social agencies for the purposes of instruction in healthcare topics including health screenings³³, early detection, and the prevention and control of diseases.
- 78.5. DOH maintains an information database of all healthcare education initiatives provided within Abu Dhabi. Defined information is collected through standardised reports that are required to be produced by all agencies receiving DOH resources.

³² Community Tool Box 2017. Chapter 2 Models for Promoting Community Health and Development PRECEDE/PROCEED Available at: <http://ctb.ku.edu/en/table-contents/overview/other-models-promoting-community-health-and-development/preceder-proceder/main>

³³ DOH Standard for School Health Screening.



79. Injury Prevention

- 79.1. DOH is aiming to reduce unintentional injuries among the population and thus develops health promotion strategies to prevent injuries from occurring among different age groups.
- 79.2. DOH collaborates with agencies to establish regulations and practices to promote for safety on public roads, residential areas, and other locations as per the needs of the population. This includes the use of child restraint devices and seat belts, compliance with speed limits using home safety checklist and other safety measures to prevent injuries in the community.
- 79.3. DOH works with healthcare facilities to implement injury prevention programs for specific age groups in order to reduce these injuries among specific target group in Abu Dhabi. These programs include:
- 79.3.1. Child car safety seat program to promote the child safe transportation after discharge by providing the education and training and ensure safe discharge of the newborn.
 - 79.3.2. Child home safety program, including basic life support and how to act in case of injuries.
 - 79.3.3. Elderly population injuries prevention programs and home injuries prevention programs.
- 79.4. DOH works with other regulatory bodies to establish regulations and practices that promote safe work practices to prevent occupational injuries.

Disease Prevention

80. Immunisation

- 80.1. DOH develops and maintains an immunisation programme³⁴ that follows the guidelines set by the WHO Expanded Programme on Immunisation.
- 80.2. For these purposes, DOH in particular:
- 80.2.1. collaborates with MOHAP and WHO to monitor and assess the impact of strategies and activities for reducing morbidity and mortality associated with vaccine-preventable diseases,
 - 80.2.2. has developed a computer-based information surveillance system of vaccine-preventable diseases, which is used to collect and report data on the effectiveness of the immunisation programme throughout Abu Dhabi,
 - 80.2.3. ensures that adequate supplies of vaccines are available to distribute to Healthcare Facilities for the purposes of immunisation,
 - 80.2.4. has developed a plan to distribute vaccines to facilities for the purposes of immunisation,
 - 80.2.5. has established Regulations³⁵ to ensure that only high quality, safe and effective vaccines are distributed to facilities.

³⁴ DOH Standard for Childhood and Young adult Immunisation.

³⁵ Including but not limited to DOH Standard for Cold Chain.



81. Disease Risk Reduction

81.1. DOH works with Healthcare Facilities to implement disease risk reduction programmes^{36,37} for specific diseases in order to reduce their incidence in Abu Dhabi.

81.2. These programmes include in particular:

81.2.1. weight³⁸ control programmes to reduce the incidence of diabetes,

81.2.2. fitness programmes to reduce the incidence of cardiac disease,

81.2.3. programmes to promote the cessation of smoking to reduce the incidence of lung-related diseases,

81.2.4. early cancer^{39 40 41} detection and prevention,⁴²

81.2.5. health screening of all applicants for residence or work,⁴³

81.2.6. other forms of screening⁴⁴ and health interventions,

81.2.7. childhood obesity management program.

81.3. DOH has also established indicators by which Healthcare Facilities may measure health outcomes as a result of these programmes, and will collect the resulting data and publish them (or an analysis of them) annually.⁴⁵

82. Communicable Disease Prevention and Control

82.1. DOH has developed a tool for risk assessment of the communicable diseases that are prevalent within Abu Dhabi.

82.2. DOH has developed a plan for managing the risk presented by those communicable diseases, which includes, in particular, the role of disease management, treatment, quarantine and the eradication of the source of the disease.

82.3. DOH maintains a statistical reporting system⁴⁶ on communicable diseases, including their risks, volume, actions and effects.

83. Road Safety

83.1. DOH works with other agencies to establish regulations and practices that promote safe vehicular handling, including by means of the use of child restraint devices and seat belts, compliance with speed limits and driving licence testing.

³⁶ DOH Standard for Weqaya Screening for Cardiovascular Risk Factors.

³⁷ DOH Standard for Smoking Cessation.

³⁸ DOH Standard for Diagnosis and Management of Interventions for Weight Management and Obesity.

³⁹ DOH Standard for Screening and Diagnosis of Breast Cancer & DOH Standard for the Management of Breast Cancer Version.

⁴⁰ DOH Standard for Colorectal Cancer Screening.

⁴¹ DOH Standard for Cervical Cancer Screening.

⁴² DOH Standard for Thiqa List of Preventive Interventions.

⁴³ DOH Standard for Visa Screening in the Emirate of Abu Dhabi.

⁴⁴ DOH Standard for Premarital Screening in the Emirate of Abu Dhabi.

⁴⁵ DOH Jawda Programme.

⁴⁶ DOH Standards for Reporting of Public Health Statistics.

84. Public Health Research

84.1. DOH identifies priorities for health research and funding that would have the potential to improve the health of the residents of Abu Dhabi.



CHAPTER XI. COMPLAINTS, INVESTIGATIONS, REGULATORY ACTION AND SANCTIONS

85. Purpose

85.1. This Chapter provides for DOH to deal with complaints, investigate, take enforcement action and impose fair and proportionate sanctions in relation to Regulated Persons.

86. Background

86.1. DOH has established an integrated system of regulation – by means of its Policies, Standards and other regulatory instruments – that is designed to ensure better access to service, continually improving quality of care and sustainability of resources in the Emirate of Abu Dhabi.

86.2. In this integrated system of regulation, duties and obligations are placed on Regulated Persons.

86.3. It is important that these duties and obligations are fulfilled consistently throughout the Emirate so as to ensure that a safe, effective, ethical and high quality healthcare system is both established and maintained.

86.4. For this purpose, DOH has the power to consider complaints, review the performance of Regulated Persons, investigate possible breaches of duty, and take all appropriate actions where it determines that a breach of duty has occurred or, based on available evidence, is likely to occur.

86.5. In this Chapter:

- 86.5.1. Part A provides for complaints to be made against a Regulated Person,
- 86.5.2. Part B sets out DOH's powers of investigation of Regulated Persons,
- 86.5.3. Part C sets out DOH's powers following an investigation,
- 86.5.4. Part D describes the role of the Disciplinary and Licensing Committees,
- 86.5.5. Part E sets out DOH's powers following a Committee hearing.

PART A. COMPLAINTS

87. Introduction

87.1. This Part A provides for:

- 87.1.1. Clinical Complaints: any person to report a clinical complaint (malpractice) against a Regulated Person related to any aspect of care at any licensed healthcare facility in the emirate of Abu Dhabi to DOH.
- 87.1.2. Non-Clinical Complaints: any person to make any non-malpractice related complaint against a Regulated Person and for DOH to consider and take action in relation to that complaint.

88. The Complaint

88.1. DOH may publish, and revise, one or more forms to be used by anyone who wishes to make a complaint against a Regulated Person (a Complaint Form).



88.2. In order to be valid, all complaints (clinical and non- clinical complaints) must:

- 88.2.1. be written and submitted on a complaint form,
- 88.2.2. be made by patients, or their legal guardian/representative,
- 88.2.3. provide all of the information and evidence requested on that Form,
- 88.2.4. be completed in total honesty and good faith.

Actions by DOH

89. DOH Review

89.1. For Clinical Complaints:

- 89.1.1. DOH will review and investigate the complaint in accordance to its Standard of Practice (SOP).

89.2. For Non-Clinical Complaints:

- 89.2.1. DOH will review a complaint received by it in accordance with the GSEC Standard for Complaints Management Procedures.
- 89.2.2. After DOH has reviewed a complaint, it may:
 - 89.2.2.1. reject the complaint,
 - 89.2.2.2. refer the complaint for investigation by a Healthcare Provider or Professional Board, or
 - 89.2.2.3. conduct its own investigation in relation to the complaint including commissioning of a clinical review panel.

89.3. The power of DOH to take any of these actions is to be interpreted in accordance with, and is subject to the conditions set out in the following provisions of this Part A.

PART B: POWERS OF INVESTIGATION

90. Introduction

90.1. This Part B provides for DOH to investigate the practice of any Regulated Person in relation to a clinical or non-clinical complaint.

91. The Investigation

91.1. DOH may investigate a Regulated Person:

- 91.1.1. in response to a complaint in accordance with Part A of this Chapter,
- 91.1.2. in response to a request made by DOH management and other higher authorities.

91.2. For the purposes of this Part B, an 'investigation' includes without limitation any process carried out by DOH of gathering, reviewing and analysing information or evidence about a Regulated Person or his activities.

92. Information

92.1. DOH may give to any licensed healthcare facility a notice in writing requesting the facility to provide DOH with any information which is required to complete the investigation.

92.2. Healthcare facilities must comply with DOH request for any information within the specified timeframe.



92.3. Escalation to higher committees in DOH may apply if the facility fails to provide DOH with the required information.

93. The General Duties

93.1. A Regulated Person must comply with the requirements of an Information Request.

93.2. A Regulated Person must take all necessary steps to ensure that the information provided to DOH in compliance with an Information Request is complete and accurate.

Audits

94. DOH Auditors

94.1. An official of DOH who is appointed by the Abu Dhabi Judicial Department or the Minister of Justice to act as a judicial officer or who is appointed by DOH as an Auditor shall be known as a DOH Auditor.

94.2. Each DOH Auditor will carry evidence of his authorisation and will produce it on request to a Regulated Person.

94.3. Each DOH Auditor will treat all members of the Regulated Person staff with courtesy and respect and observe a code of conduct.

95. Entry to Premises

95.1. Each Regulated Person must allow a DOH Auditor to obtain access to any premises which are owned or occupied by it (except for any residential accommodation):

95.1.1. at any time, where DOH has given the Regulated Person at least 48 hours' notice of the visit of the Auditor,

95.1.2. at all reasonable times, without any advance notice.

96. Audit of Premises

96.1. Each Regulated Person must permit a DOH Auditor to audit, in accordance with the following provisions, any premises to which he is entitled to obtain access.

96.2. A DOH Auditor shall be entitled to:

96.2.1. access any part of the premises, except to the extent to which by doing so he would endanger the health and safety of himself or any other person,

96.2.2. inspect any original documents,

96.2.3. take copies of any original documents,

96.2.4. inspect the operation of any computer and any associated apparatus which is used in connection with the electronic production, processing or storage of information,

96.2.5. require any information which is kept on a computer to be produced in a form in which it is legible and can be removed,

96.2.6. inspect any item, sample or equipment,

96.2.7. remove any item, sample or equipment,



96.2.8. interview any member of staff of the Regulated Person,

96.2.9. interview any Patient or visitor to the premises, subject in each case to obtaining his consent to be interviewed.

96.3. For the purposes of an inspection, references to 'information' or 'documents' should be read as excluding any information or documents which could not be required to be disclosed by a court in civil legal proceedings in Abu Dhabi.

96.4. A DOH Auditor shall also be entitled to:

96.4.1. observe any processes or activities of the Regulated Person as they are being carried on, including any staff training or meetings,

96.4.2. observe any consultations with, or the provision of any treatment to, a Patient, subject in each case to obtaining his consent to be observed,

96.4.3. examine any Patient in private, but only where:

- (a) the Patient consents to that examination,
- (b) the DOH Auditor is a Healthcare Professional with appropriate medical experience, and
- (c) the DOH Auditor has reason to believe that the Patient is not receiving an adequate standard of care.

Assistance and Co-operation

97. The General Duties

97.1. Each Regulated Person must:

97.1.1. provide DOH, including in particular any DOH Auditor visiting its premises, with all the assistance and co-operation that it may request for the purposes of carrying out an investigation,

97.1.2. treat all members of DOH staff, including in particular any DOH Auditor visiting its premises, with courtesy and respect,

97.1.3. not do anything that is intended, or likely, to hinder or frustrate an Audit being carried out by DOH.

97.2. These duties apply to a Regulated Person whether or not it is the subject of the investigation.

98. Duties on Organisations

98.1. A Regulated Person which is an organisation must, for the purposes of an investigation being carried out by DOH, ensure that:

98.1.1. each member of its staff provides DOH with all the assistance and co-operation that DOH may request,

98.1.2. senior members of the organisation – including, where that organisation is a corporate body, the members of its board – are made available to DOH on request to assist with the investigation,

98.1.3. it takes all reasonable steps to secure that its owners or shareholders provide DOH with such assistance and co-operation as DOH may request.

98.2. These duties apply to a Regulated Person whether or not it is the subject of the investigation.



99. Duties in Respect of Other Persons

99.1. A Regulated Person must take all reasonable steps to ensure that any other person to whom he has a relationship:

99.1.1. provides DOH with all the assistance and co-operation that DOH may request from that person for the purposes of an investigation,

99.1.2. makes available to DOH documents or information which that person holds, or to which he has access, and which DOH requests for the purposes of an investigation.

99.2. For these purposes, a Regulated Person has a 'relationship' to another person if, in particular, that person is his employer, Patient, or a person with whom he has a contract.

99.3. These duties apply to a Regulated Person whether or not it is the subject of the investigation.

PART C. POWERS FOLLOWING AN INVESTIGATION

100. Introduction

100.1. This Part C describes the actions that may be taken by DOH following an investigation in relation to a Regulated Person against a clinical or non-clinical complaint.

101. DOH actions:

101.1. After DOH has carried out an investigation in relation to a Regulated Person, it may take any one or more of the actions specified in the following provisions of this Part C (the Regulatory Actions), subject to any limitations or conditions set out in those provisions

102. Closure of the complaint

102.1. DOH will close the complaint if the standard of care is met and/or there is no evidence to prove the allegations made against the regulated person.

103. Referral of the complaint to DOH Disciplinary Committee

103.1. Upon completion of all investigation requirements, and if there is an evidence of violations of DOH regulations or breach of international standards, complaint will be referred to DOH Disciplinary Committee for further review and decision.

104. Report

104.1. Upon completion of investigation, DOH will issue a detailed report stating out the clinical findings, investigation findings, actions taken, and recommendations (if any).

104.2. DOH will provide a copy of the report to the Regulated Person, and to the employing Healthcare Facility where the Regulated Person is a Healthcare Professional employed by that Facility.



105. Action Plan

- 105.1. Where DOH determines that the Regulated entity has failed, is failing, or is likely in future to fail to comply with any Regulation, DOH may direct the entity to prepare an Action Plan.
- 105.2. An action plan must address how the facility will rectify the issues identified during the investigation, and provide evidence of implementation (if required).

PART D. THE ROLE OF THE COMMITTEES

106. Introduction

- 106.1. This Part D provides for the establishment and operation of DOH Disciplinary and Licensing Committees.

The Committees

107. The Committees

- 107.1. There shall be committees of DOH known as the Medical Liability Committee and the Licensing Committee (each individually, a Committee).
- 107.2. DOH shall appoint to each Committee as many members as it considers appropriate for carrying out the functions of that Committee.
- 107.3. Each Committee may include both Expert Members and Lay Members.
- 107.4. For these purposes, an Expert Member means a person who has professional and/or ethical expertise in one or more of the following areas:
- 107.4.1. a clinical, medical or scientific discipline relevant to the role of the Committee,
 - 107.4.2. other professional or administrative disciplines relevant to the role of the Committee,
 - 107.4.3. the interpretation, application and enforcement of the Regulations.
- 107.5. For these purposes, a Lay Member means a person who is not an Expert Member and who is not, and has not previously been, a health or social care professional.
- 107.6. Both Expert and Lay Members may be individuals who are either employed by DOH or are appointed by DOH specifically for the purpose of membership of the Committee.

The Role of the Committees

108. The General Role of the Committees

- 108.1. For the purposes of this Chapter:
- 108.1.1. the Licensing Committee shall consider cases relating to Healthcare Providers,
 - 108.1.2. the Medical Liability Committee shall consider cases relating to medical negligence, and
 - 108.1.3. the Disciplinary Committee shall consider cases relating to all other Regulated Persons.
- 108.2. The role of each Committee shall be to consider cases referred to it following an investigation, and in particular:
- 108.2.1. to examine an alleged failure by a Regulated Person to comply with any Regulation,
 - 108.2.2. to determine whether that Person has in fact failed to comply with the Regulation,

108.2.3. where it determines that the Person did fail to comply with the Regulation, to decide whether DOH should impose any Sanction in relation to him.

Rules of Procedure

109. The Rules of Procedure

- 109.1. DOH will issue in respect of each Committee, and may revise, one or more documents which together shall be known as the Rules of Procedure.
- 109.2. The Rules of Procedure will set out the procedure to be followed by each Committee when examining and determining the cases allocated to it, and the basis on which the Committee will make decisions.

PART E. POWERS FOLLOWING A COMMITTEE HEARING

110. Introduction

- 110.1. This Part E describes the powers that DOH may exercise following the examination and determination of a case by a Committee.

111. Precautionary Order

- 111.1. DOH may make a Precautionary Order where it determines that the Regulated Person is failing to comply with any Regulation and that his failure presents a serious and imminent risk to:
- 111.1.1. the health or safety of any Patient,
 - 111.1.2. the health or safety of any visitor to or member of staff of a Healthcare Facility,
 - 111.1.3. the health or safety of any person in proximity to a Healthcare Facility, or
 - 111.1.4. public health in Abu Dhabi.
- 111.2. A Precautionary Order is an order issued by a DOH Committee to a Regulated Person directing him to do specified actions that DOH considers necessary in order to remove serious and imminent risk.
- 111.3. A Precautionary Order may include a requirement for the Regulated Person to:
- 111.3.1. take, or cease to take, any specified actions,
 - 111.3.2. take certain actions in a specified manner, or so as to achieve specified objectives,
 - 111.3.3. comply with DOH direction by a time specified by DOH.
- 111.4. The Regulated Person must comply with the terms of any Precautionary Order given to him.
- 111.5. Where DOH issues a Precautionary Order, it will carry out an investigation of the Regulated Person either by the Disciplinary or Licensing Committee and will provide the Regulated Person with a written correspondence of its reasons for making the Order.
- 111.6. Unless the Committee has, following a full investigation of the case, determined that the Precautionary Order should continue to have effect that Order will lapse and the Regulated Person will be notified that it is no longer required to comply with it.



The Sanctions

112. The Sanctions

112.1. Where a Committee examines a case, and determines that a Regulated Person has failed to comply with any Regulation, it may decide that DOH should impose one or more of the sanctions in relation to that Person which are specified in the following provisions of this Part E (the Sanctions), subject to any limitations or conditions set out in those provisions.

Formal Censure or Warning

113. Formal Censure or Warning

113.1. DOH may issue:

- 113.1.1. a formal notice of censure to the Regulated Person in relation to his past conduct,
- 113.1.2. a formal notice of warning to the Regulated Person as to his future conduct,
- 113.1.3. a suspension or withdrawal of licence,
- 113.1.4. a financial penalty.

Licences and Authorisations

114. Suspension or Revocation

114.1. DOH may suspend or revoke any licence or authorisation which has been issued by it and is held by the Regulated Person.

115. Variation

115.1. DOH may vary any conditions or restrictions attached to a licence or authorisation issued by it and held by the Regulated Person by adding new conditions or restrictions, or by amending existing conditions of restrictions.

116. Effective Date

116.1. The suspension, revocation or variation of licence or authorisation may take place with effect from, and any suspension or variation may have effect until:

- 116.1.1. a date which is specified by the Committee, or
- 116.1.2. the occurrence of an event which is defined by the Committee.

117. Definition

117.1. For the purposes of these provisions, a reference to an 'authorisation' means any approval or authority (other than a licence) that a person must obtain from DOH in order to carry on any activity in Abu Dhabi.



Directions

118. The General Power

- 118.1. DOH may direct the Regulated Person to do specified actions that the Committee considers appropriate in order to:
- 118.1.1. bring to an end any failure to comply with the Regulations,
 - 118.1.2. prevent any such failure from being repeated in the future,
 - 118.1.3. restore the situation (as far as possible) to what it would have been if the failure had not occurred.
- 118.2. A direction may include a requirement for the Regulated Person to:
- 118.2.1. take, cease to take, or refrain from taking in the future, any specified actions,
 - 118.2.2. take certain actions in a specified manner, or so as to achieve specified objectives,
 - 118.2.3. comply with DOH direction by a time specified by DOH.

119. Specific Directions

- 119.1. DOH may in particular direct a Regulated Person to:
- 119.1.1. remove or suspend from office any specified Senior Manager or Senior Individual,
 - 119.1.2. establish or vary any practice, procedure, protocol or other internal arrangement which describes how it conducts itself.

120. Directions to Other Regulated Persons

- 120.1. Where another person who is also a Regulated Person is in a position to control the activities of the Regulated Person to whom the case relates, or to control the way in which he carries out those activities, DOH may direct it:
- 120.1.1. to exercise control over those activities in a manner that the Committee specifies or in a way that is designed to achieve objectives specified by the Committee,
 - 120.1.2. to restrict the activities that he is entitled to carry out.
- 120.2. If the Regulated Person to whom the case relates is a Healthcare Professional, DOH may in particular direct any Healthcare Provider by which he is employed to restrict any Privileges that are assigned to him.

Procedure in Relation to the Sanctions

121. Notice of Sanction

- 121.1. DOH will notify a decision to impose any Sanction to:
- 121.1.1. the Regulated Person to whom the Sanction relates,
 - 121.1.2. if that Person is employed by another Regulated Person, his employer,
 - 121.1.3. if the Sanction involves a direction given to another Regulated Person, the other Person,
 - 121.1.4. any other person DOH thinks it appropriate to notify in the circumstances of the case (which may include any person who submitted a complaint to DOH about the Regulated Person).



- 121.2. Where DOH notifies a Regulated Person of a decision to impose any Sanction in relation to him, it will also notify him of:
- 121.2.1. his right to seek to appeal that decision under Chapter XII, the time within which any appeal may be made, and whether the Sanction is immediately effective or will be suspended subject to the outcome of an appeal,
- 121.2.2. the consequence of failing to comply with any requirement placed on him by virtue of the Sanction.

122. Publication

- 122.1. Where DOH imposes any Sanction, it may in its discretion publish:
- 122.1.1. some or all of the details of that Sanction,
- 122.1.2. the name of the Regulated Person to whom it relates,
- 122.1.3. some or all of the details of its determination that the Regulated Person had failed to comply with a Regulation.
- 122.2. But DOH may not publish any of this information where an appeal has been made by the Regulated Person within the period of time permitted for an appeal.

Status of Sanctions

123. Status

- 123.1. A Regulated Person must comply with a requirement imposed on him by virtue of a Sanction imposed by DOH.
- 123.2. Where a Regulated Person fails to comply with any requirement imposed on him by virtue of a Sanction, DOH may refer that failure directly to the Committee.

Undertakings

124. Undertakings

- 124.1. DOH may accept undertakings that are offered to it by a Regulated Person as to his future conduct in lieu of imposing any Sanction that it would have otherwise imposed.
- 124.2. A Regulated Person must comply with any undertaking given by him to DOH.
- 124.3. Where a Regulated Person fails to comply with any undertaking, DOH may refer that failure directly to the Committee.
- 124.4. DOH may publish details of an undertaking, and the name of the Regulated Person who has given it, only to the extent that it has the agreement of that Person to do so.



CHAPTER XII. APPEALS

125. Purpose

125.1. This Chapter provides for the establishment and operation of a DOH Appeals Committee.

126. Background

- 126.1. DOH – together with its committees and the other bodies that it establishes for the purpose of effective regulation of healthcare in Abu Dhabi – has authority to make a large number of decisions affecting patients and the health economy in the Emirate.
- 126.2. It is good practice that many of these decisions are capable of being appealed so that they may be reconsidered by a body, which is independent of the initial decision-maker.
- 126.3. DOH therefore wishes to establish a committee to hear and determine appeals following all due process. That committee should have the power to replace the initial decision where it is appropriate to do so in order to achieve the best regulatory outcome.

The Appeals Committee

127. The Committee

- 127.1. There shall be a committee of DOH known as the Appeals Committee (the Committee).
- 127.2. DOH shall appoint to the Committee as many members as it considers appropriate for carrying out the functions of the Committee.
- 127.3. The Committee may include both Expert Members and Lay Members.
- 127.4. For these purposes, an Expert Member means a person who has professional and/or ethical expertise in one or more of the following areas:
- 127.4.1. a clinical, medical or scientific discipline relevant to the role of the Committee,
 - 127.4.2. other professional or administrative disciplines relevant to the role of the Committee,
 - 127.4.3. the interpretation, application and enforcement of the Regulations.
- 143.1 For these purposes a Lay Member means a person who is not an Expert Member and who is not, and has not previously been, a health or social care professional.
- 143.2 Both Expert and Lay Members may be individuals who are either employed by DOH or are appointed by DOH specifically for the purpose of membership of the Committee.

The Role of the Committee and the Right to Appeal

128. The Role of the Committee

- 128.1. The role of the Committee shall be to hear and determine appeals that are made:
- 128.1.1. against the decisions of bodies that fall within its remit,
 - 128.1.2. by any person who has the right to bring an appeal.



129. The Relevant Bodies

129.1. The following bodies fall within the remit of the Committee:

129.1.1. DOH,

129.1.2. other committees of DOH, including in particular the Disciplinary Committee and the Licensing Committee,

129.1.3. the Abu Dhabi Research Ethics Committee,

129.1.4. any other committee, council, board or equivalent body which has been established by DOH and with which DOH has entrusted the performance of any regulatory role.

130. The Right to Seek an Appeal

130.1. A person who has a sufficient interest in a decision made by a body falling within the remit of the Committee may seek to appeal to the Committee against that decision.

131. The Appeal Protocol

131.1. DOH will issue, and may revise, one or more documents which together shall be known as the Appeal Protocol.

131.2. The Appeal Protocol:

131.2.1. may describe types of decision which are not to be capable of appeal,

131.2.2. may specify persons or bodies whose decisions are not to be capable of appeal,

131.2.3. may limit the time within which appeals against specified categories of decision may be brought,

131.2.4. will define the circumstances in which a person is, and is not, considered to have a sufficient interest in decisions of a certain type or of a specified person or body.

131.3. The Committee has no power to hear or determine an appeal against a decision if the Appeal Protocol provides that it cannot be appealed.

131.4. The Committee has no power to hear or determine an appeal against a decision if the Appeal Protocol sets a time limit for appeals and the appeal has not been brought within that time.

131.5. No person has the right to appeal to the Committee against a decision if the Appeal Protocol provides that he lacks a sufficient interest in that decision or that the decision is not capable of appeal.

The Grounds of Appeal

132. The Grounds of Appeal

132.1. A decision made that is capable of appeal may be appealed on one or more of the following grounds:

132.1.1. the body which made that decision did not have the power to make it,

132.1.2. the person who made that decision did not have the delegated authority to make it,

132.1.3. the decision was based on a significant error of fact,

132.1.4. the decision was based on an error of law,

132.1.5. the decision-maker failed to consider relevant matters,



- 132.1.6. the procedure followed by the decision-maker was inadequate or unfair,
- 132.1.7. the decision discriminated between one person and another without good reason,
- 132.1.8. the decision was arbitrary, or irrational, or disproportionate,
- 132.1.9. the decision was significantly unfair in its effect on any one or more persons.

The Appeal Rules

133. The Appeal Rules

- 133.1. The Committee shall issue, and may revise, one or more documents which together shall be known as the Appeal Rules.
- 133.2. The Appeal Rules will set out:
 - 133.2.1. the steps that must be taken by a person wishing to bring an appeal,
 - 133.2.2. the basis on which the Committee will make decisions,
 - 133.2.3. the procedure to be followed by the Committee when hearing and determining the appeals made to it.
- 133.3. The Appeal Rules may in particular make provision for:
 - 133.3.1. the appeal to be brought in a specified manner,
 - 133.3.2. the circumstances in which an appeal will require permission to proceed,
 - 133.3.3. the power of the Committee to suspend implementation of the decision that is being appealed,
 - 133.3.4. the steps to be taken by persons interested in the appeal.

134. Making an Appeal

- 134.1. The Appeal Rules may provide that a person who wishes to appeal against a decision must:
 - 134.1.1. bring the appeal by completing any forms that the Committee may publish for that purpose,
 - 134.1.2. provide all the information and evidence that the Committee may require.
- 134.2. A person bringing an appeal must comply with any requirements of the Appeal Rules and act in total honesty and good faith.
- 134.3. The Committee may reject an appeal without further consideration if it is not validly brought in accordance with the Appeal Rules.

135. Permission

- 135.1. The Appeal Rules may provide that certain types of appeal will require the permission of the Committee before they may proceed.
- 135.2. Where permission is required, it may be refused only if, in the opinion of the Committee, the appeal is trivial in nature or clearly has no merit.

136. Interim Measures

- 136.1. The Appeal Rules may provide that the Committee may, on receiving an appeal, direct that interim measures must be taken prior to the outcome of the appeal by:



- 136.1.1. the decision-maker,
 - 136.1.2. the person bringing the appeal,
 - 136.1.3. any other person who was required to take action by virtue of the decision.
- 136.2. Where the Appeal Rules make such provision, they will also set out the process by which any person making the appeal may apply for interim measures in relation to the decision.
- 136.3. Any person who is subject to a direction from the Committee must comply with it.

137. Steps to be Taken in the Appeal

- 137.1. The Appeal Rules may set out the steps that must, or may, be taken by:
- 137.1.1. the person bringing the appeal,
 - 137.1.2. DOH,
 - 137.1.3. the person who made the decision being appealed,
 - 137.1.4. any other specified person who has an interest in the appeal or has information or evidence that is relevant to the appeal, together with any time limits within those steps that must, or may, be taken.
- 137.2. Any person on whom the Appeal Rules impose a duty must comply with it.
- 137.3. The Appeal Rules:
- 137.3.1. will ensure that both the person bringing the appeal and the decision-maker have the opportunity to be heard and to make submissions to the Committee,
 - 137.3.2. may allow other persons – including any person who would be directly affected by the outcome of the appeal – the opportunity to make submissions to the Committee.
- 137.4. The Appeal Rules may make provision for:
- 137.4.1. some cases to be assessed as urgent and to be given expedited consideration,
 - 137.4.2. the Committee to give directions as to the conduct of a case,
 - 137.4.3. any other matters relating to the conduct of a case or the procedure of the Committee as the Committee thinks appropriate.

The Determination

138. The Determination

- 138.1. Where the Committee has heard an appeal and determines that one or more of the grounds of appeal is met, it must decide the appeal in favour of the person who brought it.
- 138.2. The Committee may then:
- 138.2.1. strike down the decision against which the appeal was brought, and
 - a) substitute for that decision an alternative decision of its own, or
 - b) direct the decision-maker to reconsider the decision as if its original decision had not been made,
 - 138.2.2. vary the decision in a manner that it considers appropriate,
 - 138.2.3. where it determines that the decision would have been the same had the ground of appeal not existed, confirm the decision.



- 138.3. Where the Committee has heard an appeal and has not determined that at least one ground of appeal is met, it must decide the appeal in favour of the decision-maker and confirm the decision.
- 138.4. In any case, the Committee may issue directions to deal with matters which are consequent on its determination.

139. Notice of Determination

- 139.1. DOH will notify a determination of the Committee to:
- 139.1.1. the person who brought the appeal
 - 139.1.2. the decision-maker whose decision was appealed,
 - 139.1.3. any other person DOH considers it appropriate to notify in the circumstances of the case.
- 139.2. The determination of the Committee will be final and binding.
- 139.3. The determination and any directions issued by the Committee must be complied with by any person to whom they are addressed.

140. Record of Proceedings

- 140.1. The Committee will keep a full written record of its proceedings in each appeal.
- 140.2. The Committee will produce a written summary of the reasons for its determination in each appeal, and will give a copy of the summary to the person who brought the appeal and to the decision-maker whose decision was appealed.

141. Publication

- 141.1. DOH may, in its discretion, publish:
- 141.1.1. some or all of the details of the appeal,
 - 141.1.2. the name of the person who brought the appeal,
 - 141.1.3. some or all of the details of its determination and of the reasons for it.



CHAPTER XIII.

INTERPRETATION AND DEFINITIONS

142. Interpretation

- 142.1. In this Manual, the following rules of interpretation shall apply.
- 142.2. Unless the context requires otherwise:
 - 142.2.1. words in the masculine gender are to be read as including the feminine gender (and vice versa),
 - 142.2.2. words in the singular are to be read as including the plural (and vice versa), and
 - 142.2.3. references to a numbered Chapter, Part, section or paragraph are to the provision bearing that number within this Manual.
- 142.3. The words 'including' and 'in particular' indicate a list of examples and should not be read as limiting the scope of the words that occur before them.
- 142.4. Any reference to another Policy, Standard, Law, Rule or other legal instrument is to be read as a reference to that legal instrument as it may be revised or reissued.
- 142.5. Where this Manual requires any duty to be complied with by a specified time, and where the duty has not been complied with by that time, that duty shall continue to be binding until it has been satisfied and the continuing failure to comply with it shall be treated as an ongoing and repeated breach of this Manual.
- 142.6. The words 'employ', 'employed' and 'staff', when used in relation to any person performing functions on behalf of DOH or any other organisation, refer to any arrangement (whether or not of full-time employment) by which that person is engaged to undertake activities on behalf of DOH or that other organisation.
- 142.7. The words 'notice', 'notification' and 'notify' refer to notice that is given in writing and which is communicated by the delivery of a hard copy to the recipient or an electronic copy to a valid electronic mailing address of the recipient.
- 142.8. The words 'treat' or 'treatment' when used in respect of a Patient refer to any intervention - including advice, clinical investigation, diagnosis, monitoring, clinical and/or surgical intervention, the prescription of medicines and the supervision of care - that falls within the professional activities of the relevant Healthcare Professional providing healthcare to the Patient.
- 142.9. The word 'year' means a year according to the Gregorian calendar.



143. Definitions

143.1. In this Manual, the following words shall have the meanings given to them below:

Adverse Drug Reaction	Has the meaning given in Chapter VI.
Appeals Committee	The committee of DOH established in accordance with Chapter XII to hear and determine appeals.
Authorised Insurance Provider	Has the meaning given in the Health Insurance Manual.
Capacity Master Plan	A document produced in accordance with Chapter IV which identifies the requirements for additional healthcare capacity in Abu Dhabi.
Clinical Complaint	An expression of dissatisfaction by a user of the service as a result of a clinical intervention.
Complainant	The person making the complaint, whether on behalf of themselves or another.
Complaint Form	A form to be used by anyone who wishes to make a complaint against a Regulated Person.
Data Standards and Procedures	Has the meaning given in Chapter VIII.
Disciplinary Committee	The committee of DOH established in accordance with Chapter IX to consider cases referred to it following an investigation.
Expert Member	A member of the Disciplinary Committee, Licensing Committee or Appeals Committee who has professional and/or ethical expertise in one or more of the areas referred to at (respectively) Part D of Chapter XI and Chapter XII.
Healthcare Facility (or simply Facility)	Has the meaning given in the Healthcare Providers Manual.
Healthcare Professional	Has the meaning given in the Healthcare Professionals Manual.
Healthcare Provider (or simply Provider)	Has the meaning given in the Healthcare Providers Manual.
Hospital	Has the meaning given in the Healthcare Providers Manual.
Independent Clinical Review (ICR)	A review of the clinical care standards concerning the clinical care provided to a complainant, or other specified cases, undertaken by an independent third party expertise to evaluate and advise on adherence, or otherwise, to evidence based internationally recognized standards of care. DOH commissions ICR from expert healthcare professionals within the Abu Dhabi healthcare sector, the United Arab Emirates and/or internationally.
Information Request	A notice in writing given to a Regulated Person and requiring him to provide DOH with any information which he holds or to which he has access.
Informed Consent	Has the meaning given in the Standard on Informed Consent.



Insurer	Has the meaning given in the Health Insurance Manual.
Lay Member	A member of the Disciplinary Committee, Licensing Committee or Appeals Committee who is not an Expert Member and is not, and has not previously been, a health or social care professional.
Licensed Healthcare Professional	A Healthcare Professional who holds a current and valid licence issued by DOH and authorising him or her to engage in certain professional activities.
Licensing Committee	The committee of DOH which is responsible for the issuance of licences to Healthcare Professionals, and is established in accordance with Chapter XI to consider cases referred to it following an investigation.
Medical Liability Committee	The Committee which is entrusted by the Decreed Federal Law no. 4, 2016 with determining medical negligence.
Medical Product	Has the meaning given in Chapter VI.
Patient	Any individual who seeks or is receiving healthcare services or treatment through a Healthcare Provider.
Precautionary Order	An order given by DOH to a Regulated Person in accordance with Part C of Chapter XI.
Privileges	The entitlements of a Healthcare Professional, assigned by a Healthcare Provider, to provide treatments to Patients within a Facility operated by that Provider.
Regulated Person	Any person who is subject to a duty under a Law, or a Policy Standard, Licence or related document issued by DOH.
Regulation	Any provision of a Law, or of a Policy, Standard, Licence or related document issued by DOH, which imposes a duty on a Regulated Person.
Regulatory Actions	The actions that may be taken by DOH following an investigation as set out at Part C of Chapter XI.
Sanction	One of the sanctions that may be imposed by DOH in accordance with Part E of Chapter XI.
Scope of Practice	Has the meaning given in the Healthcare Professionals Manual.
Senior Individual	Has the meaning given in the Healthcare Providers Manual.
Senior Manager	Has the meaning given in the Healthcare Providers Manual.
Standard	Means a Standard issued by DOH in accordance with a Policy or with any provision of law.



The Law	All applicable Federal Healthcare laws, the DOH's establishing law and the bylaws in implementation of these laws.
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